



# Sales Catalog

## Clinical Chemistry Products





**PERFORMANCE DIAGNOSTICS  
FOR A CHANGING WORLD**

Disclaimer: This document is only for internal use.

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## INTRODUCTION

Avantor™ Performance Materials is a global leader, providing advanced chemistries that drive the next generation of pharmaceutical, biopharmaceutical, electronics and diagnostics development. These performance materials enable advances in research and laboratory processes while providing unmatched quality, purity and consistency.

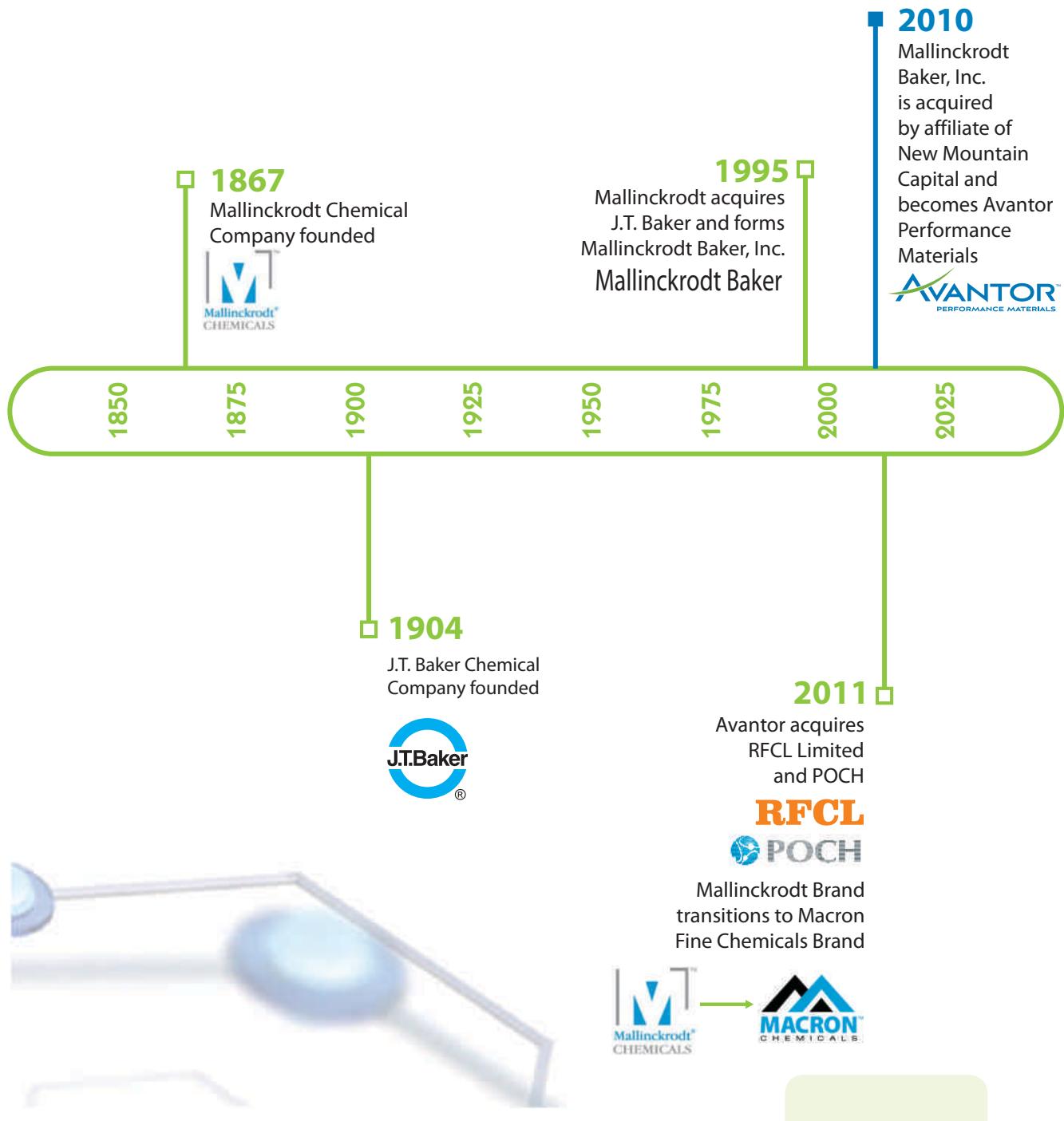
With over 250 distributors worldwide, the mission of our global diagnostics business is to improve the quality and affordability of diagnostic tools to help benefit the health and well-being of people around the world.

Our offering includes J.T.Baker® clinical reagents, Diagnova diagnostics products and soon to be officially announced BeneSphera™ diagnostics solutions. We feature proven *in vitro* reagents and instruments for clinical chemistry, immunology, hematology, microbiology, histology and cytology and genetic testing. We also provide instruments for *in vivo* diagnostics as well as consumables and instruments for life sciences research in academia, government and pharmaceutical laboratories.

**We are building this new global diagnostics offering on a strong foundation: Avantor's passion for quality, consistency and reliability in performance materials.**

**Global presence across developed  
and emerging markets**

## A PROUD HISTORY



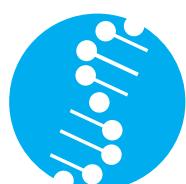


# One Company

## Two World-class Diagnostic Brands



**"Soon, we  
will introduce  
a new brand."**



**BeneSphera™**

**Diagnostics Solutions**

**A legacy of quality,  
service and reliability.**

## WELLNESS FOR THE WORLD



Avantor's reliable, affordable diagnostic technologies and easy-to-use products make a difference in healthcare outcomes around the world, with solutions uniquely engineered to provide:

**Performance** – state-of-the-art accuracy, precision and reliability, giving healthcare professionals and patients full confidence in results they receive.

**Ease** – enhanced efficiency and ease of use for end-users at all market levels; ease of service and support by distributors and OEM partners.

**Expansive** – a diverse and expanding portfolio of reagents, instruments and systems.

**Well-being** – comprehensive diagnostic technology, service and support tailored to the needs of each market.

### Key Products

- *In-vitro* reagents and instruments for clinical chemistry, immunology, hematology, microbiology, histology, cytology and generic testing
- Instruments for *in-vivo* diagnostics – currently sold under the Diagnova name in India
- Consumables and instruments for life science research in academia, government and pharmaceutical laboratories – currently sold under the Diagnova name in India

### Key Capabilities

- Strong, in house research & development resources
- Global manufacturing capability
- High quality infrastructure
- Regulatory compliance with certifications
- Established & dynamic product management and sales network
- After sales service & technical support



## OUR MISSION



To improve the quality and affordability  
of diagnostic tools...



To benefit the healthcare and  
well-being of people around the world.



## **MANUFACTURING FACILITIES**



## MANUFACTURING FACILITIES

Serving your markets globally with performance diagnostics solutions



### Deventer- The Netherlands

#### Diagnostics manufacturing footprint across two continents:

1. Deventer-Europe
2. Dehradun-Asia

#### Deventer – The Netherlands

The chemical know-how, manufacturing and purifications competencies form the basis of a comprehensive range of hematology and histopathology products produced at the Deventer facility.



#### Production

The diagnostics products are produced using state-of-the-art production techniques in modern, certified manufacturing facilities, to assure the highest level of accuracy and precision. Production is centralized at the town of Deventer, the Netherlands. The commitment to the International Responsible Care program is contributing to environmental friendly and efficient manufacturing. The high quality water and solvents manufactured by Avantor, guarantees the quality of the solutions produced. The products are bottled under controlled conditions to prevent contamination and degradation, thus assuring maximum stability.

## MANUFACTURING FACILITIES

### Quality Control

Every batch of a reagent manufactured is subjected to stringent quality tests and approved in compliance with ISO 9001, 14001 & ISO 13485 regulations. A highly educated team of diagnostics specialists, working in well-equipped R&D and QC laboratories, guarantees lot-to-lot consistency and provides technical customer support.

### Certificates

Avantor Performance Materials B.V. holds the certificates of:

- 1.ISO 9001:2008
- 2.ISO 1400:2004
- 3.ISO 13485:2003

Most of the hematology and histo-pathology products produced at the Deventer facility are CE marked.



### Dehradun - India

At this facility, we have cGMP infrastructure for the manufacturing for hematology, clinical chemistry, ELISA, chemiluminescence, rapid test and microbiology range of products.

### Production

A well equipped and state of the art manufacturing unit comprising of dedicated facility for manufacturing of series of diagnostic kits/reagents which includes; biochemistry, immunology, serology, rapid tests and hematology with different pack presentations. One of the largest hematology reagents manufacturing plant in the country consisting of reactors made with pharmaceutical grade ss-316 material. PLC controlled semi- automated systems have been installed to yield a maximum capacity of approximately 10 million liters of reagents per year.

### Air Handling & Water systems

Double skinned, re-circulation and environment friendly Air Handling Unit (AHU), equipped with temperature and humidity sensors, have been installed in the manufacturing area. Purified air filtered through three stages (pre-filter, micro filter, HEPA filter) is supplied to the manufacturing area. High grade water (0.2-3.0 $\mu$ s/cm) is generated by the water plant at a throughput of 1000 liter/hr.

## MANUFACTURING FACILITIES

### Quality Control

Apart from the world class products manufactured, the diagnostics division has a team of technically qualified professionals which strives to provide solutions to quality related queries, within 48 hours. Some of the key highlights are:

- Accelerated stability studies at 37°C and 45°C on every batch produced
- Real time stability studies till three months after expiry date.
- Post Marketing Surveillance at two times of the year: Mid summer and Mid Monsoon

### Certifications

The entire facility has been designed as per cGMP requirements. RFCL Limited (now a part of Avantor Performance Materials), India holds the certificates of:

1. ISO 9001:2008
2. ISO 14001:2004
3. ISO 13485:2003
4. CE marked (Hematology and Clinical Chemistry)





# CERTIFICATIONS

## ISO 9001: 2008

Avantor's ongoing pursuit of Total Quality has resulted in an ISO 9001:2008 certified quality system for Avantor India. The ISO-9001 certification includes design, development, production and supply of the products.

## ISO 14001 : 2004

Since January 2011 Avantor India is also ISO 14001:2004 certified. ISO 14001 is ISO's environmental management system that describes the efforts taken to minimize harmful effects to the environment.

## ISO 13485 : 2003

Since December 2010 Avantor India is also ISO 13485:2003 certified. This certification is dedicated for *in-vitro* diagnostic products.

[ CE Mark, European IVD directive, 98/79/EC From January 2011 *Invitro* Diagnostic Medical Devices (IVDs), sold in the European market, have to be in compliance with the IVD Directive 98/79/EC and have to show the CE mark. ]

At Avantor, almost all Chemistry and Hematology products are CE marked.

### Label information

CE marking requires some additional information on the label. Symbols instead of text are used to express some data:

**REF**

Product Number

**IVD**

For *in-vitro* diagnostic use



Use before date: Year - Month



Store and use at room temperature



Manufactured by

**CE**

CE registered product

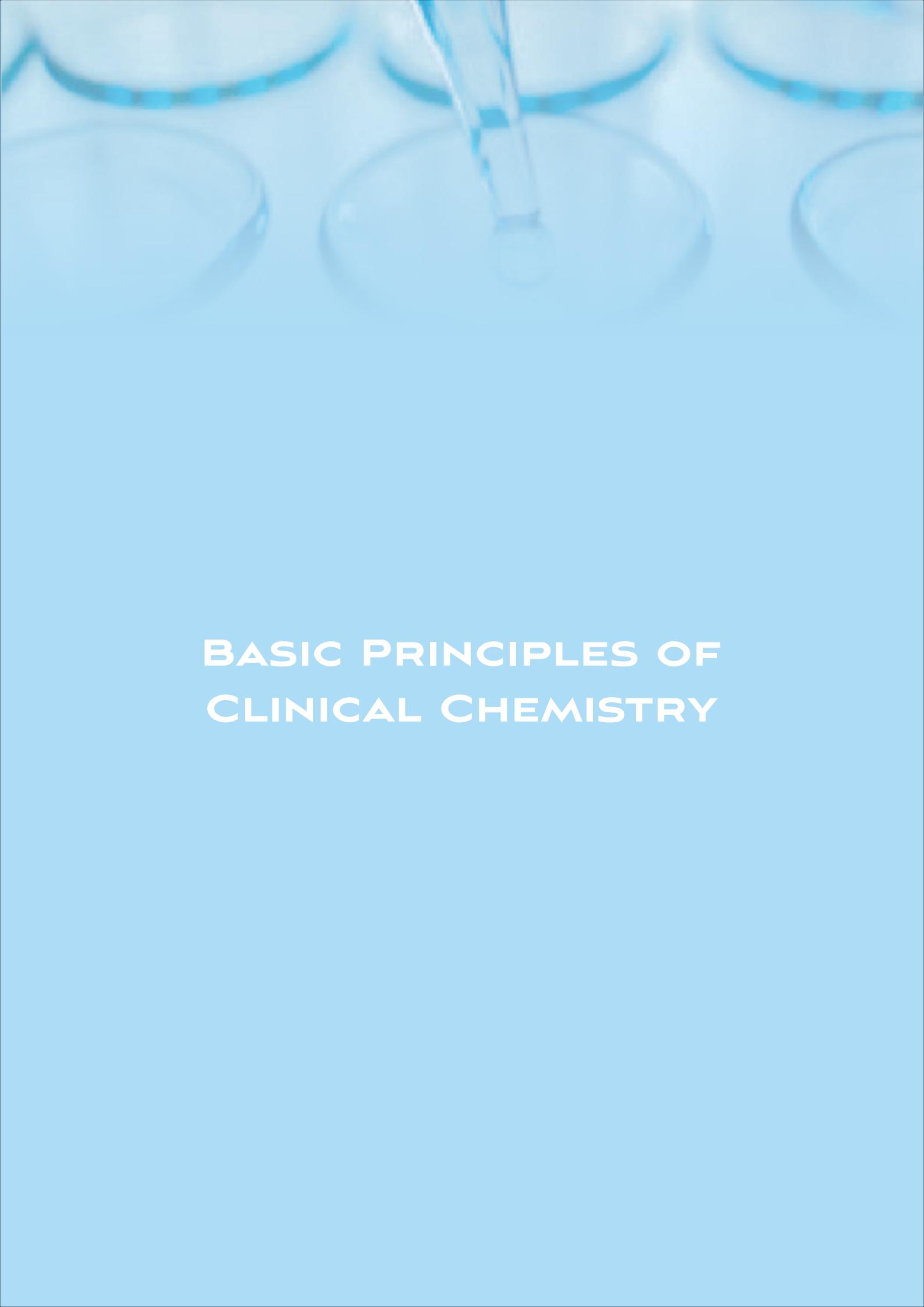
**LOT**

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# **BASIC PRINCIPLES OF CLINICAL CHEMISTRY**



## BASIC PRINCIPLES OF CLINICAL CHEMISTRY

### History

Originally, it was believed that life was not subject to the laws of science the way non-life was. It was thought that only living beings could produce the molecules of life (from previously existing biomolecules). In 1828, Friedrich Wohler published a paper on the synthesis of urea, proving that organic compounds can be created artificially.

Biochemistry is the study of the chemical processes in living organisms. It deals with the structure and function of cellular components, such as proteins, carbohydrates, lipids, nucleic acids, and other biomolecules.

The dawn of biochemistry was the discovery of the first enzyme, diastase (today called amylase), in 1833 by Anselme Payen.

Eduard Buchner contributed the first demonstration of a complex biochemical process outside of a cell in 1896 i.e. alcoholic fermentation in cell extracts of yeast. Although the term "biochemistry" seems to have been first used in 1882, it is generally accepted that the formal coinage of biochemistry occurred in 1903 by Carl Neuberg, a German chemist. Previously, this area was being referred to as physiological chemistry.

Another significant historic event in biochemistry was the discovery of the gene and its role in the transfer of information in the cell. This part of biochemistry is often called molecular biology. In the 1950s, James D. Watson, Francis Crick, Rosalind Franklin, and Maurice Wilkins were instrumental in solving DNA structure and suggesting its relationship with genetic transfer of information. In 1958, George Beadle and Edward Tatum received the Nobel Prize for work in fungi genome establishing that one gene produces one enzyme.

There are three main types of biochemistry as established by Michael E. Sugar. Plant biochemistry involves the study of the biochemistry of autotrophic organisms such as photosynthesis and other plant specific biochemical processes. General biochemistry encompasses both plant and animal biochemistry. Human/medical/medicinal biochemistry focuses on the biochemistry of humans and medical illnesses.

Although there are a vast number of different biomolecules, many are complex and large molecules (called polymers) that are composed of similar repeating subunits (called monomers). Each class of polymeric biomolecule has a different set of subunit types. For example, a protein is a polymer whose subunits are selected from a set of 20 or more amino acids. Biochemistry studies the chemical properties of important biological molecules, like proteins, in particular the chemistry of enzyme-catalyzed reactions.

### Bio Chemical Reaction

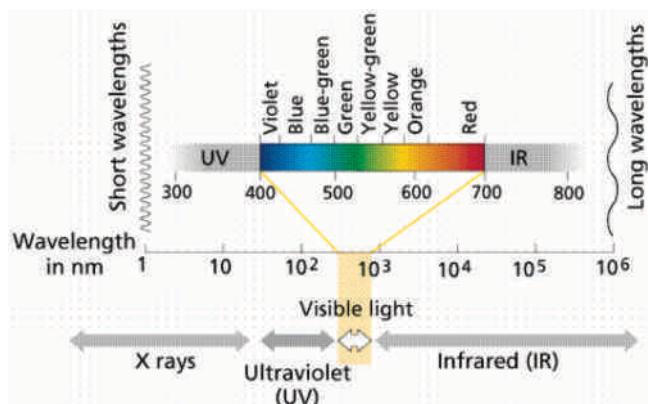
Biochemical reactions are based upon the specimen analyte reacting with one or more reagent(s) which then produce a measurable change in detection response. In most of the biochemical reactions the process is catalyzed by means of some enzymes. Enzymes increase the rate of a reaction many folds without getting consumed. They are required in very less quantity.

The concentration of the product formed is determined by calculating the rate of the reaction.

### Photometry

Photometry measures transmitted light to determine reaction absorbance.

- In photometry, an aliquot a sample containing the analyte is mixed in a cuvette with a liquid reagent.
- The reagent reacts with the analyte producing a change in absorbance (color) within the reaction solution.
- The absorbance is measured using a photometry system. (Colorimeter/Analyzer) in the Visible/ultra



### Violet Light Spectrum

- The term "Visible Light Spectrum" refers to that section of the electromagnetic radiation spectrum that can be viewed by the naked human eye.

Electromagnetic radiation spectrum is spread across a wide range of wavelengths, but only the spectrum in the range of 400 nm ( $4 \times 10^{-7}$  m) to 700 nm ( $7 \times 10^{-7}$  m) is visible to human eye. Hence this particular wavelength spectrum is called the visible light spectrum. It is also known as the optical spectrum of light.

Any biochemical determination is based on the following two basic laws of photometry:

#### Beer's Law

Beer's Law is the principle behind most of the

biochemical calculations. The law states that the absorbance of a coloured solution is directly proportional to its concentration.

### Absorbance $\alpha$ concentration

#### Lambert's Law

Lambert's Law states that absorbance of coloured solution is directly proportional to the length of the light path (b). However (b) has now been made a constant i.e. 1cm, in all photometers with the exception of some fully automated analyzers.

### Absorbance $\alpha$ Path length of light

#### Beer-lambert law

$$A = abc$$

#### Where

A=Absorbance

a=absorptivity constant

b=length of the light path (cm)

c=concentration

#### Reading Principles

Automated photometers use different methods for mixing of reagents and reading of absorbance signals:

#### End Point Reaction

In an end point the reaction is allowed to reach its completion before any measurement is made. The reaction rate rises rapidly initially because at this stage none of the reactants are limiting. As time progresses, the rate of the reaction decreases and comes to an end, due to the following reasons:

- A) Substrate depletion
- B) Enzyme inactivation
- c) Negative feed back from the end product
- This method utilizes signal development as a function of time.
- Examples of analytes which typically utilize the endpoint-up reaction are glucose, cholesterol, phosphorus, and albumin, triglycerides.

#### Calculation

$$\text{Conc. of Test} = \frac{\text{Abs. Test} - \text{Abs. Blank}}{\text{Abs. Std.} - \text{Abs. Blank}} \times \text{Conc. Std.}$$

$$\text{Abs. Std.} - \text{Abs. Blank}$$

#### Kinetic Reaction

In this type of reaction, absorbances are recorded while the reaction is still in progress. A semi automated /automated biochemistry analyzer is required to record absorbance readings at programmed time intervals at a specified time and temperature. Change in absorbance ( $\Delta$  Abs) is generally recorded every minute for a duration of 3-4 minutes. An average of the  $\Delta$  Abs/min is used to calculate the final result.

**Important:** The first 60 seconds (lag phase, incubation time) are not taken into consideration while calculating the

average  $\Delta$  Abs/min, because this time is given for the enzyme-substrate reaction to stabilize.

#### Calculation: Conc. of test= $\Delta$ Abs/min X Factor.

#### Initial Rate Reaction

Here the rate of change of reaction taking place in the initial phase of the reaction is measured. Rate of the reaction is measured for 1 to 2 minutes only.

#### Calculation: Conc. of Test= $\Delta$ Abs of Test X conc. Std.

$$\Delta \text{ Abs of Std.}$$

Many of the kinetic reactions are calculated with the help of a factor.

The factor in a kinetic reaction can be calculated by using the following formula:

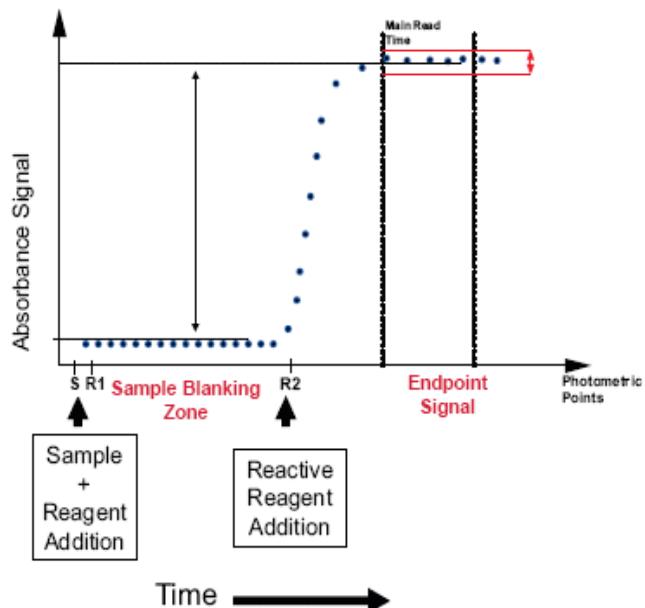
$$\text{Factor} = \frac{\text{Total volume} \times 1}{\text{Sample Volume} \times \epsilon}$$

$$\text{Sample Volume} \times \epsilon$$

Where  $\epsilon$  is the molar absorptivity coefficient.

Total volume and the sample volume must be expressed in the same units i.e. ml or  $\mu$ l.

#### Endpoint-Up Reaction



#### Sample Blank/Test Blank

It is included in a test protocol to nullify any interference caused by the substances present in the sample (e.g. lipemic, icteric) other than the analyte to be estimated. Sample blanking is recommended when the sample volume is high i.e. 200  $\mu$ l.

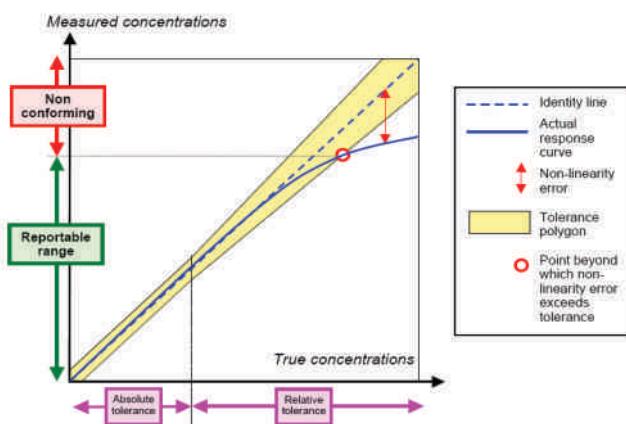
#### Reagent Blank

It is included in a test protocol to nullify any effect of the absorbance contributed by the reagents. The absorbance of the reagent blank is subtracted from the absorbance of the test to obtain the actual absorbance for the analyte being estimated.

## Linear Range

Concentration range over which the intensity of the signal obtained is directly proportional to the concentration of the species producing the signal.

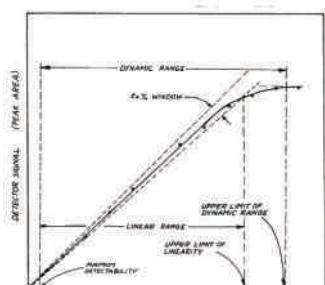
**Linearity of a Reagent:** Linearity of a reagent is that concentration upto which the dose (concentration)-response (absorbance) curve is linear or obeys the Beer's Law.



- The dynamic range of a detector is that range of concentration of a substance over which an incremental change in concentration produces an incremental change in detector signal.
- The lower limit of the dynamic range is the minimum detectability. The upper limit is the highest concentration at which a further increase in concentration will still give an observable increase in detector signal, and the dynamic range is the ratio of the upper and lower limits. The dynamic range is greater than the linear range.
- Numerically the dynamic range can be expressed as the ratio of the upper limit of the dynamic range obtained from the plot and the minimum detectability, both measured for the same substance.

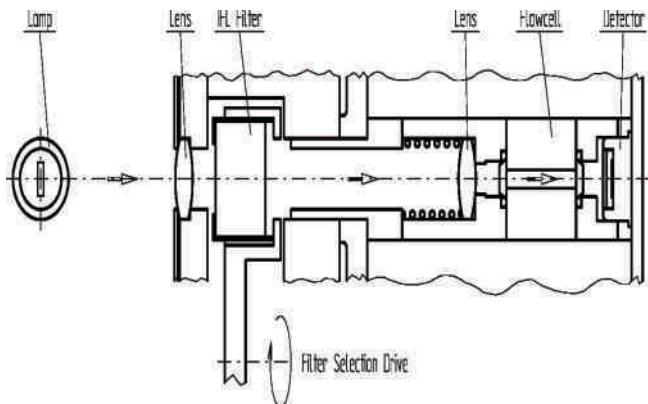
## Colorimetry or spectrophotometry:

This method involves measuring the intensity of a colour in a solution and relating it to the concentration of the analyte. While some materials of interest are already colored, most of these analyses require the analyst to add some chemical *reagents* (reacting chemicals) to a sample to produce a characteristic colour. A precise measurement can be made using a *colorimeter*. A colorimeter is a device consisting of



- 1) A light source, which can be as simple as tungsten-filament light bulb

- 2) Some optics for focusing the light



3) A coloured filter, which passes light of the colour which is absorbed by the treated sample

4) A sample compartment to hold a transparent tube or cell containing the sample

5) A light-sensitive detector, which converts the light intensity into an electric current

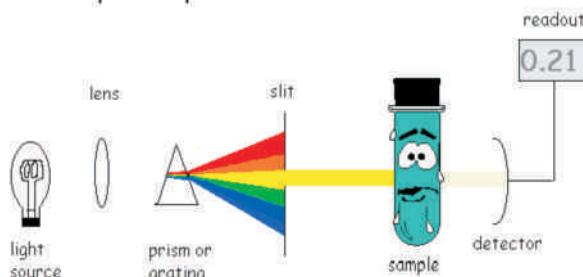
6) Electronics for measuring and displaying the output of the detector.

Some colorimeters may be designed to read out directly in concentration units, while others may show the results in units of light absorbance which need to be compared to a calibration curve. The filter is not the same color as the solution being tested, but rather the complementary color.

**Depending on the colour of the resulting solution the filter should be selected as below:**

If more precise and more interference-free measurements are required, a *spectrophotometer* can be used. This is very similar to a colorimeter, except that instead of using a filter to select the color of light to pass through the sample, the white light is split up into a

## Spectrophotometer

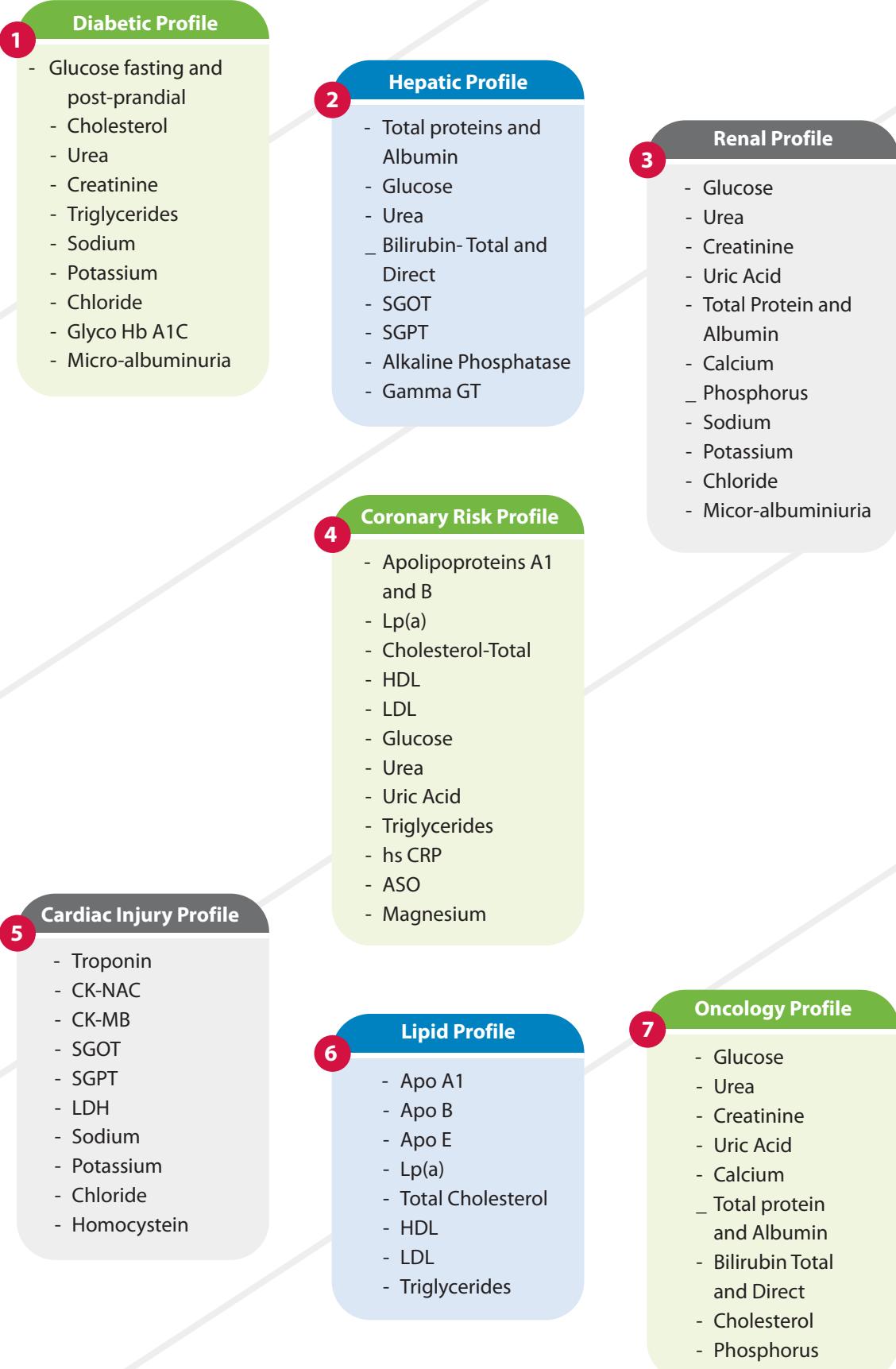


rainbow (*spectrum*) of colors using a prism or a *diffraction grating*. The light is passed through a narrow opening (slit) before reaching the sample. By rotating the prism or grating, the color ("wavelength") of light can be selected more precisely. The principle is shown in the diagram below.

While many tests are done using visible light, some analysis also make use of the invisible ultraviolet or infrared portions of the spectrum.

Sr.No.	Colour of the solution after the reaction is over	Filter to be used.
1	Red	Green
2	Orange	Blue
3	Yellow	Violet
4	Green	Red

## Clinical Chemistry Tests Done for Various Profiles:



## **CLINICAL SIGNIFICANCE**



## CLINICAL SIGNIFICANCE

Parameter	Reference Range	Clinical Significance
Glucose	70-100mg/dl(fasting) Upto 140 mg/dL(PP)	<ul style="list-style-type: none"> <li>High value indicates Diabetes.</li> <li>Low value indicates hypoglycemia.</li> </ul>
SGOT	up to 46 IU/L	<ul style="list-style-type: none"> <li>Increase of aspartate aminotransferase (formerly called "SGOT") is seen in any condition involving death of liver cells, myocardial cells, or skeletal muscle cells.</li> <li>Decreased serum AST is of no known clinical significance.</li> </ul>
SGPT	Up to 49 IU/L	<ul style="list-style-type: none"> <li>Increase of serum alanine aminotransferase (formerly called "SGPT") is seen in any condition involving death of liver cells, myocardial cells, erythrocytes, or skeletal muscle cells.</li> <li>The SGOT/SGPT ratio is significantly elevated in patients with alcoholic hepatitis.</li> </ul>
Creatinine	0.6 - 1.2 mg/dL	<ul style="list-style-type: none"> <li>Increase in serum creatinine is seen in Kidney functional impairment.</li> <li>A rise in blood creatinine levels is observed only with marked damage to functioning Kidney cells(Nephrons)</li> </ul>
Urea	Urea 10-45 mg/dL BUN 5-21 mg/dL	<ul style="list-style-type: none"> <li>The blood urea nitrogen (BUN) test is a measure of the amount of nitrogen in the blood that comes from urea. It is used as a marker of renal function</li> <li>Increased in acute and chronic intrinsic renal disease, by decreased effective circulating blood volume, with decreased renal excretion, in post renal obstruction of urine flow and in high protein intake states.</li> <li>Decreased serum urea nitrogen (BUN) is seen in high carbohydrate/low protein diets, late pregnancy, infancy, poor absorption states, and severe liver damage.</li> </ul>
Albumin	3.2-5.5 gm/dL	<ul style="list-style-type: none"> <li>Increased absolute serum albumin content is not seen as a natural condition. High albumin is almost always caused by dehydration. In some cases of retinol (Vitamin A) deficiency the albumin level can become raised to borderline or High-normal values. This is because retinol causes cells to swell with water (this is also the reason too much Vitamin A could be toxic).</li> <li>Low albumin (hypoalbuminaemia) may be caused by liver disease, over hydration, loss of excessive protein from the kidney, liver disease and malnutrition.</li> </ul>
Total Protein	6.0 - 8.5 gm/dL	<ul style="list-style-type: none"> <li>Increase in serum total protein reflects increases in albumin, globulin or both. It occurs during dehydration due to vomiting and diarrhoea, chronic liver infection.</li> <li>Decrease in the concentration is seen in renal diseases, malnutrition, Albuinuria and terminal liver failure.</li> </ul>
Bilirubin	Direct: up to 0.4 mg/dL Total: up to 1.0 mg/dL	<ul style="list-style-type: none"> <li>Total bilirubin measures both unconjugated and conjugated Bilirubin. Total and direct bilirubin levels can be measured from the blood but indirect bilirubin is calculated from the total and direct bilirubin.</li> <li>Indirect bilirubin is fat soluble and direct bilirubin is water soluble.</li> <li>Rise in bilirubin may be caused by increased breakdown of red blood cells, mild jaundice.</li> <li>Very high levels of bilirubin may be caused by large bile duct obstruction, severe liver failure, sever hepatitis.</li> </ul>
Triglycerides	Men 60-165 mg/dL Women 40-140 mg/dL	<ul style="list-style-type: none"> <li>In the human body, high levels of triglycerides in the bloodstream have been linked to the risk of heart disease. The risk can be partly accounted for by a strong inverse relationship between triglyceride levels and HDL-cholesterol levels.</li> <li>Another disease caused by high triglycerides is pancreatitis.</li> <li>Decreased serum triglycerides are seen in hyperthyroidism, malnutrition, and malabsorption states.</li> </ul>

## CLINICAL SIGNIFICANCE

Parameter	Reference Range	Clinical Significance
Cholesterol	Less than 200 mg/dL	<ul style="list-style-type: none"> <li>Increased level of Cholesterol may be found in coronary artery disease, uncontrolled Diabetes mellitus, hypothyroidism and hepatic malfunctions.</li> <li>Conditions with elevated concentrations of LDL particles leads to block formation in the walls of arteries, a condition known as <i>atherosclerosis</i>, which is the principal cause of coronary heart disease.</li> <li>Increased concentrations of HDL correlate with lower rates of atherosclerosis.</li> <li>Elevated levels of cholesterol are regarded as <i>atherogenic</i> (prone to cause atherosclerosis).</li> <li>The total cholesterol can be within normal limits, yet be made up primarily of large LDL fraction and small HDL fraction under such conditions atheroma growth rates would be high.</li> <li>If LDL fraction is low and the HDL fraction is high, then atheroma growth rates are usually low, even negative, for any given total cholesterol concentration</li> </ul>
Uric Acid	Men 3.0-5.7 mg/dL Women 1.5-6.0 mg/dL	<ul style="list-style-type: none"> <li>Increase in serum uric acid is seen in renal failure, liver disease, high alcohol consumption, etc.</li> <li>Excess serum accumulation of uric acid can lead to a type of disease known as gout. Elevated serum uric acid (hyperuricemia) can result from high intake of purine-rich foods or impaired excretion by the kidneys.</li> <li>Saturation levels of uric acid in blood may result in kidney stones.</li> <li>Decreased serum uric acid level may not be of clinical significance.</li> </ul>
Alkaline Phosphatase	Adult 110-310 IU/L Children 270-810 IU/L	<ul style="list-style-type: none"> <li>Increased serum alkaline phosphatase is seen in states of increased osteoblastic (activity of young bone cells), hyperparathyroidism, osteomalacia and disease of bileduct/liver and in during pregnancy.</li> <li>Decreased serum alkaline phosphatase may not be clinically significant. However, decreased serum levels have been observed in hypothyroidism and scurvy.</li> </ul>
Amylase	25-125 IU/L	<ul style="list-style-type: none"> <li>Increased plasma levels in humans are found in Mumps, Pancreatitis (because of damage to the cells that produce amylase) and renal failure (due to reduced excretion).</li> <li>Decreased levels are found in acute or chronic hepatocellular damage.</li> </ul>
Gamma GT	8-54 IU/L	<ul style="list-style-type: none"> <li>GGT may be high in liver disease. It is observed in cases of obstruction in the bile duct.</li> <li>GGT serum measurement provides a very sensitive indicator of the presence or absence of hepatobiliary (disease of liver and bile duct) disease.</li> <li>Raised GGT levels are seen in pancreatic disease, myocardial infarction, renal failure, diabetes, obesity and alcoholism.</li> </ul>
Creatine Kinase	Male: upto 160 IU/L Female: upto 130 Children 2-3 times the normal adult value.	<ul style="list-style-type: none"> <li>Elevation of CK is an indication of damage to muscle. (Skeletal and cardiac) It is therefore indicative of injury, myocardial infarction</li> <li>Lowered CK can be an indication of alcoholic liver disease and rheumatoid arthritis.</li> </ul>
Calcium	8.5 - 10.5 mg/dL (normally slightly higher in children)	<ul style="list-style-type: none"> <li>Increased level of calcium is seen incases of hyperparathyroidism, vitamin D intoxication and some diseases of bone.</li> <li>Long-term calcium deficiency can lead to rickets and poor blood clotting and in case of a menopausal woman, it can lead to osteoporosis, in which the bone deteriorates and there is an increased risk of fractures.</li> <li>While a lifelong deficit can affect bone and tooth formation.</li> <li>High serum concentration can cause hypocalcaemia (elevated levels of calcium in the blood), impaired kidney function and decreased absorption of other minerals.</li> <li>Vitamin D is needed to absorb calcium.</li> </ul>
Inorganic Phosphorus	3.0 - 4.5 mg/dL (inorganic)	<ul style="list-style-type: none"> <li>Increase in the concentration of Inorganic Phosphorus is seen in the case of vitamin D excess, renal failure, hypoparathyroidism, Diabetes mellitus etc.</li> </ul>



**BeneSphera™**

## **PRODUCT BROCHURE**



# BeneSphera™ Liquid Stable Clinical Chemistry Reagents



## Features and Benefits

- ◆ CE Certified
- ◆ ISO 13485 : 2003 Certified
- ◆ Single/Double Reagent
- ◆ Stable Blank Reagent Absorbance
- ◆ Total Quality Assurance
- ◆ In House R & D/Manufacturing
- ◆ Long Shelf Life of 18-24 Months
- ◆ Cost Effective
- ◆ Application Support

 **BeneSphera™**

Now part of  
 **AVANTOR™**  
PERFORMANCE MATERIALS



# **PACK PRESENTATIONS**



## PACK PRESENTATIONS

### Clinical Chemistry Reagents

Part No.	Material Description	Method	Reagent Type	Pack Size	(mL)
15000387	α-AMYLASE	CNP - G3	SINGLE REAGENT	1 X 10	10
15000386	α-AMYLASE	CNP - G3	SINGLE REAGENT	2 X 30	60
15000000	ALBUMIN	BCG	SINGLE REAGENT	4 X 50	200
15000505	ALKALINE PHOSPHATASE	DGKC	DOUBLE REAGENT	4 x 10, 1 x 10	50
15000506	ALKALINE PHOSPHATASE	DGKC	DOUBLE REAGENT	4 x 20, 1 x 20	100
15000507	ALKALINE PHOSPHATASE	DGKC	DOUBLE REAGENT	4 x 40, 1 x 40	200
15000500	BILIRUBIN T&D	JENDRASSIK & GROFF.	TRIPLE REAGENT	2 x 50, 1 x 10, 1 x 50	100
15000501	BILIRUBIN T&D	JENDRASSIK & GROFF.	TRIPLE REAGENT	4 x 50, 1 x 20, 2 x 50	200
15000388	TOTAL CHOLESTEROL	CHOD - POD	SINGLE REAGENT	4 X 25	100
15000389	TOTAL CHOLESTEROL	CHOD - POD	SINGLE REAGENT	4 X 50	200
15000390	GLUCOSE	GOD - POD	SINGLE REAGENT	4 X 250	1000
15000391	GLUCOSE	GOD - POD	SINGLE REAGENT	1 X 1000	1000
15000496	SGOT/AST	IFCC-KINETIC	DOUBLE REAGENT	4 x 20, 1 x 20	100
15000497	SGOT/AST	IFCC-KINETIC	DOUBLE REAGENT	4 x 40, 1 x 40	200
15000498	SGPT/ALT	IFCC-KINETIC	DOUBLE REAGENT	4 x 20, 1 x 20	100
15000499	SGPT/ALT	IFCC-KINETIC	DOUBLE REAGENT	4 x 40, 1 x 40	200
15000009	HAEMOGLOBIN	CYANMETHEMOGLOBIN	SINGLE REAGENT	1 X 1000	1000
15000011	TOTAL PROTEIN	BIURET	SINGLE REAGENT	4 X 50	200
15000392	TRIGLYCERIDES	GPO - POD	SINGLE REAGENT	4 X 25	100
15000393	TRIGLYCERIDES	GPO - POD	SINGLE REAGENT	4 X 50	200
15000394	URIC ACID	URICASE - POD	SINGLE REAGENT	4 X 25	100
15000395	URIC ACID	URICASE - POD	SINGLE REAGENT	4 X 50	200
15000502	UREA UV	GLDH	DOUBLE REAGENT	4 x 10, 1 x 10	50
15000503	UREA UV	GLDH	DOUBLE REAGENT	4 x 20, 1 x 20	100
15000504	UREA UV	GLDH	DOUBLE REAGENT	4 x 40, 1 x 40	200
15000004	CREATININE	Mod.Jaffe	SINGLE REAGENT	4 x 50	200
15000005	CREATININE	Mod.Jaffe	SINGLE REAGENT	4 x 100	400
15000060	CALCIUM	Arsenazo III	SINGLE REAGENT	100	100
	CK-MB	Immunoinhibition	DOUBLE REAGENT	5 x 10	50
	CK-MB	Immunoinhibition	DOUBLE REAGENT	5 x 20	100
	CK-NAC	Kinetic IFCC	DOUBLE REAGENT	5 x 10	50
	CK-NAC	Kinetic IFCC	DOUBLE REAGENT	5 x 20	100
	SODIUM	Phosphonazo III	SINGLE REAGENT	Launching Soon	
	MAGNESIUM	Phosphonazo III	SINGLE REAGENT	Launching Soon	



# **TECHNICAL SPECIFICATIONS**



## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>α-AMYLASE</b>	15000387	1 X 10
	15000386	2 X 30
Method	CNP G3	
Sample Type	Human Serum	
Reagent	Single	
Reaction	Kinetic	
Standard	No	
Linearity	2000 IU/L	
Shelf Life	18 months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>ALBUMIN</b>	15000000	4 X 50
Method	BCG	
Sample Type	Human Serum/Plasma	
Reagent	Single	
Reaction	End Point	
Standard	Human Serum Calibrator	
Linearity	6 gm/dL	
Shelf Life	15 months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>ALKALINE PHOSPHATASE</b>	15000505	4x10, 1x10
	15000506	4x20, 1x20
	15000507	4x40, 1x40
Method	DGKC	
Sample Type	Human Serum	
Reagent	Double	
Reaction	Kinetic	
Standard	No	
Linearity	1500 IU/L	
Shelf Life	12 months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>BILIRUBIN T&amp;D</b>	15000500	2x50, 1x10, 1x50
	15000501	4x50, 1x20, 2x50
Method	Jendrassik & Groff	
Sample Type	Human Serum/Plasma	
Reagent	Triple	
Reaction	End Point	
Standard	No/Calibration Factor	
Linearity	20 mg/dL	
Shelf Life	24 months	
Storage	Room Temperature	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>TOTAL CHOLESTEROL</b>	15000388	4 X 25
	15000389	4 X 50
Method	CHOD-POD	
Sample Type	Human Serum/Plasma	
Reagent	Single	
Reaction	End Point	
Standard	Yes, 200 mg /dL	
Linearity	750 mg/dl	
Shelf Life	12 months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>GLUCOSE</b>	15000390	4 X 250
	15000391	1 X 1000
Method	GOD-POD	
Sample Type	Serum or Plasma	
Reagent	Single	
Reaction	End Point	
Standard	Yes, 100 & 500 mg/dL	
Linearity	500 mg / dL	
Shelf Life	15 months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>SGOT/AST</b>	15000496	4x 20, 1x 20
	15000497	4x 40, 1x 40
Method	IFCC/Kinetic	
Sample Type	Human Serum/Plasma	
Reagent	Double	
Reaction	Kinetic	
Standard	No	
Linearity	350 IU/L	
Shelf Life	18 Months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>SGPT/ALT</b>	15000498	4x 20, 1x 20
	15000499	4x 40, 1x 40
Method	IFCC/Kinetic	
Sample Type	Human Serum/Plasma	
Reagent	Double	
Reaction	Kinetic	
Standard	No	
Linearity	350 IU/L	
Shelf Life	18 Months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>HAEMOGLOBIN</b>	15000009	1 X 1000
Method	CYANMETHAEMOGLOBIN	
Sample Type	Whole Blood	
Reagent	Single	
Reaction	End point	
Standard	Human Blood Calibrator	
Linearity	20 gm/ dL	
Shelf Life	15 months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>TOTAL PROTEIN</b>	15000011	4 X 50
Method	BIURET	
Sample Type	Serum or Plasma	
Reagent	Single	
Reaction	End Point	
Standard	Human Serum Calibrator	
Linearity	10 gm/ dL	
Shelf Life	15 months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>TRIGLYCERIDES</b>	15000392	4 X 25
	15000393	4 X 50
Method	GPO-POD	
Sample Type	Human Serum/Plasma	
Reagent	Single	
Reaction	End Point	
Standard	Yes, 200 mg/dL	
Linearity	1000 mg/dL	
Shelf Life	12 months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>URIC ACID</b>	15000394	4 X 25
	15000395	4 X 50
Method	URICASE-POD	
Sample Type	Human Serum, Plasma & Urine	
Reagent	Single	
Reaction	End Point	
Standard	Yes, 6 mg/dL	
Linearity	25 mg/dL	
Shelf Life	15 months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>UREA UV</b>	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40
Method	GLDH	
Sample Type	Human Serum, Plasma/Urine	
Reagent	Double	
Reaction	Initial Rate, Kinetic	
Standard	Yes, 50 mg/dL	
Linearity	300 mg/dL	
Shelf Life	15 Months	
Storage	2-8° C	

<b>Parameter</b>	<b>Part Number</b>	<b>Pack Size (mL)</b>
<b>CREATININE</b>	15000004	4 x 50 ml
	15000005	4 x 100 ml
Method	Mod. Jaffe	
Sample Type	Human Serum, Plasma/Urine	
Reagent	Single	
Reaction	Initial Rate, Fix Time	
Standard	Yes, 2 mg/dL	
Linearity	25 mg/dL	
Shelf Life	18 Months	
Storage	2-8° C	

## TECHNICAL SPECIFICATIONS

Parameter	Part Number	Pack Size (mL)
<b>CALCIUM</b>	15000060	100 mL
Method	Arsenazo III	
Sample Type	Human Serum	
Reagent	Single	
Reaction	End Point	
Standard	Yes, 10 mg/dL	
Linearity	15 mg/ dL	
Shelf Life	18 Months	
Storage	2-8° C	

# KIT INSERTS





## Clinical Chemistry Reagent

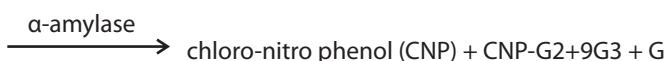
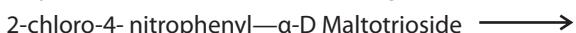
### Liquid Stable

#### INTENDED USE:

(For the *in vitro* diagnosis of  $\alpha$ -Amylase in human serum.)

#### TEST PRINCIPLE:

Defined oligosaccharides such as 2-chloro-4-nitrophenyl- $\alpha$ -D Maltotrioside are cleaved under the catalytic action of  $\alpha$ -amylases. The release of the chromogen CNP is then measured.



The intensity of chromogen CNP formed is directly proportional to the  $\alpha$ -amylase activity and is measured kinetically at 405nm.

#### KIT CONTENTS:

##### Reagent 1 : AMYLASE SINGLE REAGENT

Potassium Thiocyanate: 0.45 m/l

2 Chloro-p-nitrophenyl- $\alpha$ -D-maltotrioside: 0.8 mM/l

Sodium Azide : 0.05%

#### Insert: 1 No.

#### PREPARATION OF WORKING REAGENT:

Liquid stable calcium reagents are ready to use.

**STORAGE AND STABILITY:** 2°C - 8°C.

The reagent should be stored in 2-8°C and are stable till the expiry date mentioned in the labels. Do not freeze the reagent.

#### SPECIMEN:

Unhemolysed serum is the specimen of choice. E.D.T.A., oxalate or citrate inhibit Amylase activity hence cannot be used. Amylase in serum is reported to stable for one week at room temperature and for two months when stored refrigerated at 2-8°C.

#### PRECAUTIONS:

**Liquid Stable Amylase** reagent is for *in vitro* diagnostic use only . Reagent -1 contains 0.1% sodium azide. It may react with lead and copper plumbing to form highly explosive metal azides. Flush with large volumes of water upon disposal.

#### PROCEDURE (Automated):

Refer to specific instrument application instructions.

## $\alpha$ - Amylase

(CNP G3 Method)

#### TEST PROCEDURE (Manual):

Pipette into test tubes	Test
Amylase single reagent	1.0 ml
Sample	25 $\mu$ l

Mix thoroughly and transfer the assay mixture immediately to the thermo-stated cuvette and record the first absorbance reading after 60 seconds and subsequently two more absorbance readings with 60 seconds interval at 405 nm.

#### CALCULATIONS:

Calculate the average change in absorbance per minute ( $\Delta$ Abs/minute)

Activity of  $\alpha$ -amylase in IU/l =  $\Delta$ Abs/minute X 3178 (Kinetic factor)

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### EXPECTED VALUES\*:

Serum: 25 – 140 IU/l

\*It is recommended that each laboratory should establish its own normal range.

#### PERFORMANCE

1. **Linearity:** 2000 IU/l

2. **Comparison:**  $r = 0.98$

$$y=0.97x + 4.5$$

#### 3. Precision:

	Within Run			Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	10.0	0.7	1.0	12.0	0.8	3.0
High	1400	6.8	0.8	148	15.6	1.3

4. **Specificity:** No interference with 1gm/L Haemoglobin & Bilirubin (30 mg/dl)

#### CLINICAL SIGNIFICANCE:

The  $\alpha$ -amylases (1,4- $\alpha$ -D-Gluca-4-glucano-hydrolase, EC 3.2.1.1) catalyze the hydrolytic degradation of polymeric carbohydrates such as amylose, amylopectin and glycogen by cleaving 1,4- $\alpha$ -glucosidic bonds. In polysaccharides and oligosaccharides, several glycosidic bonds are hydrolyzed simultaneously. Maltotriose, the smallest such unit, is converted into maltose and

glucose, albeit very slowly. Because of the spared of specific clinical symptoms of pancreatic diseases,  $\alpha$ -amylase determinations are of considerable importance in pancreatic diagnostics. They are mainly used in the diagnosis and monitoring of acute pancreatitis. Hyperamylasemia does not, however, only occur with acute pancreatitis or in the inflammatory phase of chronic pancreatitis, but also in renal failure (reduced glomerular filtration), tumours of the lungs or ovaries, pulmonary inflammation, diseases of the salivary gland, diabetic ketoacidosis, cerebral trauma, surgical interventions or in the case of macroamylasemia.

#### AUTOMATED APPLICATIONS :

**Liquid Stable Amylase** reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbachem-5, Ranlab etc. Application sheets for use on specific semi automatic / batch analysers are available on request. Input parameters for semi auto / auto analyzers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Factor	3178
Incubation time	60 seconds
Interval time	60 seconds
Interval no.	2
Units	IU/l
Temperature	37°C
Upper Normal value	140
Lower Normal value	25
Linearity	2000
Working reagent volume	1.0 ml
Sample volume	25 $\mu$ l

#### NOTES:

1. To avoid possible contamination do not pipette by mouth and avoid contact of the reagent and pipette tips with skin.
2. Reagent contains Potassium Thiocyanate, therefore pipetting by mouth should be avoided.
3. The expected values of Amylase are dependent on the substrate used in the formulations using other substrates.
4. Reagent should not be used if its absorbance exceeds 0.800 at 405 nm against distilled water.

#### REFERENCES:

1. Young DS, Effects of drugs on clinical laboratory tests. 4th ed AAC press. Washington DC ; 3-43 to 3-47 1995.
2. Junge W, Troge B, Klein G et al. Evaluation of a New Assay for Pancreatic Amylase: Performance Characteristics and Estimation of Reference Intervals. Clin Biochem 1989;22:109-114
3. Junge W, Waldenström J, Bouman A et al. Evaluation of the Assay for Total and pancreatic Alpha-Amylase based on 100% Cleavage of Et-G7-PNP at 6 European Clinical Centres (Poster Medlab 97). Basel, Switzerland: 12.IFCC European Congress of Clinical Chemistry, August 17-22, 1997.
4. Kurrale-Jarres JD, Hafkenscheid JCM, Hohenwallner W et al. Evaluation of a New  $\alpha$ -Amylase Assay Using 4,6-Ethyldene-(G7)-1-4-nitrophenyl-(G1)- $\alpha$ -D-maltoheptaoside as Substrate. J Clin Chem Clin Biochem 1989;27:103-113.
5. Kurrale-Weitenhiller A, Hözel W, Engel D et al. Method for the Determination of Total and Pancreatic  $\alpha$ -Amylase based on 100% Cleavage on the protected substrate Ethylidene-4-nitrophenyl- Maltoheptaoside. Clin Chem 1996; 42:98.
6. Lorentz K. Approved Recommendation on IFCC Methods for the Measurement of Catalytic Concentration of Enzymes. Part 9.IFCC-Method for  $\alpha$ -Amylase (1,4- $\alpha$ -D-Gluca 4-Glucanohydrolase, EC 3.2.1.1.). Clin Chem Lab Med 1998;38:195-203
7. Salt WB II, Schenker S. Amylase-its clinical significance: a review of the literature [Review]. Medicine 1976; 55:269-281 .
8. Steinberg WM, Goldstein SS, Davies ND et al. Diagnostic assays in acute Pancreatitis [Review]. Ann Intern Med 1985; 102:576 - 580.

#### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.



Manufactured by:  
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LTD/ELA/DELAS1



## Clinical Chemistry Reagent

### Liquid Stable

### Albumin

(BCG)

#### INTENDED USE:

For quantitative estimation of serum and plasma albumin

#### TEST PRINCIPLE:

Under acidic conditions, albumin present in the serum sample binds to bromocresol green to form a green coloured albumin - BCG complex, which is photometrically measured at 628 nm. Intensity of the colour formed is directly proportional to albumin concentration in the sample.

#### KIT CONTENTS:

##### Reagent 1 : BCG Reagent

Succinate buffer, pH 4.2      75 mM/l  
Bromocresol green      0.14g/l

##### Reagent 2: Calibrator

Human Albumin (Conc : as indicated on the label)

Insert                          01 No.

#### PREPARATION OF WORKING REAGENT:

Liquid Stable ALBUMIN reagent is ready to use.

**STORAGE AND STABILITY:** 2°C

**Liquid Stable ALBUMIN** reagent is stable till the expiry date indicated on the labels when stored at 2-8°C. All reagents must be brought to room temperature prior to use. All reagents must be returned back to refrigerator after use.

#### SPECIMEN COLLECTION & STORAGE:

Serum or heparinised plasma can be used. Samples should preferably be used on the same day. If necessary, may be preserved upto one week if stored at 2-8°C. Samples must be brought to room temperature prior to use.

#### PRECAUTIONS:



**ALBUMIN** reagents are for *in vitro* diagnostic use only.

Avoid contact with skin, eyes and clothes. Do not pipette by mouth.

#### PROCEDURE (Automated):



Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):



Pipette into Test Tubes	Blank	Standard	Test
BCG Small Reagent	1.0 ml	1.0 ml	1.0 ml
Calibrator	-	10 µl	-
Sample	-	-	10 µl
Distilled water	10 µl	-	-
Mix and read the absorbance of the Test ( $A_T$ ). Calibrator ( $A_g$ ) and Blank ( $A_B$ ) after 1 min. and within 10 min. at 628 nm (600 to 650 nm) or with red filter against distilled water.			

#### CALCULATIONS :

$$\text{Albumin (gm/dl)} = \frac{A_T - A_B}{A_g - A_B} \times \text{Albumin concentration}$$

provided on Calibrator label

#### EXPECTED VALUES\* :

Albumin : 3.2 - 5.5 gm/dl

\*It is recommended that each laboratory should establish its own normal range.

#### PERFORMANCE

##### 1. Comparison: $r = 0.98$

$$y=0.96x - 0.2$$

##### 2. Precision:

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 3.0	0.1	1.5	3.0	0.2	3.0
High 4.0	0.2	3.0	4.0	0.1	2.0

##### 3. Specificity:

Amticyllin has been found to be highly interfered substance in BCG method. No interference upto 1gm/l Haemoglobin & Bilirubin ( 30 mg /dl)

#### CLINICAL SIGNIFICANCE :

Elevated levels of serum albumin are associated with dehydration and stasis during venepuncture. Decreased levels of albumin are found during over hydration, excessive protein loss from kidney, skin or intestine, decreased synthesis due to dietary deficiency, liver disease or malnutrition and increased catabolism.

#### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

## AUTOMATED APPLICATIONS :

**Liquid Stable ALBUMIN** reagents can be used with Hitachi 700 series, 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa BTR 810/820/830, RA 50, Erbachem-5 plus etc.

Application sheets for use on specific semi automatic, batch and auto analysers are available on request. Input parameters for semi auto / auto analysers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	End point
Wavelength	628 nm
Incubation time	1 min
Calibrator concentration	as on label
Units	gm/dl
Upper Normal value	5.5 gm/dl
Lower Normal value	3.2 gm/dl
Linearity	6 gm/dl
Reagent volume	1 ml
Sample / Calibrator volume	10 µl

## REFERENCES :

- Kaplan, A. and Szabo, L.L. (1983) : Clinical Chemistry. In Interpretation of techniques. 2nd edition. Lea and Febiger Philadelphia pp 403.
- Gustafsson, J.E.C. (1976) Clin Chem 22 : 616



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LTDAL/DELAS1



## Clinical Chemistry Reagent

### Liquid Stable

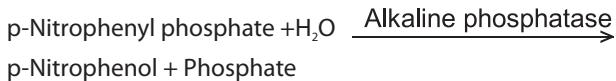
# Alkaline Phosphatase

(DGKC)

#### INTENDED USE:

(For quantitative *in vitro* determination of alkaline phosphatase (ALP) in human serum)

#### TEST PRINCIPLE



Under alkaline condition, colorless p-Nitrophenyl phosphate is converted to phosphate and p-nitrophenol which develops a very intense yellow color.

Its intensity is proportional to the activity of alkaline phosphatase in the sample.

#### KIT CONTENTS:

##### Reagent 1: Buffer :

Diethanolamine	: 1 M/l
Magnesium Chloride	: 0.5 mM/l

##### Reagent 2: Enzyme concentrate :

Tris Buffer (Tris Hydroxymethylaminoethane)	: 85 mM/l
pNPP (p-Nitrophenyl phosphate)	: 20 mM/l
Insert	: 01

#### PREPARATION OF THE WORKING REAGENT

Mix 4 parts of reagent 1 with 1 part of reagent 2

#### REAGENT STABILITY AND STORAGE

Conditions: protect from light  
close immediately after use

##### Working Reagent:

Stability:	at 2-8°C	4 weeks
	at 21-25°C	3 days

Maximum allowable absorbance of working reagent measured at 405 nm against water as reference is 1.0.

#### SAMPLE STABILITY AND STORAGE

Stability:	at 2-8°C	7 days
	at -20°C	2 months
Loss of activity:	at 21-25°C	within 2-3 days

#### PRECAUTIONS



1. Liquid Stable ALKALINE PHOSPHATASE reagents are for *in vitro* Diagnostic use only [IVD]. Avoid contact with skin, eyes and clothes. Do not pipette by mouth.

#### PROCEDURE (Automated):



Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):



Wavelength : 405 nm

Reaction Temperature : 37°C

Pipette into Test Tubes	Volume
Working Reagent	1 ml
Sample	20 µl

Mix and after 1 minute incubation, measure change in absorbance (DOD/min) for 1 minute and use it for calculation.

#### CALCULATIONS:

Alkaline phosphatase activity (IU/l) =  $\Delta\text{OD}/\text{min} \times 2757$  (Factor)

Temperature conversion factors for human serum

Assay	Desired Temperature		
	25°C	30°C	37°C
25°C	1.00	1.32	1.82
30°C	0.76	1.00	1.39
37°C	0.55	0.72	1.00

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### EXPECTED VALUES\*:

Children	270-810 IU/l
Adults	110-310 IU/l

\*It is recommended that each laboratory should establish its own normal range.

#### PERFORMANCE

1. Linearity: 1500 IU/L

2. Comparison:  $r = 0.97$   
 $y = 0.97x - 2.0$

3. Precision:

	Within Run			Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	50.0	0.5	1.0	52.0	2.0	2.0
High	150.0	1.0	0.5	151.0	1.5	1.0

## **CLINICAL SIGNIFICANCE :**

Elevated level of serum alkaline phosphatase is associated with bone degeneration and the activity increases in rickets and osteomalacia. Higher values of activity are also found in post hepatic jaundice and infective or toxic hepatitis. Elevated levels of activity also occur during pregnancy and due to intake of certain drugs like steroids, sulphonamides etc.

## **INTERFERING SUBSTANCES:**

Anticoagulants other than heparin, ammonium and phosphate salts, improperly cleaned glassware may inhibit alkaline phosphatase activity. The method is relatively free of interference from commonly used drugs and other body metabolites.

## **AUTOMATED APPLICATIONS:**

**Liquid Stable ALKALINE PHOSPHATASE** reagents can be used with most of the commonly available semi-auto and fully-automated biochemistry analyzers.

Application sheets for use on specific semi-automatic, batch analyzers are available on request. Input parameters for semi-auto/auto analyzers are given below.

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Increasing
Wavelength	405 nm
Incubation time	60 sec.
Interval time	60 sec.
Interval no.	1
Factor	2757
Flowcell temperature	37°C
Molar extinction coefficient	18.7
DOD/min limit	0.55
Units	IU/l
Upper Normal value	810 IU/l
Lower Normal value	110 IU/l
Linearity	1500 IU/l
Working Reagent volume	1 ml
Sample volume	20 µl

## **QUALITY CONTROL:**

It is recommended that each laboratory must establish their own frequency of controlled determination.

## **REFERENCES**

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LTD/EL/DELAS1

**Clinical Chemistry Reagent**
**Liquid Stable**
**BILIRUBIN T&D**
**(Jendrassik & Grof method)**
**INTENDED USE:**

For quantitative estimation of Bilirubin T and D in serum and plasma. For *in vitro* Diagnostics use only. **IVD**

**TEST PRINCIPLE :**

Both conjugated and unconjugated bilirubin react with diazotized sulphanilic acid. Reaction with unconjugated bilirubin is hastened by the use of caffeine sodium benzoate as accelerator for total bilirubin estimation. The pink colour developed is measured at 540 nm and the intensity of colour formed is directly proportional to bilirubin concentration in the sample.

**KIT CONTENTS :**

Reagent 1 Diazo A:

Sulphanilic Acid: 26 mM/l, Hydrochloric Acid- 180 mM/l

Reagent 2 Diazo B:

Sodium Nitrite: 10 mM/l

Reagent 3 Activator:

Sodium Benzoate: 340 mM/l, Caffeine: 200 mM/l

Insert : 01 No.

**PREPARATION OF WORKING SOLUTION**

All reagents are ready to use.

**STORAGE AND STABILITY :** 2-8°C 

**Liquid Stable BILIRUBIN T&D** reagents are stable till the expiry date mentioned on the labels when stored at 2-8°C.

**SPECIMEN :**

Unhemolysed serum or heparinised plasma. Samples should be used on the same day. If necessary, the samples may be preserved in a refrigerator at 2-8°C for 24 hours.

**PRECAUTIONS:** 

1. **Liquid Stable BILIRUBIN T&D** is for *in vitro* diagnostic use only. **IVD**
2. Avoid contact with skin or eyes.
3. Do not perform the test in direct light.

**NOTE :**

Please note that Reagent 3 may develop needle shaped crystals at low temperatures, which should be dissolved by warming at 37°C before use.

**INTERFERING SUBSTANCES :**

**Liquid Stable BILIRUBIN T&D** method is relatively free of

interference from commonly occurring substances in the blood.

**PROCEDURE (Automated):** 

Refer to specific instrument application instructions.

**PROCEDURE (Manual):** 

Direct Bilirubin		
Pipette into the tube	Blank	Test
Reagent 1	250 µl	250 µl
Reagent 2	-	25 µl
Mix thoroughly and proceed		
Purified water	750 µl	750 µl
Samples/ Controls	50 µl	50 µl
Mix well and incubate for one minute at CRT (21-25°C), and read the absorbance exactly after one minute at 540 nm filter.		

Total Bilirubin		
Pipette into the tube	Blank	Test
Reagent 1	250 µl	250 µl
Reagent 2	-	25 µl
Mix thoroughly and proceed		
Reagent 3	250 µl	250 µl
Purified water	500 µl	500 µl
Samples/ Controls	50 µl	50 µl
Mix well and keep the test tubes in dark at CRT (21-25 °C) for 5 minutes, read the absorbance at 540 nm filter.		

**CALCULATION OF RESULTS :**

Calculations for obtaining Direct and Total Bilirubin concentration in mg/dl :-

Corrected absorbance of Direct Bilirubin i.e.  $(A_{T1} - A_{B1}) \times 28$

Corrected absorbance of Total Bilirubin i.e.  $(A_{T2} - A_{B2}) \times 28$

**EXPECTED VALUES\*:**

Reference Ranges for Bilirubin	
Conjugated (Direct)	upto 0.25 mg/dl
Unconjugated	0.2 - 0.8 mg/dl
Total	upto 1.0 mg/dl

Reference Ranges for Infant Total Bilirubin		
Infants, Premature, Total Full-Term, Total		
24 h	1.0-6.0 mg/dl	2.0-6.0 mg/dl
48 h	6.0-8.0 mg/dl	6.0-7.0 mg/dl
3-5 days	10.0-12.0 mg/dl	4.0-6.0 mg/dl

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

#### AUTOMATED APPLICATIONS :

**Liquid Stable BILIRUBIN T&D** reagents can be used with most of the semi-automated analysers. Input parameters for semi auto/auto analysers are given as follows :

INPUT PARAMETERS	VALUES
Type of reaction	End Point
Wavelength	540 nm
Incubation time (Total Bilirubin)	5 minutes
Incubation time (Direct Bilirubin)	1 minutes
Incubation temperature	Room temperature (21-25°C)
Units	mg/dl
Upper Normal value	1 mg/dl (Total) 0.25 mg/dl (Direct)

#### CLINICAL SIGNIFICANCE

Defects in bilirubin metabolism resulting in jaundice can occur at each step in the metabolic pathway. The disorders are usually classified as (1) inherited disorders of bilirubin metabolism and (2) jaundice of the newborn. All of these disorders are characterised by pre-dominant elevations in either conjugated or unconjugated bilirubin in the absence of other abnormal liver tests. It is only in these disorders that bilirubin fractionation is clinically useful.

#### Inherited disorders of bilirubin metabolism:

- Gilbert's syndrome is a group of disorders characterized by increases of less than 3 mg/dl ( $51 \mu\text{mol/l}$ ) of unconjugated bilirubin. This benign condition occurs in approximately 2% of the population and is probably inherited as an autosomal recessive trait.

- Crigler-Najjar syndrome Type 1 is a rare disorder caused by complete absence of UDP glucuronyltransferase and manifested by very high levels of unconjugated bilirubin (25-50 mg/dl). It is inherited as an autosomal recessive trait. Most patients die of severe brain damage caused by kernicterus (encephalopathy related to increased bilirubin that leads to permanent brain damage) within the first year of life.
- Crigler-Najjar Syndrome-Type 2 is characterized by a partial deficiency of UDP glucuronyltransferase. Unconjugated bilirubin is usually 5 to 20 mg/dl. Unlike Crigler Najjar syndrome type 1, type 2 responds dramatically to phenobarbital and a normal life can be expected.

#### Jaundice in the neonate:

Disorders that cause jaundice in the neonate are classified as either unconjugated or conjugated hyper-bilirubinemia. Thus, fractionation of bilirubin in neonates is a useful diagnostic tool.

#### • Unconjugated Hyperbilirubinemias

The significance of unconjugated hyperbilirubinemia is potential for development of kernicterus, especially in low-birth-weight infants. With it, the infant becomes lethargic, with gradual progression to seizures. Seventy percent of affected infants die within the first week and the remaining have severe brain damage. This syndrome can be prevented by phototherapy and exchange transfusion.

Causes of unconjugated hyper-bilirubinemia in the neonate are physiological jaundice of the newborn, hemolytic disease and breast milk hyperbilirubinemia.

#### • Conjugated Hyperbilirubinemias

These syndromes are characterized by hyperbilirubinemia in which the conjugated bilirubin is more than 30% of the total. The most important are idiopathic neonatal hepatitis and biliary atresia.

#### REFERENCES :

- Jendrassik, Land Grof, S. (1938) A short text book of Clinical Pathology, 3rd edition, Reprinted in 1979.
- Tietz text book of Clinical Chemistry, Chapter 33, 3rd edition, 2000.



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LTD/ELA/DELAS1



## Clinical Chemistry Reagent

### Liquid Stable

## Cholesterol

(CHOD-POD Method)

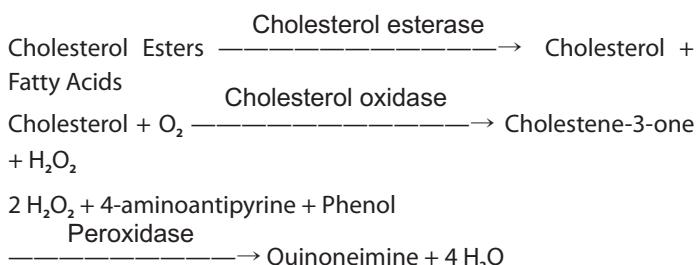
#### INTENDED USE:

(For the *in vitro* diagnosis of Total Cholesterol in human serum and plasma)

#### TEST PRINCIPLE:

Cholesterol methodologies have been critically reviewed by Tonks(1) and more recently by Zak(2). The enzymatic method described below, and used in this assay, is a modification of that described in 1974 by Allain et.al.(3) and Roschlau et.al(4). The use of enzymes to assay cholesterol has been studied by many investigators (5,6,7). This reagent is based on the formulation of Allain, et al.(3) and the modification of Roschlau(4) with further improvements to render the reagent stable in solution.

Cholesterol esters are enzymatically hydrolyzed by cholesterol esterase to cholesterol and free fatty acids. Free cholesterol, including that originally present, is then oxidized by cholesterol oxidase to cholest-4-ene-3-one and hydrogen peroxide. The hydrogen peroxide combines with phenol and 4-aminoantipyrine to form a chromophore (quinoneimine dye) which is quantitated at 500 nm.



#### KIT CONTENTS:

##### Reagent 1: Cholesterol Reagent

Phosphate Buffer : pH 7.0  
(Di Sodium Hydrogen Phosphate-4.5 g/l,  
Potassium Di Hydrogen Phosphate-2.5 g/l)

Phenol : 10 mmol/l

Cholesterol Esterase : 400 U/l

Cholesterol Oxidase : 125 U/l

Peroxidase : 4 kU/l

4 - Aminoantipyrine 0.3 mM/l

##### Reagent 2 : Cholesterol Standard

Cholesterol 200 mg/dl

#### Insert: 1 No.

#### PREPARATION OF THE WORKING REAGENT

All reagents are ready to use.



#### STORAGE AND STABILITY:

All the reagents should be stored in 2-8°C and are stable till the expiry date mentioned in the labels.

#### SPECIMEN:

Unhemolysed serum (fasting) is recommended. Heparinised plasma may be used. Cholesterol in serum is stable for seven days at room temperature and six months when frozen and properly protected against evaporation.

#### PRECAUTIONS:

**Liquid Stable Cholesterol** reagents are for *in vitro* diagnostic use only [IVD]. Reagent-1 and standard contains 0.1% sodium azide. It may react with lead and copper plumbing to form highly explosive metal azides. Flush with large volumes of water upon disposal.

#### PROCEDURE (Automated):

Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):

Pipette into test tubes labeled Blank (B), Standard (S) and Test (T) as follows:

Prepare into Test Tube	Blank	Standard	Test
Cholesterol Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	—	10 µl	—
Sample	—	—	10 µl

Mix well and incubate for 5 minutes at 37°C or 10 minutes at RT.

Read absorbance of Standard ( $A_s$ ), and Test ( $A_t$ ) against Blank ( $A_b$ ) at 505 nm or with green filter (500 - 540 nm).

#### CALCULATIONS:

Cholesterol Conc. in mg/dl =

$$\frac{\text{Abs of } A_t - A_b}{\text{Abs of } A_s - A_b} \times 200 \text{ (Conc. of Standard)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### EXPECTED VALUES\*:

Normal < 200 mg/dl

Border line high 200 - 239 mg/dl

High > 240 mg/dl

\*It is recommended that each laboratory should establish its own normal range representing its patient population.

#### PERFORMANCE

1. **Linearity:** 750 mg/dl

2. **Comparison:**  $r=0.98$

$$y=1.2x+7.4$$

### 3. Precision:

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 150.0	1.0	0.6	160.0	4.0	2.0
High 230.0	2.0	1.0	225.0	4.0	2.0

4. Specificity: No interference, enzymes are specific.

### CLINICAL SIGNIFICANCE :

Increased levels of cholesterol may be found in coronary artery disease, uncontrolled diabetes mellitus, hypothyroidism, nephrotic syndrome and hepatic malfunctions. Cholesterol level may be low in acute hepatitis, malnutrition, anaemia, hyperthyroidism and Gaucher's disease. Normal Cholesterol levels can be altered by age, stress, pregnancy and hormonal imbalance.

### AUTOMATED APPLICATIONS:

**Liquid Stable Cholesterol** reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbachem-5, Ranlab etc. Application sheets for use on specific semiautomatic / batch analysers are available on request. Input parameters for semiauto / auto analyzers are given below :

INPUT PARAMETERS	VALUES
Type of reaction	End point
Wavelength	505 nm
Incubation time	5 minutes
Standard concentration	200
Units	mg/dl
Temperature	37°C
Upper Normal value	200
Lower Normal value	0.0
Linearity	750
Cholesterol reagent volume	1.0 ml
Sample/ Standard volume	10 µl

### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

### NOTES:

1. Cholesterol reagent on storage at 2-8°C develops a slight pink colour. However this does not affect the performance of the test.
2. As with all the diagnostic procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

### REFERENCES

1. Tonks, D.B., The Estimation of Cholesterol in Serum, A Classification and Critical Review of Methods, Clin. Biochem. 1, 12 (1967).
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3. Allain, C.C., Poon, L., Chan, S.G., Richmond, W., Fu, P., Enzymatic Determination of Total Serum Cholesterol, Clin. Chem. 20, 470 (1974).
4. Roschlau, P., Bernt, E., Gruber, W., Enzymatische Bestimmung des Gesamt-Cholesterins in Serum, Z. Klin. chem. Klin. Biochem. 12, 226. (1974).
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6. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, Third Edition, 1990.
7. Witte, D.L., Barrett II, D.A., Wycoff, D.A., Evaluation of an Enzymatic Procedure for Determination of Serum Cholesterol with the Abbott-100, Clinical Chemistry 20, No. 10, 1282-1286 (1974).



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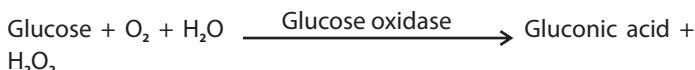
**Clinical Chemistry Reagent**
**Liquid Stable**
**Glucose**
**(GOD-POD Method)**
**INTENDED USE:**

(For the *in vitro* diagnosis of Glucose in human serum and plasma)

**TEST PRINCIPLE:**

Glucose present in the plasma is oxidized by the enzyme glucose oxidase (GOD) to gluconic acid with the liberation of hydrogen peroxide, which is converted to water and oxygen by the enzyme peroxidase (POD).

4-aminoantipyrine, an oxygen acceptor, takes up the oxygen and together with phenol forms a pink coloured chromogen which can be measured at 505 nm.


**KIT CONTENTS:**
**Reagent 1 : GLUCOSE REAGENT**

Phosphate Buffer : pH 7.0  
 (Di Sodium Hydrogen Phosphate - 7.5 g/l, Potassium Di Hydrogen Phosphate - 5.5 g/l)  
 4AAP (4Amino antipyrine) : 0.2 mM/l  
 Glucose Oxidase:18 U/ml  
 Peroxidase: 1.5 U/ml  
 Phenol: 6 mM/l

**Reagent 2 : Glucose Standard**

Glucose 100 mg/dl

**Reagent 3 : Glucose Standard**
**(For Confirmation of Higher Linearity)**

Glucose 500 mg/dl

**Insert: 1 No.**
**PREPARATION OF THE WORKING REAGENT**

All reagents are ready to use.


**STORAGE AND STABILITY: 2°C**

All the reagents should be stored in 2-8°C and are stable till the expiry date mentioned in the labels.

**SPECIMEN:**

Serum/plasma/CSF can be used as sample. Serum should be separated from blood as soon as possible. For plasma; collect venous blood in tubes containing oxalate fluoride.

**PRECAUTIONS:**

**Liquid Stable Glucose** reagents are for *in vitro* diagnostic use only [IVD]. Reagent-1 and standard contains 0.1% sodium azide. It may react with lead and copper plumbing to form highly explosive metal azides. Flush with large volumes of water upon disposal.

**PROCEDURE (Automated):**

Refer to specific instrument application instructions.

**TEST PROCEDURE (Manual): END POINT**

Pipette into test tubes labeled Blank (B), Standard (S) and Test (T) as follows:

Prepare into Test Tube	Blank	Standard	Test
Glucose Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	—	10 µl	—
Sample	—	—	10 µl

Mix well and incubate for 10 minutes at 37°C or 20 minutes at RT.

Read absorbance of Standard ( $A_s$ ), Test ( $A_t$ ) and Reagent Blank ( $A_b$ ) at 505 nm or with green filter (500 - 540 nm).

**CALCULATIONS:**

$$\text{Glucose Conc. in mg/dl} = \frac{\text{Abs of } A_t - A_b}{\text{Abs of } A_s - A_b} \times 100 \text{ (Conc. of Standard)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

**TEST PROCEDURE (Manual) : INITIAL RATE KINETIC**

Pipette into test tubes Standard ( $A_s$ ) and Test ( $A_t$ ) as follows:

Prepare into Test Tube	Standard	Test
Glucose Reagent	1.0 ml	1.0 ml
Standard	10 µl	—
Sample	—	10 µl

Mix and aspirate. After 1 minute incubation measure the change in absorbance ( $\Delta A_{bs}$ ) for one minute for standard and test. Use this ( $\Delta A_{bs}$ ) for calculations.

**CALCULATIONS:**

Glucose Conc. in mg/dl =

$$\frac{\Delta A_{bs} T}{\Delta A_{bs} S} \times 100 \text{ (Concentration of Standard)}$$

**EXPECTED VALUES\*:**

Fasting: 70-110 mg/dl Post-prandial: 70-140 mg/dl

CSF: 40-70 mg/dl

\*It is recommended that each laboratory should establish its own normal range.

**PERFORMANCE**
**1. Linearity: 500mg/dl**
**2. COMPARISON:**

A comparison between **Liquid Stable Glucose** (y) and a commercially available test(x) using 45 samples gave the following results:

$$Y = 1.017x - 2.410$$

$$r = 0.99$$

### 3. Precision:

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 100.0	0.5	0.5	100.0	2.0	2.0
High 250.0	1.5	1.0	257.0	3.0	1.5

**4. Specificity:** No interference upto Hemoglobin (1gm/l) & Bilirubin (30 mg /dl)

### CLINICAL SIGNIFICANCE:

Glucose is a reducing monosaccharide that serves as the principal fuel of all the tissues. It enters the cell through the influence of insulin and undergoes a series of chemical reactions to produce energy.

Lack of insulin or resistance to its action at the cellular level causes diabetes. Therefore, in diabetes mellitus the blood glucose levels are very high. Some patients with very high blood glucose levels may develop metabolic acidosis and ketosis caused by the increased fat metabolism, the alternate source for energy. Hyperglycaemia is also noted in gestational diabetes of pregnancy and may be found in pancreatic disease, pituitary and adrenal disorders.

A decreased level of blood glucose, hypoglycaemia is often associated with starvation, hyperinsulinaemia and in those who are taking high insulin dose for therapy.

### AUTOMATED APPLICATIONS:

**Liquid Stable Glucose** reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbachem-5, Ranlab etc. Application sheets for use on specific semiautomatic / batch analysers are available on request. Input parameters for semi-auto / auto analyzers are given below:

### END POINT METHOD

INPUT PARAMETERS	VALUES
Type of reaction	End point
Wavelength	505 nm.
Incubation time	10 minutes
Standard concentration	100
Units	mg/dl
Temperature	37°C
Upper Normal value	140
Lower Normal value	70
Linearity	500
Working reagent volume	1.0 ml
Sample/ Standard volume	10 µl

### KINETIC METHOD

INPUT PARAMETERS	VALUES
Type of reaction	Initial rate kinetic
Wavelength	505 nm.
Incubation time	60 seconds
Reading time	60 seconds
Standard concentration	100
Units	mg/dl
Temperature	37°C
Upper Normal value	140
Lower Normal value	70
Linearity	500
Working reagent volume	1.0 ml
Sample/ Standard volume	10 µl

### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

### NOTES:

- Contamination of standard and reagents must be avoided. After use, all the reagents must be immediately stored back at 2-8°C.
- Use clean glassware/microtips while pipetting glucose standard.
- For sample volume higher than 500 mg/dl, dilute the sample with normal saline and multiply the results with the appropriate dilution factor.

### REFERENCES:

- Trinder, P. (1969). Annals of Clin. Biochem. 6: 24 – 27.
- Barham D and Trinder P. (1972). Analyst 97: 142 – 145.
- Bergmayer, H.V. (1974) Method of Enzymatic Analysis., P.1196



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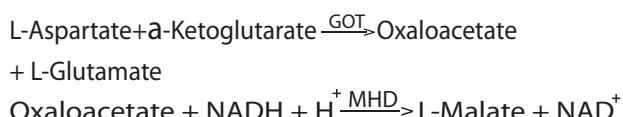
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**INTENDED USE:**

(For quantitative *in vitro* determination of GOT/AST in human serum or plasma).

**TEST PRINCIPLE**

NADH is oxidized to NAD, the resulting decrease in absorbance at 340 nm is directly proportional to the activity of GOT in the sample.


**ABBREVIATIONS**

GOT	=	Glutamate Oxaloacetate Transaminase
MDH	=	Malate Dehydrogenase
NAD	=	Nicotinamide Adenine Dinucleotide
NADH	=	reduced NAD
LDH	=	Lactate Dehydrogenase

**KIT CONTENTS :**
**Reagent 1: Buffer:**

MOPS Buffer [3-(N-Morpholino) propanesulfonic Acid], pH	
7.5	: 65 mM/l
L-Aspartate	: 260 mM/l
Malate Dehydrogenase (MDH)	: 4500 U/l
Lactate dehydrogenase (LDH)	: 8800 U/l
a-Ketoglutarate	: 12 mM/l

**Reagent 2 : Enzyme concentrate:**

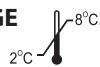
Tris Buffer (Tris Hydroxymethylaminoethane)	: 100 mM/l
NADH (Nicotinamide Adenine dinucleotide)	: 0.3 mM/l
Insert	: 01 No.

**PREPARATION OF THE WORKING REAGENT**

Mix 4 parts of Reagent 1 with 1 part of Reagent 2

**REAGENT STABILITY AND STORAGE**

Conditions: protect from light



close immediately after use  
do not freeze the reagents!

**Working Reagent:**

Stability: at 2-8°C      4 weeks  
at 21-25°C      2 days

Minimum allowable absorbance of the working reagent measured at 340 nm against water as reference is 1.0.

**SPECIMEN COLLECTION AND STORAGE**

Unhemolysed serum or heparinised plasma from fasting patients is recommended.

Loss of activity: at 2-8°C      < 8 % within 3 days  
at 21-25°C      < 10% within 3 days

Stability: at -20°C      at least 3 months

Discard contaminated specimens.

**PRECAUTIONS**

1. **Liquid Stable GOT/AST** reagents are for *in vitro* Diagnostic use only **[IVD]**.
2. The reagents contain sodium azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

**PROCEDURE (Automated):**

Refer to specific instrument application instructions.

**TEST PROCEDURE (Manual):**

Wavelength: 340 nm

Temperature: 37°C

**Bring reagents and samples to room temperature (21-25°C).**

Pipette into test tubes	Volume
Working reagent	1000 µl
Sample	100 µl

Mix and after one minute incubation, measure the change in absorbance ( $\Delta\text{OD}/\text{min}$ ) for 3 minutes. Determine the mean absorbance change per minute ( $\Delta\text{OD}/\text{min}$ ) and use this for calculation.

**CALCULATION:**

$$\text{GOT/AST activity (IU/l)} = \text{DOD/min} \times \text{Factor (1746)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

## REFERENCE RANGE \*(IU/I)

Males : upto 46

Females : upto 40

\* It is recommended that each laboratory establishes its own normal range.

## PERFORMANCE

1. **Linearity:** 350IU/I

2. **Comparision:**

r=0.985

y=0.98x2.1

3. **Precision:**

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 25	1.5	2.5	26	1.5	2.5
High 300	2.0	1	301	4.5	1.5

4. **Specificity:** Procedure is specifies. No interference with commonly occurring substances in serum and plasma.

## CLINICAL SIGNIFICANCE

GOT activity is predominantly associated with cardiac tissues, followed by comparatively low levels in the liver, muscles and kidneys. Quantitation of GOT levels is of significance in the diagnosis of myocardial infarction. Increased activity is observed within 3-9 hours of the onset of attack, peak levels are attained in about 18-24 hrs. which come back to normal levels in 6-7 days. Duration and extent of increase in enzyme levels is proportional to severity of the attack.

## INTERFERING SUBSTANCES

The procedure is specific for GOT/AST. It is relatively free of interference from commonly occurring circumstances in serum or plasma.

## AUTOMATED APPLICATIONS

**Liquid Stable GOT/AST** reagents can be used with most of the commonly available semi-auto and fully-automated biochemistry analyzers. Application sheets for use on specific semi-automatic, batch analyzers are available on request. Input parameters for semi-auto/auto analyzers are given below.

## QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

## Automated Applications:

Copy from exohit Liqued GOT/AST insert.

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Factor	1746
Incubation time	60 seconds
Interval time	60 seconds
Interval no.	3
Flowcell temperature	37°C
DOD / min. limit	0.2
Units	IU/I
Upper Normal value Male	: 46 IU/I
Female	: 40 IU/I
Lower Normal value	0 IU/I
Linearity	Upto 350 IU/I
Working reagent	1000 µl
Sample volume	100 µl

## REFERENCES:

1. **Clin. Chem. Acta 105 (1980)** S. 147 - 172.
2. **Synopsis der Leberkrankheiten:**  
H. Wallhöfer, E. Schmidt u. F. W. Schmidt, G. Thieme Verlag, Stuttgart 1974.
3. Thefeld W. et al, **Dt. Med. Wschr. 99** (1974), 343.



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LTDAL/DELAS1

## Liquid Stable

**INTENDED USE:**

(For quantitative *in vitro* determination of GPT/ALT in human serum or plasma).

Loss of activity: at 2-8°C < 10% within 3 days  
at 21-25°C < 17% within 3 days

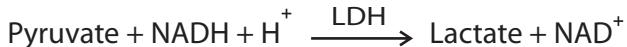
Stability: at -20°C at least 3 months  
Discard contaminated specimens.

**TEST PRINCIPLE**

NADH is oxidized to NAD<sup>+</sup>, the resulting decrease in absorbance at 340 nm is directly proportional to the activity of GPT in the sample.



L-Glutamate


**KIT CONTENTS :**
**Reagent 1: Buffer:**

Tris Buffer

(Tris Hydroxymethylaminomethane),

pH 7.5 : 110 mM/l

L-Alanine : 550 mM/l

LDH : 1000 U/l

$\alpha$ -Ketoglutarate : 16 mM/l

**Reagent 2: Enzyme concentrate:**

Tris Buffer

(Tris Hydroxymethylaminomethane) : 100 mM/l

NADH (Nicotinamide Adenine dinucleotide) : 0.3 mM/l

Insert : 01

**PREPARATION OF THE WORKING REAGENT**

Mix 4 parts of Reagent 1 with 1 part of Reagent 2

**REAGENT STABILITY AND STORAGE**

Conditions: protect from light



close immediately after use

do not freeze the reagents!

**Working Reagent:**

Stability: at 2-8°C 4 weeks

at 21-25°C 2 days

Minimum allowable absorbance of the working reagent measured at 340 nm against water as reference is 1.0.

**SPECIMEN COLLECTION AND STORAGE**

Unhemolysed serum or heparinised plasma from fasting patients is recommended.

**PRECAUTIONS**


1. **Liquid Stable GPT/ALT** reagents are for *in vitro* Diagnostic use only
2. The reagents contain sodium azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

**PROCEDURE (Automated):**


Refer to specific instrument application instructions.

**TEST PROCEDURE (Manual):**


Wavelength: 340 nm

Temperature: 37°C

**Bring reagents and samples to room temperature (21-25°C).**

Pipette into test tubes	Volume
Working reagent	1000 µl
Sample	100 µl
Mix and after one minute incubation, measure the change in absorbance ( $\Delta\text{OD}/\text{min}$ ) for 3 minutes. Determine the mean absorbance change per minute ( $\Delta\text{OD}/\text{min}$ ) and use this for calculation.	

**CALCULATION:**

$$\text{GPT/ALT activity (IU/l)} = \text{DOD/min} \times \text{Factor (1746)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

**REFERENCE RANGE \*(IU/l)**

upto 49 IU/l

\* It is recommended that each laboratory establishes its own normal range.

## PERFORMANCE

<b>1. Linearity:</b> 350 IU/
<b>2. Comparison:</b> $r = 0.98$ $y=0.95x + 2.3$
<b>3. Precision:</b>
Within Run
Mean      S.D.      C.V.%
Low    20.0      1.0      2.0
High   300.0      3.0      1.0
Run to Run
Mean      S.D.      C.V.%
21.0      1.0      2.0
301.0      2.0      1.0

- 4. Specificity:** Procedure is specific. No interference with commonly occurring substances in serum and plasma.

## INTERFERING SUBSTANCES

The procedure is specific for GPT/ALT. It is relatively free of interference from commonly occurring circumstances in serum or plasma.

## CLINICAL SIGNIFICANCE

GPT activity is predominantly associated with liver tissues followed by comparatively low levels in the heart, muscles and kidneys. Quantitation of GPT is a useful parameter in evaluating the liver function. Elevated levels of this enzyme are found in cases of hepatitis, obstructive jaundice, metastatic carcinoma, hepatic congestion and in kidney diseases.

## AUTOMATED APPLICATIONS

**Liquid Stable GPT/ALT** reagents can be used with most of the commonly available semi-auto and fully-automated biochemistry analyzers. Application sheets for use on specific semi-automatic, batch analyzers are available on request. Input parameters for semi-auto/auto analyzers are given below.

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Factor	1746
Incubation time	60 seconds
Interval time	60 seconds
Interval no.	3
Flowcell temperature	37°C
DOD / min. limit	0.2
Units	IU/l
Upper Normal value	49 IU/l
Lower Normal value	0 IU/l
Linearity	Up to 350 IU/l
Working reagent	1000 µl
Sample volume	100 µl

## QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

## REFERENCES:

1. **Clin. Chem. Acta 105 (1980)** S. 147 - 172.
2. **Synopsis der Leberkrankheiten:**  
H. Wallhöfer, E. Schmidt u. F. W. Schmidt, G. Thieme Verlag, Stuttgart 1974.
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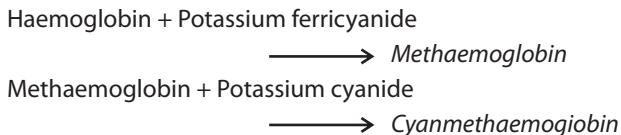
## Clinical Chemistry Reagent

### Liquid Stable

#### INTENDED USE:

(For quantitative estimation of haemoglobin in whole blood)

#### TEST PRINCIPLE:



The cyanmethaemoglobin formed is measured at 540 nm and the intensity of the colour formed is directly proportional to the haemoglobin concentration.

#### KIT CONTENTS:

##### Reagent 1 : Cyanmeth Reagent

(Ready to use)

##### Reagent 2: Standard

(Ready to use) 60 mg/dl

Insert: 01 No.

#### PREPARATION OF THE WORKING REAGENT

All reagents are ready to use.



**STORAGE AND STABILITY:** 2-8°C

The Cyanmeth Reagent is stable at room temperature ( $25 \pm 5^\circ\text{C}$ ) in unopened bottles till the expiry date indicated on the label. After opening the bottle, the Cyanmeth Reagent should preferably be stored at 2-8°C in dark. The Cyanmeth Reagent is stable for 12 months at 2-8°C.

#### SPECIMEN COLLECTION & STORAGE :

Whole blood. Blood samples should be used on the same day. Whole blood collected under sterile conditions may be preserved upto 72 hrs. at 2-8°C, if stored in tightly capped containers.

#### PRECAUTIONS:



HAEMOGLOBIN reagents are for *in vitro* diagnostic use only. [IVD]

Avoid contact with skin, eyes and clothes. Do not pipette by mouth as the reagent is POISONOUS.

#### CALIBRATION CURVE:

HAEMOGLOBIN standard (60mg/dl), equivalent to haemoglobin concentration of 15 gm/dl is used for plotting the calibration curve.

## Haemoglobin

(CYANMETHAEMOGLOBIN)

Pipette into test tubes	1	2	3	4
<b>Cyanmeth Reagent</b>	5.0 ml	4.0 ml	2.0 ml	-
<b>Standard</b>	-	2.0 ml	4.0 ml	5.0 ml
<b>Cone. in gm/dl</b>	0.0	5.0	10.0	15.0

Mix and read absorbance of tubes 2,3 & 4 against tube 1 as blank at 540 nm (520 to 560 nm) or with green filter. Plot a graph of absorbance[A<sub>T</sub>] against concentration in gm/dl (x-axis). Use this calibration curve for finding out concentration in gm/dl of the testsample.

#### PROCEDURE (Automated):



Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):



Pipette into Test Tubes	Blank	Test
Cyanmeth Reagent	5.0 ml	5.0 ml
Sample	-	20 pi (One Haemoglobin Pipette)

Mix thoroughly and after incubation for 3 minutes at room temperature read absorbance of test (A<sub>T</sub>) against the blank (A<sub>B</sub>) at 540 nm (520 to 560 nm) or with green filter.

#### CALCULATIONS:

The calibration curve is used to convert the absorbance A, to haemoglobin concentration in gm/dl. However, if a calibration curve is not prepared, a standard (S) should be run along with the test (T) and values calculated.

$$\text{Haemoglobin concentration (gm/dl)} = \frac{A_T}{A_B} \times \text{Factor}$$

Factor = 15 gm/dl when using HAEMOGLOBIN STANDARD of 60 mg/dl

or = Concentration of standard in gm/dl x 250

When using a precalibrated spectrophotometer, both calibration curve and individual standards are not required and the values can be calculated directly.

$$\text{Hb concentration (gm/dl)} = A_T \times 36.77$$

## **EXPECTED VALUES:**

Adult Males : 13 to 18 gm/dl  
 Adult Females : 11 to 16 gm/dl  
 Children (at 1 year) : 10 to 14 gm/dl  
 Infants : 14 to 20 gm/dl

## **PERFORMANCE**

**1. Linearity:** 20 gm/dl

**2. Comparison:**  $r = 0.97$

$$y=0.97x + 0.08$$

**3. Precision:**

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 8.0	0.1	1.0	8.1	0.2	2.0
High 15.0	1.0	0.5	15.2	0.2	2.0

**4. Specificity:** No interference upto Bilirubin ( 30 mg /dL)

## **CLINICAL SIGNIFICANCE:**

Haemoglobin is the oxygen carrier and is essential for adequate transport of oxygen and carbon dioxide between lungs and other tissues. Decreased haemoglobin levels result in reduced oxygen carrying capacity leading to anoxemia, ischaemic changes and ultimately to necrosis. Estimation of blood haemoglobin concentration is important as an initial step in the detection of anaemia or erythrocytosis. Blood haemoglobin concentration, may be diminished as a consequence of haemorrhage or hemolysis or as a result of impaired blood cell formation in the bone marrow. Elevated haemoglobin levels can be observed in polycythaemias and congenital cyanotic heart diseases.

## **QUALITY CONTROL:**

It is recommended that each laboratory must establish their own frequency of controlled determination.

## **REFERENCES:**

- Van Kampen, E.L. and Zijistra, W.G, Clin. Chem. Acta, 6:538(1961).
- Brit. J. Haemat, 13 (Suppl): 71, (1967).



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## Clinical Chemistry Reagent

### Liquid Stable

## TOTAL PROTEIN

(BIURET)

#### INTENDED USE:

(For quantitative estimation of serum and plasma Total Proteins)

#### TEST PRINCIPLE:

In alkaline medium, peptide bonds of proteins react with cupric ions in Biuret reagent to form violet coloured complex with an absorption maximum at 546 nm (530 - 570 nm). Intensity of the colour formed is directly proportional to the concentration of total proteins in the sample.

#### KIT CONTENTS :

##### REAGENT 1

###### Biuret Reagent

Copper sulfate	30 mM
Sodium hydroxide	3.8 M
Potassium sodium tartrate	100 mM

##### REAGENT 2

##### CALIBRATOR

Human Proteins	Conc : As indicated on the label.
Insert	01 No.

#### PREPARATION OF WORKING REAGENT :

Reconstitute reagents as per instructions on individual bottle labels to prepare working reagent.

#### STORAGE AND STABILITY :

**Liquid Stable TOTAL PROTEIN** reagents are stable till the expiry date indicated on the labels when stored at 2-8°C. The working reagent is stable for six months at room temperature. Use distilled water of good quality for reconstitution to avoid precipitation of the reagent.

#### SPECIMEN COLLECTION & STORAGE :

Serum or heparinised plasma can be used. Samples should preferably be used on the same day. If necessary, may be preserved upto one week if stored at 2-8°C. Sample should be brought to room temperature prior to use.

#### PRECAUTIONS :

**TOTAL PROTEIN** reagents are for *in vitro* diagnostic use only [IVD]. Avoid contact with skin, eyes and clothes. Do not pipette by mouth.

#### PROCEDURE (Automated):

#### TEST PROCEDURE (Manual):



Pipette into Test Tubes	Blank	Standard	Test
<b>Working Reagent</b>	1 ml	1 ml	1 ml
<b>Calibrator</b>	-	20 µl	-
<b>Sample</b>	-	-	20 µl
<b>Distilled water</b>	20 µl	-	-

Mix and allow to stand at room temperature (21-25°C) for 20 minutes. Read absorbance of the Test ( $A_T$ ), Calibrator ( $A_C$ ) and Blank ( $A_B$ ) at 546 nm (530 to 570 nm) or with Green filter against distilled water.

#### CALCULATIONS:

$$\text{Total Proteins (gm/dl)} = \frac{A_T - A_B}{A_C - A_B} \times \text{Total Protein concentration}$$

$A_C - A_B$  provided on calibrator label It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### EXPECTED VALUES\*:

Total Proteins : 6.0 - 8.5 gm/dl

\*It is recommended that each laboratory should establish its own normal range representing its patient population.

#### PERFORMANCE

1. **Linearity:** 10 gm/dl

2. **Comparison:**  $r = 0.99$

$$y=1.5x + 0.5$$

3. **Precision:**

	Within Run			Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	4.0	0.5	1.0	4.5	0.5	2.0
High	7.0	0.1	1.0	7.5	0.3	2.0

4. **Specificity:**

**TOTAL PROTEIN** reagent is free of interference from moderate levels of hemoglobin, bilirubin, lipids and salicylates. Avoid use of grossly hemolysed samples or lipemic sera.

Refer to specific instrument application instructions.

### **CLINICAL SIGNIFICANCE :**

Elevated levels of total proteins are associated with dehydration due to vomiting and diarrhoea, multiple myeloma, chronic liver diseases and chronic infections. Decreased levels are found in renal diseases, malnutrition, albuminuria and terminal liver failure. Increase in total protein levels is generally due to an increase in total globulin with the concentration of albumin remaining normal or decreasing marginally.

### **QUALITY CONTROL:**

It is recommended that each laboratory must establish their own frequency of controlled determination.

### **AUTOMATED APPLICATIONS :**

**Liquid Stabile TOTAL PROTEIN** reagents can be used with Hitachi 700 series, RA 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa 200, BTR 810/820/830, RA 50, Erbachem-5 plus etc.

Application sheets for use on specific semi automatic, batch and auto analyzers are available on request. Input parameters for semi auto/auto analysers are given below :

INPUT PARAMETERS	VALUES
Type of reaction	End point
Wavelength	546 nm
Incubation time	20 min.
Calibrator Concentration	Provided on the label
Temperature	21-25°C.
Units	gm/dl
Upper Normal value	8.5 gm/dl
Lower Normal value	6.0 gm/dl
Linearity	10 gm/dl
Reagent volume	1 ml
Calibrator / Sample volume	20 µl

### **REFERENCES :**

- Vatzidis, H. (1977) Clin. Chem. 23: 908
- Weichselbaum, T.E. (1957) Am. J. Clin. Path. 16:40-48



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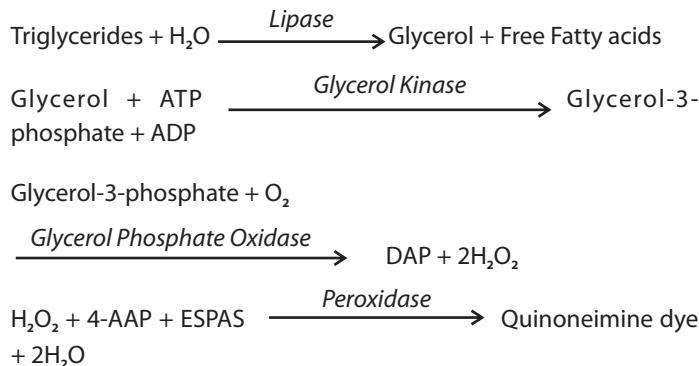
LTD/AL/DELAS1

**Clinical Chemistry Reagent**
**Liquid Stable**
**Triglycerides**
**(GPO-POD Method)**
**INTENDED USE:**

(For the *in vitro* diagnosis of Triglycerides in human serum and plasma)

**TEST PRINCIPLE**

This reagent is based on the method of Wako(2) and the modifications by McGowan et al (3) and Fossati et al. (4)



Triglycerides are enzymatically hydrolysed by lipase to free fatty acids and glycerol. The glycerol is phosphorylated by adenosine triphosphate (ATP) with glycerol kinase (GK) to produce glycerol-3-phosphate and adenosine diphosphate. Glycerol-3-phosphate is oxidised by dihydroxyacetone phosphate (DAP) by glycerolphosphate oxidase producing hydrogen peroxide ( $\text{H}_2\text{O}_2$ ). In a Trinder(5) type colour reaction catalyzed by peroxidase, the  $\text{H}_2\text{O}_2$  reacts with 4-aminoantipyrine (4-AAP) and ESPAS to produce a purple coloured dye. The absorbance of this dye is proportional to the concentration of triglycerides present in the sample.

**KIT CONTENTS:**
**Reagent1: Triglycerides Reagent**

PIPES buffer (Piperazine-1, 4-bis (2-ethane-sulfonic acid) : pH 7.2: 50 mM/l,

4 Amino Antipyrene: 0.5 mM/l

Glycerol Phosphate Oxidase: 2500 U/l

Lipoprotein Lipase : 5000 U/l,

Glycerol Kinase : 0.5 KU/l,

Peroxidase : 2KU/l

**Reagent 2 :Triglycerides Standard**

Triglycerides 200 mg/dl

**Insert: 1 No.**
**PREPARATION OF THE WORKING REAGENT**

All reagents are ready to use.

**STORAGE AND STABILITY:**  2°C - 8°C.

All the reagents should be stored in 2-8°C and are stable till the

expiry date mentioned in the labels.

Contamination must be avoided when opened.

**SPECIMEN COLLECTION AND STORAGE :**

Serum (fasting) is preferred to plasma. Heparinised plasma may be used. Samples should be used on the same day. If necessary they may be preserved at 2-8°C for upto 4 days.

**PRECAUTIONS:** 

**Liquid Stable Triglycerides** reagents are for *in vitro* diagnostic use only **IVD**. Reagent -1 and standard contains 0.1% sodium azide. It may react with lead and copper plumbing to form highly explosive metal azides. Flush with large volumes of water upon disposal.

**PROCEDURE (Automated):** 

Refer to specific instrument application instructions.

**TEST PROCEDURE (Manual):**

Pipette into test tubes labeled Blank (B), Standard (S) and Test (T) as follows:

Prepare into Test Tube	Blank	Standard	Test
Triglycerides Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	—	10 µl	—
Sample	—	—	10 µl

Mix well and incubate for 5 minutes at 37°C or 20 minutes at RT.

Read absorbance of Standard ( $A_s$ ), and Test ( $A_t$ ) against Blank ( $A_b$ ) at 546 nm or with green filter (520-570nm).

**CALCULATIONS:**

Triglycerides Conc. in mg/dl =

$$\frac{\text{Abs of } A_t - A_b}{\text{Abs of } A_s - A_b} \times 200 \text{ (Conc. of Standard)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

**EXPECTED VALUES :**

Men : 60 - 165 mg/dl

Women : 40 - 140 mg/dl

It is recommended that each laboratory should establish its own normal range representing its patient population.

**PERFORMANCE**

1. **Linearity:** 1000mg/dl

## 1. Precision:

	Within Run			Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	90.0	1.5	1.5	90.0	2.0	2.5
High	200.0	1.5	0.5	280.0	6.5	2.5

2. **Specificity:** No interference upto Hemoglobin (1gm/L) & Bilirubin ( 30 mg /dl)

## METHOD COMPARISON:

A comparison between **Liquid Stable Triglycerides** (y) and a commercially available test (x) using 60 sample gave the following results:

$$Y = 1.102x - 6.803$$

$$R= 0.99$$

## CLINICAL SIGNIFICANCE

Triglycerides are a family of lipids absorbed from the diet and produced endogenously from carbohydrates. Measurement of triglycerides is important in the diagnosis and management of hyperlipidaemias. These diseases can be genetic or secondary to other disorders including nephrosis, diabetes mellitus, and endocrine disturbances.

Elevation of triglycerides has been identified as a risk factor for atherosclerotic disease(1).

## AUTOMATED APPLICATIONS :

**Liquid Stable Triglycerides** reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830. Erbachem-5, Ranlab etc.

Application sheets for use on specific semiautomatic / batch analysers are available on request. Input parameters for semiauto / auto analysers are given below :

## INPUT PARAMETERS VALUES

Type of reaction	End point
Wavelength	546 nm.
Incubation time	5 minutes
Standard concentration	200
Units	mg/dl
Temperature	37°C
Upper Normal value	165
Lower Normal value	40
Linearity	1000
Working reagent volume	1.0 ml
Sample/ Standard volume	10 µl

## QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

## NOTES:

- Do not use recycled plastic tubes as they react with the chromogen leading to the false results. Always use soap and glycerol free glass tubes.
- Contamination of standard and reagents must be avoided. All the reagents must be stored back at 2-8°C after use.
- Replug the Triglycerides standard vial after use. Use clean glasswares & micropipettes while pipetting Triglycerides standard.
- Contamination by soap or glycerol will affect the assay.
- As with all the diagnostics procedures, the physician should evaluate the data obtained by the use of this kit in light of other clinical information.

## REFERENCES

- Stein E.A. and Myers G.L. "Lipids, Lipoproteins and Apolipoproteins" in Tietz Textbook of Clinical Chemistry. Burtis C.A. and Ashwood E.R. (Ed). WB Saunders Company, Second Edition. 1994; 23:1002-93.
- Product Data Sheet, Triglyceride - G Code No 997-69801, Wako Pure Chemical Industries Ltd., Dallas TX.
- McGowan MW, et al. Clin Chem 1983;29: 538.
- Fossati P, Prencipe L. Clin Chem 1982;28: 2077-80.
- Trinder P. Ann Clin Biochem 1969;6:24-7.
- National Institute of Health Consensus Development Conference Statement. Triglyceride, High Density Lipoprotein and Coronary Heart Disease. Feb 26-28 1992.
- Klotzsh, S.G and Mc Namara, R.J Clin Chem 1990;36:1605-13.
- Young DS, Effects of Drugs on Clinical Laboratory Test. Third Edition.1990;3:19-25.



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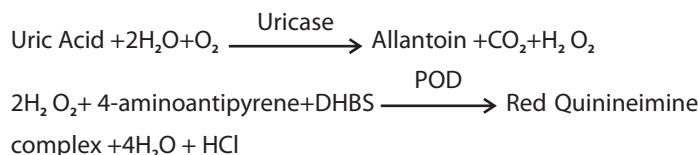
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**INTENDED USE:**

(For the *in vitro* diagnosis of Uric acid in human serum, plasma and urine)

**TEST PRINCIPLE:**

**Liquid Stable Uric Acid Assay Kit** provides a method for detecting uric acid in serum/plasma/urine. In the assay, uricase catalyzes the conversion of uric acid to allantoin, hydrogen peroxide ( $H_2O_2$ ) and carbon dioxide. The  $H_2O_2$  then, in the presence of horseradish peroxidise (HRP), reacts with 4-aminoantipyrine and DHBS to generate red quinoneimine complex, which is measured spectro-photometrically in Abs max of 505 (505-520) nm.


**KIT CONTENTS:**
**Reagent 1 : Uric Acid Reagent**

Citrate Buffer: pH 7.0 (Tri Sodium Citrate) :

40 mM/l

DHBS (3,5-dichloro-2-hydroxybenzenesulfonic acid): 1.8 mM/l

Uricase: 300 U/l,

Peroxidase: 4KU/l,

4 Amino Antipyrine: 0.3 mM/l

**Reagent 2 : Uric Acid Standard**

Uric acid 6 mg/dl

**Insert: 1 No.**
**PREPARATION OF THE WORKING REAGENT**

All reagents are ready to use.

  $2^\circ\text{C}$  to  $8^\circ\text{C}$ .

**STORAGE AND STABILITY:**

All the reagents should be stored in  $2$ - $8^\circ\text{C}$  and are stable till the expiry date mentioned in the labels.

**SPECIMEN:**

Unhemolysed serum/heparinised plasma is recommended.  
Urine should be diluted 1:10 with distilled water before use.

**PRECAUTIONS:** 

**Liquid Stable Uric Acid** reagents are for *in vitro* diagnostic use only . Reagent -1 and standard contains 0.1% sodium azide. It may react with lead and copper plumbing to form highly

explosive metal azides. Flush with large volumes of water upon disposal.

**TEST PROCEDURE:** 

Pipette into test tubes labeled Blank (B), Standard (S) and Test (T) as follows:

Prepare into Test Tube	Blank	Standard	Test
Uric Acid Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	—	20 $\mu\text{l}$	—
Sample	—	—	20 $\mu\text{l}$

Mix well and incubate for 5 minutes at  $37^\circ\text{C}$ .

Read absorbance of Standard ( $A_s$ ), and Test ( $A_t$ ) against Blank ( $A_b$ ) at 505 nm or with green filter (500-540nm).

**CALCULATIONS:**

Serum Uric Acid Conc. in mg/dl

$$= \frac{\text{Abs of } A_t - A_b}{\text{Abs of } A_s - A_b} \times 6 \text{ (Conc. of Standard)}$$

Urine Uric Acid Conc. in mg/dl

$$= \frac{\text{Abs of } A_t - A_b}{\text{Abs of } A_s - A_b} \times 6 \times 10$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

**EXPECTED VALUES\* :**

Serum Uric acid

Women : 2.4-5.7 mg/dl

Men : 3.4-7.0 mg/dl

**Urine Uric acid :** 250-750 mg/24 hrs urine

\*It is recommended that each laboratory should establish its own normal range.

**PERFORMANCE**
**1. Linearity:** 25 mg/dl

**2. Precision:**

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 5.5	0.5	1.0	5.5	0.2	2.5
High 10.0	0.5	0.5	10.5	0.25	2.0

- 3. Specificity:** No interference upto 1gm/L Hemoglobin & Bilirubin ( 20 mg /dl)

#### CLINICAL SIGNIFICANCE:

Serum uric acid is the end product of purine metabolism in the body tissues and is cleared through the kidneys by glomerular filtration.(1). Most animals can metabolize uric acid to more readily excreted products, but humans lack the necessary enzyme, urate oxidase (uricase), as a result of the presence of two "mutations" in the human gene for uricase.(2) Increased uric acid levels may result from leukemia, polycythemia, ingestion of foods high in nucleoproteins (e.g. liver and kidney) or impaired renal function. Gout results from the deposit of uric acid in body joints.(3)

#### AUTOMATED APPLICATIONS :

**Liquid Stable Uric Acid** reagents can be used with Hitachi 700 series, RA 50, 1000 XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbacheim-5, Ranlab etc. Application sheets for use on specific semiautomatic / batch analysers are available on request. Input parameters for semiauto / auto analyzers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	End point
Wavelength	505 nm.
Incubation time	5 minutes
Standard concentration	6
Units	mg/dl
Temperature	37°C
Lower Normal value	
Women	2.4
Men	3.4
Upper Normal value	
Women	5.7
Men	7.0
Linearity	25
Working reagent volume	1.0 ml
Sample/ Standard volume	20 µl

#### 2. METHOD COMPARISON:

A comparison between **Liquid Stable Uric Acid** (y) and a commercially available test(x) using 65 samples gave the following results:

$$y = 0.935x + 0.554$$

$$r= 0.99$$

#### QUALITY CONTROL:

It is recommended that each laboratory must establish their own frequency of controlled determination.

#### NOTES:

1. Reagent must be stored at 2-8°C till expiry.
2. The rate of increase in the reagent blank absorbance can be reduced by ensuring the storage of reagent (highly photosensitive) at 2-8°C.
3. As with all the diagnostics procedures, the physician should evaluate data obtained by the use of this kit in light of other clinical information.

#### REFERENCES:

1. ARCHIBALD RM. Colorimetric measure-ment of uric acid. *Clin Chem.* 1957 Apr; 3(2):102–105.
2. GJORUP S, POULSEN H, PRAETORIUS E. The uric acid concentration in serum de-termined by enzymatic spectrophotometry. *Scand J Clin Lab Invest.* 1955;7 (3):201-203.
3. KUZELL WC, SCHAFFARZICK RW, NAUGLER WE, KOETS P, MANKLE EA, BROWN B, CHAMPLIN B. Some observations on 520 gouty patients. *J Chronic Dis.* 1955 Dec;2(6):645–669.



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LTD/ELA/DELAS1



## Clinical Chemistry Reagent

### Liquid Stable

### UREA UV

(GLDH METHOD)

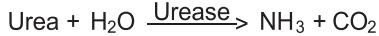
#### INTENDED USE:

(For quantitative *in vitro* determination of urea in human serum, plasma or urine

Urine diluted 1 ml to 100 ml in distilled water and apply the dilution factor to calculate the final result.

Discard contaminated specimens.

#### TEST PRINCIPLE



Following an initial lag phase, the rate of the reaction is constant for 60 seconds. Decrease in absorbance, resulting from the GLDH-reaction, is proportional to the concentration of Urea in the sample.

#### 4. SPECIFICITY:

Do not use ammonium heparin as Anticoagulants improperly cleaned glassware may inhibit urea activity. The method is relatively free of interference from commonly used drugs and other body metabolites.

#### PRECAUTIONS



- Liquid Stable UREA UV** reagents are for *in vitro* Diagnostic use only [IVD].
- The reagents contain sodium azide (0.95 g/l) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.

#### PROCEDURE (Automated):



Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):



Wavelength : 340 nm  
Temperature : 30°C

#### Bring reagents and samples to room temperature (21-25°C)

Pipette into Test Tubes	Standard	Test
Working Reagent	1.0 ml	1.0 ml
Standard	10 µl	-
Sample	-	10 µl

Mix and record the change in absorbance of the test ( $\Delta A_T$ ) and standard ( $\Delta A_S$ ) between 30 seconds and 90 seconds.

#### CALCULATIONS :

$$\text{Urea Concentration (mg/dl)} = \frac{\Delta A_T}{\Delta A_S} \times 50 \text{ (Standard concentration)}$$

$$\text{Blood Urea Nitrogen (BUN) concentration (mg/dl)} = 0.467 \times \text{urea concentration (mg/dl)}$$

To convert urea concentration (mg/dl) to mmol/l  
mmol/l = 0.167 X urea conc in mg/dl

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### Reagent 1: Buffer:

Tris Buffer (Tris Hydroxymethylaminoethane), pH-7.55	: 75mM/l
Urease	: 150000 U/l
GLDH	: 500 U/l
α-Ketoglutarate	: 10 mM/l

#### Reagent 2: Enzyme concentrate:

Tris Buffer (Tris Hydroxymethylaminoethane):200 mM/l  
NADH (Nicotinamide Adenine dinucleotide):0.3 mM/l

#### Reagent 3: Standard:

Urea	: 50 mg/dl
Insert	: 01

#### PREPARATION OF THE WORKING REAGENT

Mix 4 parts of Reagent 1 with 1 part of Reagent 2.

#### REAGENT STABILITY AND STORAGE

Conditions: protect from light  
close immediately after use

#### Working Reagent:

Stability:	at 21-25°C	3 days
	at 2-8°C	4 weeks

Minimum allowable absorbance of working reagent measured at 340nm against water as reference is 1.0.

#### SAMPLE STABILITY AND STORAGE

Do not use Ammonium Heparin Plasma.



<b>serum or plasma:</b>	at 21-25°C	7 days
	at 2-8°C	7 days
	at -20°C	1 year
<b>urine:</b>	at 21-25°C	2 days
	at 2-8°C	7 days
	at -20°C	1 month

**EXPECTED VALUES\*:**

Serum Urea : 15 to 45 mg/dl  
Urine : 20 to 35 g/24 hrs.

\*It is recommended that each laboratory should establish its own normal range.

**PERFORMANCE**

1. **Linearity:** 300 mg/dl

2. **Comparison:**  $r = 0.98$

$$y=0.097x+0.54$$

3. **Precision:**

Within Run			Run to Run		
Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low 15.0	0.5	3.0	15.0	1.0	3.0
High 60.0	2.0	3.0	60.0	2.0	3.0

**CLINICAL SIGNIFICANCE:**

Urea is the major end product of protein metabolism. Impaired renal function (viz, glomerulonephritis, pyelonephritis etc.) is associated with elevated levels of urea. Increased levels of urea are also found during severe dehydration and massive gastrointestinal bleeding. Decreased levels are associated with liver damage and pregnancy.

**AUTOMATED APPLICATIONS:**

**Liquid Stable UREA UV** reagents can be used with most of the commonly available semi-auto and fully-automated biochemistry analyzers. Application sheets for use on specific semi-automatic, batch analyzers are available on request. Input parameters for semi-auto/auto analyzers are given below.

INPUT PARAMETERS	VALUES
Type of reaction	Initial rate, Kinetic
Slope of reaction	Decreasing
Wavelength	340 nm
Standard concentration	50 mg/dl
Incubation time	30 sec.
Interval time	60 sec.
Interval no.	1
Flowcell temperature	30°C
Units	mg/dl

Upper Normal value (serum)	45 mg/dl
Lower Normal value (serum)	15 mg/dl
Linearity	300 mg/dl
Working Reagent volume	1.0 ml
Sample / Standard volume	10 µl

**QUALITY CONTROL:**

It is recommended that each laboratory must establish their own frequency of controlled determination.

**REFERENCES**

- Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 374-7.
- Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 1838.
- Taike H, Schubert GE. Enzymatische Hamstoffbestimmung in Blut und Serum im optischen Test nach Warburg (Enzymatic determination of urea in blood and serum with the optical test according to Warburg). Klin Wschr 1965;43:174-5.



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LTD/ELA/DELAS1



## Clinical Chemistry Reagent

### Liquid Stable

## CALCIUM

(Arsenazo III METHOD)

#### INTENDED USE:

For quantitative estimation of calcium in serum.  
For *in vitro* Diagnostics use only.

#### TEST PRINCIPLE :

Calcium reacts with Arsenazo III under neutral conditions to form a purple coloured complex which has maximum absorbance at 650 nm. The intensity of the colour formed is directly proportional to calcium concentration in the sample.

#### KIT CONTENTS

##### Reagent 1 : Calcium Reagent

Arsenazo III	200 µmol/l
MES	100 mmol/l, pH 6.50

##### Reagent 2 : Calcium Standard

Calcium	10 mg/dl
---------	----------

**Insert:**           **01 No.**

#### PREPARATION OF THE WORKING REAGENT

All reagents are ready to use.

**STORAGE AND STABILITY** 2°C - 8°C.

**Liquid Stable CALCIUM** reagents are stable till the expiry date mentioned on the labels when stored at 2-8°C.

#### SPECIMEN

Fresh, unhemolysed serum or heparinized plasma. Remove serum from clot as soon as possible, since red cells can absorb calcium. Serum calcium is stable for one week at 2-8°C.

Calcium in urine can be estimated by diluting urine 1:3 with distilled water and adjusting the pH to 3-4 with N/10 HCl.

#### PRECAUTIONS

**CALCIUM** reagents are for *in vitro* diagnostic use only. Reagent may be irritating to the skin. Therefore avoid contact. Flush with sufficient amount of water in case of contact.

#### PROCEDURE (Automated):

Refer to specific instrument application instructions.

#### TEST PROCEDURE (Manual):

Pipette into Test Tubes	Blank	Standard	Test
Calcium Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	-	10 µl	-
Sample	-	-	10 µl

Mix and incubate for 1 min. Zero the spectrophotometer and read the absorbances of Test ( $A_T$ ), Standard ( $A_S$ ) and Blank ( $A_B$ ).

#### PROCEDURAL NOTES

1. Samples with calcium levels above 16 mg/dl should be diluted 1:2 with saline, reassayed and the result multiplied by two.
2. Severely lipemic samples require a serum blank. Add 10 µl of sample to 1 ml distilled water. Read against water at 650 nm and subtract the absorbance reading from the absorbance of test.
3. The sample size can be increased, in parallel with the standard, upto 25µl, without any change in performance.

#### CALCULATIONS

$$\text{Calcium (mg/dl)} = \frac{A_T - A_B}{A_S - A_B} \times 10 \text{ (Concentration of standard)}$$

It is recommended that user determine calibration frequency as this will depend on the instrument & type/number of the assays being run.

#### EXPECTED VALUES\*

Serum/Plasma      8.8 - 10.2 mg/dl

Urine                100- 400 mg/24hrs.

\*It is recommended that each laboratory should establish its own normal range.

#### PERFORMANCE

1. **Linearity:** 16mg/dl

2. **Comparison:**  $r = 0.99$

$$y=0.98x + 0.2$$

3. **Precision:**

	Within Run			Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	10.0	0.2	1.5	11.0	0.2	1.0
High	14.0	0.2	1.0	14.0	0.2	1.5

#### 4. SPECIFICITY

1. Substances that contain or form a complex with calcium may produce inaccurate results.
2. Glass test tubes often are coated with residues containing calcium, hence glass tubes should be acid washed or plastic test tubes should be used.

3. Bilirubin upto 20 mg/dl and hemoglobin upto 500 mg/dl do not interfere.

### **CLINICAL SIGNIFICANCE**

Increased serum calcium may be observed in hyperparathyroidism, vitamin D intoxication, multiple myeloma and some neoplastic diseases of bone. Decreased serum calcium may be observed in hypoparathyroidism, vitamin D deficiency, nephrosis and nephritis.

### **QUALITY CONTROL:**

It is recommended that each laboratory must establish their own frequency of controlled determination.

### **AUTOMATED APPLICATIONS**

**Liquid Stable CALCIUM** reagents can be used with Hitachi 700 series, RA 50, 1000, XT, Express 550, Syncron CX4, LISA 200, BTR 810/820/830, Erbachem-5 etc. Application sheets for use on specific semi automatic, batch and auto analyzers are available on request. Input parameters for semi auto/auto analysers are given below.

INPUT PARAMETERS	VALUES
Type of reaction	End Point
Wavelength	650 nm
Incubation time	60 sec.
Standard concentration	10 mg/dl
Temperature	CRT (22-25°C)
Upper normal value	10.2 mg/dl (Serum)
Lower normal value	8.8 mg/dl (Serum)
Linearity	16 mg/dl
Reagent volume	1.0 ml
Sample/Standard volume	10 µl

### **REFERENCES**

— Baver. et. al., (1981) Clin. Chem. 110 : 61



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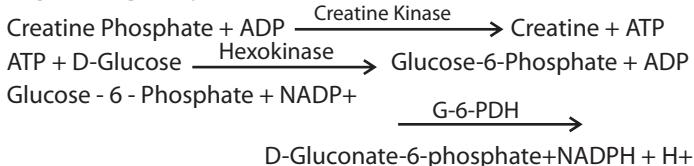
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LTD/AL/DELAS1

**Clinical Chemistry Reagent**
**Liquid Stable**
**CREATINE KINASE**
**(CK-NAC)**
**INTENDED USE:**

(For quantitative estimation of Creatine Kinase in serum).

**TEST PRINCIPLE :**


CK catalyses the reversible phosphorylation of ADP in the presence of creatine phosphate to form ATP and creatine. The enzyme Hexokinase catalyses phosphorylation of glucose by the ATP formed, to produce ADP and glucose-6-phosphate (G-6-P). The G-6-P is oxidised to Gluconate-6-phosphate with concomitant production of NADPH. The rate of NADPH formation, measured at 340 nm, is directly proportional to serum CK activity.

**KIT CONTENTS:**
**Reagent 1 : Buffer**

Imidazole (pH 6.7)	125 mmol/l
N - Acetyl - L - Cysteine	25 mmol/l
Magnesium acetate	11 mmol/l
D-Glucose	25 mmol/l
EDTA	2 mmol/l
AMP	6.26 mmol/l
NADP	2.5 mmol/l
Diadenosine pentaphosphate	13 µmol/l
Hexokinase	>6800 U/l

**Reagent 2 : Substrate**

Creatine phosphate	166 mmol/l
ADP	15 mmol/l
G - 6 - PDH	> 8800 U/l

Insert 01 No.

**PREPARATION OF THE WORKING REAGENT**

Mix 4 volumes of reagent 1 with 1 volume of reagent 2.

**STORAGE AND STABILITY**


**LIQUID STABLE CREATINE KINASE** reagents are stable till the expiry date mentioned on the labels when stored at 2-8°C and protected from light. The working reagent is stable for 7 days at 2-8°C and 24 hours at CRT (21-25°C)

**SPECIMEN COLLECTION AND STORAGE :**

Serum free from hemolysis or can be used. CK in serum is stable for 48 hours at room temperature 7 days when refrigerated and one month when frozen. Exercise or physical activity can produce elevated levels of CK in serum.

**PRECAUTIONS:**


**Liquid Stable CREATINE KINASE** reagents are for diagnostic use only. Discard reagent, if cloudy. Avoid contamination by using clean laboratory material. These reagents contain sodium azide. Flush with large volumes of water upon disposal to prevent azide build up.

**TEST PROCEDURE:**


**Wavelength: 340 nm**

**Temperature: 37°C**

**Read against distilled water.**

Pipette into test tubes	Volume
<b>Working Reagent</b>	1.0 ml
<b>Sample</b>	40 µl

Mix and incubate for 2 minutes. Measure the change in absorbance per min ( $\Delta\text{OD}/\text{min}$ ) for the next 3 minutes. Use the mean  $\Delta\text{OD}/\text{min}$ . for calculation.

**CALCULATIONS:**

Creatine Kinase Activity (IU/l) =  $\text{DOD}/\text{min.} \times 4127$

**NORMAL VALUES:**

Female	165 IU/l
Male	upto 190 IU/l
Babies	upto 325 IU/l (1-12 month)
Children	upto 225 IU/l (above 12 months)

**CLINICAL SIGNIFICANCE:**

Creatine Kinase is primarily found in skeletal muscle, cardiac muscle and brain tissue. Damage to any of these tissues can result in increased levels of CK activity in serum. Cardiac muscle damage following myocardial infarction usually results in an increase of 7-12 times the upper normal limit. Elevated CK activity is also seen in hypothyroidism, various types of muscular dystrophy, viral myositis and similar types of skeletal muscle diseases. The determination of serum CK activity is used to aid in the diagnosis of myocardial infarction and various types of muscle diseases.

**INTERFERING SUBSTANCES:**

Elevated levels of bilirubin and hemoglobin have been found to have negligible effect on the assay.

**PERFORMANCE CHARACTERISTICS:**
**1. LINEARITY:**

Upto 1000 IU/l

## **2. Comparison / Accuracy**

Validation studies establish that KINASE has excellent accuracy and reproducibility. For accuracy comparative studies were conducted on random samples using KINASE and a reference method. The resultant coefficient of correlation was 0.8 and the corresponding regression equation was  $y=1.130x-4.6$ .

## **3. Precision**

For precision within run and run to run studies were carried out using controls having normal and abnormal values (116-363 IU/l). The detail is as below.

Within run			Run to Run		
Mean	SD	CV%	Mean	SD	CV%
148	1.25	1.0	145	1.4	1.1
250	1.5	0.8	255	2.0	0.6

## **4. Specificity**

No interference with bilirubin level upto 20 mg/dl. and haemoglobin 500 mg/dl

## **AUTOMATED APPLICATIONS:**

KINASE reagents can be used with Hitachi 700 series, RA 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa 200, BTR 810/820/830, RA 50, Erbachem 5 plus etc.

Application sheets for use on specific semiautomatic, batch and auto analysers are available on request. Input parameters for semiauto/auto analysers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Increasing
Wavelength	340 nm
Factor	4127
Incubation time	2 minutes
Reading time	180 seconds
Flowcell temperature	37°C
Linearity	1000
Units	IU/l
Upper Normal value	335 IU/l
Lower Normal value	165 IU/l

## **REFERENCES :**

- Mathieu, M. et. al., Ann. Biol. Clin. 40, 87, (1982).



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**INTENDED USE:**

**Wavelength: 340 nm**

**Temperature: 37°C**

**Read against distilled water.**


**TEST PRINCIPLE :**

The procedure involves measurement of CK activity in the presence of an antibody to the CK-M monomer. This antibody completely inhibits the activity of CK-MM and half of the activity of CK-MB while not affecting the B subunit activity of CK-MB and CK-BB. The CK-NAC method is used to quantitatively determine the CK-B activity. The CK-MB activity is obtained by multiplying the CK-B activity by two.

**Pipette into test tubes**
**Volume**

**Working Reagent**

1.0 ml

**Sample**

50 µl

Mix and incubate for 5 minutes. Measure the change in absorbance per min (DOD/min) for the next 2 minutes. Use the mean DOD/min. for calculation.

**KIT CONTENTS:**
**Reagent 1 + Reagent 2 :**

Imidazole, (pH 6.7)	100 mmol/l
Creatine phosphate	30 mmol/l
D-Glucose	20 mmol/l
N - Acetyl - L - Cysteine	20 mmol/l
Magnesium acetate	10 mmol/l
EDTA	2 mmol/l
ADP	2 mmol/l
NADP	2 mmol/l
AMP	5 mmol/l
Diadenosine pentaphosphate	10 µmol/l
G - 6 - PDH	> 1500 U/L
Hexokinase	> 2500 U/L

**Insert**

01 No.

Anti human polyclonal CK-M antibody sufficient to inhibit upto 2000 U/L of CK-MM

**CALCULATIONS:**

CK - MB Activity (IU/l) = mean DOD/min. x 6752

**NORMAL VALUES:** 0-24 IU/l

**CK - MB ratio :** 6-25%

**CLINICAL SIGNIFICANCE:**

CK-MM and CK-MB are found primarily in skeletal and heart muscles respectively, while CK-BB is found mainly in the brain and smooth muscle tissue. CK-MM activity increases following exercise, muscle trauma, shock and major surgery. The CK-BB iso-enzyme is usually present in serum at very low concentration and has been found to be rather unstable. Its activity increases in brain damage, malignant neoplasms, liver metastasis and damage to the pregnant uterus. CK-MB is also present in low concentrations in normal human serum but is increased as a result of heart injury and rarely skeletal muscle damage. CK-MB is widely used as an indicator of acute myocardial infarction, as the detection of elevated activity is considered highly specific for this condition.

**LIMITATION OF THE PROCEDURE**

- Hemolysed samples should not be used since erythrocytes contain contaminants and enzymes which might interfere with the assay.
- The method will also measure any CK-BB isoenzyme present in serum. The activity of the iso-enzyme is usually negligible, however, if a significant amount of CK-BB activity is present, the CK-MB activity will be overestimated.
- A macro form of BB (immunoglobulin complexed) has been observed which will be measured as B in the assay. If the measured CK-B activity exceeds 20% of the total CK-activity, the presence of macro BB should be suspected.

**PREPARATION OF THE WORKING REAGENT**

Mix 4 volumes of reagent 1 with 1 volume of reagent 2.

**STORAGE AND STABILITY**


**LIQUID STABLE CREATINE KINASE-MB** reagents are stable till the expiry date stated on the labels when stored at 2-8°C and protected from light.

The working reagent is stable for 5 days at 2-8°C

**SPECIMEN COLLECTION AND STORAGE :**

Serum free from hemolysis can be used. The sample should be used on the same day. If necessary, it should be stored frozen.

**PRECAUTIONS:**

Liquid Stable CREATINE KINASE-MB reagents are for *in vitro* diagnostic use only **[IVD]**.

The reagents contain sodium azide. Flush with large volumes greater upon disposal to prevent azide build up.

**PERFORMANCE CHARACTERISTICS:**
**1. LINEARITY:**

175 IU/l

**2. Comparison / Accuracy**

Validation studies establish that CREATINE KINASE-MB has excellent accuracy and reproducibility.

For accuracy comparative studies were conducted on random samples using CREATINE KINASE-MB and a reference method. The resultant coefficient of correlation was 0.996 and the corresponding regression equation was  $y=0.985 x-1.33$ .

### 3. Precision

For precision within run and run to run studies were carried out using controls having normal and abnormal values (18-163 IU/l). The detail is as below.

Within run			Run to Run		
Mean	SD	CV%	Mean	SD	CV%
33.7	0.52	2.3	40.0	0.75	3.9
125.0	2.15	1.8	135.5	2.20	1.8

### AUTOMATED APPLICATIONS:

Liquid Stable CREATINE KINASE-MB reagents can be used with Hitachi 700 series, RA 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa 200, BTR 810/820/830, RA 50, Erbachem 5 - plus etc. Application sheets for use on specific semiautomatic, batch and auto analysers are available on request. Input parameters for semiauto/auto analysers are given below:

INPUT PARAMETERS	VALUES
Type of reaction	Kinetic
Slope of reaction	Increasing
Wavelength	340 nm
Factor	6752
Incubation time	5 Minutes
Reading time	120 seconds
Flowcell temperature	37OC
Linearity	175 IU/l
Units	IU/l
Upper Normal value	24 IU/l
Lower Normal value	0 IU/l

### REFERENCES :

- Mathieu, M. Ann. Biol.Clin. 40, 99, (1982).
- Neumeier, D. et. al., Clin. Chim. Acta. 73, 445, (1976)



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# **APPLICATION SHEETS**



## APPLICATION SHEETS

Technical documentation is available on request to provide information about the application of the reagents on a broad range of automatic analyzers.

The application sheets are available for the following instruments:

Beckman Coulter Synchron CX  
 CIBA Express 550  
 Hitachi 704  
 Hitachi 902  
 Mindray BS120, BS200, BS300, BS400  
 Olympus AU 640, AU 400  
 Selectra XL, E, Junior

### Package Inserts

All kits are supplied with instructions for use.

### Value Sheets

For target mean and ranges, kindly refer to calibrators and controls Value Sheets used.

<b>Clinical Chemistry Reagents - Liquid Stable</b>			
<b>Application Sheets</b>			
Company/Manufacturer	Model	Automation	Platform
Abbott Spectrum	00000	Fully Automated	Floor Model
Flexor JR	00000	Fully Automated	Floor Model
Hitachi	902	Fully Automated	Floor Model
Mindray	BS 300	Fully Automated	Floor Model
	BS 380	Fully Automated	Floor Model
Olyumpus	AU400	Fully Automated	Floor Model
Robochem	0000	Fully Automated	Floor Model
Siemens/Bayer	Express Plus	Fully Automated	Benchtop Model
	Express 550	Fully Automated	Benchtop Model
Transasia/ERBA	EM 360	Fully Automated	Floor Model
	XL 300	Fully Automated	Floor Model
Vital Sctentific	Selectra/Flexor XL	Fully Automated	Floor Model

## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### ALBUMIN

ENTRY NAME	:	ALB
REPORT NAME	:	ALBUMIN
RATIO REFERENCE	:	ALB
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	NO
CALIBRATOR	:	WATER
LEVEL (C)	:	0.0
SAMPLE (UL) NORMAL	:	3.00
LOW	:	6.00
HIGH	:	1.50
UNITS PRIM	:	G/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	3.2 TO 5.50
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	727
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	ALB
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	60
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 8
INITIAL AD	:	0.15
ABS LIMIT (AD)	:	0.84
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	3
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
636/564	A	1.00	0.00	0.00	0.00
636/564	A	1.00	0.00	0.00	0.00
636/564	A	1.00	0.00	0.00	0.00
636/564	A	1.00	0.00	0.00	0.00
636/564	A	1.00	0.00	0.00	0.00
636/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4x10,1x10
	15000506	4x20,1x20
	15000507	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### ALKALINE PHOSPHATASE

ENTRY NAME	:	ALKP
REPORT NAME	:	ALKPHOS
RATIO REFERENCE	:	ALKP
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG RATE KIN BLNK
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	6.00
LOW	:	12.0
HIGH	:	3.0
UNITS PRIM	:	IU/L
UNITS SEC	:	IU/L
SEC. UNITS FACTOR	:	1.00
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	110 TO 810
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	ALK P
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	180
NUMBER OF READS	:	3
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 1500
INITIAL AD	:	0.50
ABS LIMIT (AD)	:	1.80
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	2
AFTER WASH CYCLES	:	3
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
412/452	A	1.00	14.4	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### **$\alpha$ -Amylase**

For use on the automatic analyzer

#### **ABBOTT SPECTRUM**

Parameter	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters**

##### **AMYLASE**

ENTRY NAME	:	AMY
REPORT NAME	:	AMYLASE
RATIO REFERENCE	:	AMY
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG RATE KIN BLNK
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	6.00
LOW	:	12.0
HIGH	:	3.0
UNITS PRIM	:	IU/L
UNITS SEC	:	IU/L
SEC. UNITS FACTOR	:	1.00
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	25.0 TO 140.10
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	AMY
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	240
NUMBER OF READS	:	4
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 2000
INITIAL AD	:	0.80
ABS LIMIT (AD)	:	2.20
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	5
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
412/452	A	1.00	12.9	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/452	A	1.00	0.00	0.00	0.00
412/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
CHOLESTEROL TOTAL	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### CHOLESTEROL

ENTRY NAME	:	CHOL
REPORT NAME	:	CHOLESTEROL
RATIO REFERENCE	:	CHOL
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	NO
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	3.00
LOW	:	6.00
HIGH	:	1.50
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	120 TO 240
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	727
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	CHOL
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	240
LAST READ TIME (SEC)	:	300
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 750
INITIAL AD	:	0.15
ABS LIMIT (AD)	:	0.84
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	3
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### CK-NAK

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### CK-NAK

ENTRY NAME	:	CK
REPORT NAME	:	CK-NAK
RATIO REFERENCE	:	CK
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG RATE KIN BLNK
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	12.00
LOW	:	24.00
HIGH	:	6.00
UNITS PRIM	:	IU/L
UNITS SEC	:	IU/L
SEC. UNITS FACTOR	:	1.00
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	165 TO 335
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	
% TOL OF CAL	:	
% TOL OF CAL FACTOR	:	
INTCPT TOL (C)	:	

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	CK
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	120
LAST READ TIME (SEC)	:	240
NUMBER OF READS	:	4
READ INTERVAL (SEC)	:	30.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 1000
INITIAL AD	:	0.80
ABS LIMIT (AD)	:	2.00
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	5
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	2.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
340/380	A	1.00	12.9	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### **ABBOTT SPECTRUM**

Parameter	Part Number	Pack Size (mL)
<b>CREATININE</b>	15000004	4x50
	15000005	4x100

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters**

##### **CREATININE**

ENTRY NAME	:	CREA
REPORT NAME	:	CREATININE
RATIO REFERENCE	:	CREA
TEST NUMBER	:	19
TEST TYPE	:	CALIBRATED
MATH	:	CAL LIN RATE
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	30.00
LOW	:	50.00
HIGH	:	15.00
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	0.4 TO 1.50
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	0
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	UREA
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	0.00
HIGH	:	300
FIRST READ TIME (SEC)	:	30
LAST READ TIME (SEC)	:	120
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 20
INITIAL AD	:	0.40
ABS LIMIT (AD)	:	1.20
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
516/604	A	1.00	0.00	0.00	0.00
516/604	A	1.00	0.00	0.00	0.00
516/604	A	1.00	0.00	0.00	0.00
516/604	A	1.00	0.00	0.00	0.00
516/604	A	1.00	0.00	0.00	0.00
516/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
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- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### GLUCOSE

ENTRY NAME	:	GLUC
REPORT NAME	:	GLUCOSE
RATIO REFERENCE	:	GLUC
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	NO
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	3.00
LOW	:	6.0
HIGH	:	1.50
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	70 TO 110
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	727
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	GAUC
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	240
LAST READ TIME (SEC)	:	300
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 500
INITIAL AD	:	0.15
ABS LIMIT (AD)	:	1.84
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	3
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/604	A	1.00	0.00	0.00	0.00
500/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
SGOT/AST	15000496	4x20, 1x20
	15000497	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### SGOT/AST

ENTRY NAME	:	GOT/AST
REPORT NAME	:	GOT/AST
RATIO REFERENCE	:	GOT/AST
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG RATE KIN BLNK
REACTION DIRECTION	:	DOWN
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	10.00
LOW	:	20.0
HIGH	:	5.0
UNITS PRIM	:	IU/L
UNITS SEC	:	IU/L
SEC. UNITS FACTOR	:	1.00
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	0 TO 46
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	GOT/AST
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	240
NUMBER OF READS	:	4
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 350
INITIAL AD	:	0.80
ABS LIMIT (AD)	:	0.36
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
340/380	A	1.00	4.85	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### SGPT/ALT

ENTRY NAME	:	GPT/ALT
REPORT NAME	:	GPT/ALT
RATIO REFERENCE	:	GPT/ALT
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG RATE KIN BLNK
REACTION DIRECTION	:	DOWN
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	10.0
LOW	:	20.0
HIGH	:	5.0
UNITS PRIM	:	IU/L
UNITS SEC	:	IU/L
SEC. UNITS FACTOR	:	1.00
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	0 TO 40
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	GPT/ALT
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	240
NUMBER OF READS	:	4
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 350
INITIAL AD	:	0.60
ABS LIMIT (AD)	:	4
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
340/380	A	1.00	4.85	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### **ABBOTT SPECTRUM**

Parameter	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### **TOTAL PROTEIN**

ENTRY NAME	:	TP
REPORT NAME	:	TOTAL PROTEIN
RATIO REFERENCE	:	TP
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	NO
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	6.00
LOW	:	12.00
HIGH	:	3.00
UNITS PRIM	:	G/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	6.0 TO 8.5
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	727
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	TP
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	60
LAST READ TIME (SEC)	:	60
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 10
INITIAL AD	:	0.15
ABS LIMIT (AD)	:	1.84
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	3
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
564/600	A	1.00	0.00	0.00	0.00
564/600	A	1.00	0.00	0.00	0.00
564/600	A	1.00	0.00	0.00	0.00
564/600	A	1.00	0.00	0.00	0.00
564/600	A	1.00	0.00	0.00	0.00
564/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4 X 25
	15000393	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### TRIGLYCERIDES

ENTRY NAME	:	TRIG
REPORT NAME	:	TRIGLYCERIDES
RATIO REFERENCE	:	TRIG
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	NO
CALIBRATOR	:	USER DEF'D
LEVEL (C)	:	USER DEF'D
SAMPLE (UL) NORMAL	:	3.00
LOW	:	6.00
HIGH	:	1.50
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	40 TO 165
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	0
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	TRIG
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	240
LAST READ TIME (SEC)	:	300
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	1 TO 1000
INITIAL AD	:	0.250
ABS LIMIT (AD)	:	2.40
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	5
AFTER WASH CYCLES	:	6
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
548/636	A	1.00	0.00	0.00	0.00
548/636	A	1.00	0.00	0.00	0.00
548/636	A	1.00	0.00	0.00	0.00
548/636	A	1.00	0.00	0.00	0.00
548/636	A	1.00	0.00	0.00	0.00
548/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### ABBOTT SPECTRUM

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4x10,1x10
	15000503	4x20,1x20
	15000504	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### UREA-UV

ENTRY NAME	:	UREA
REPORT NAME	:	UREA
RATIO REFERENCE	:	UREA
TEST NUMBER	:	20
TEST TYPE	:	CALIBRATED
MATH	:	CAL LIN RATE
REACTION DIRECTION	:	DOWN
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	3.00
LOW	:	6.00
HIGH	:	1.50
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	0
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	15 TO 40
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	0
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	UREA
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	0.00
HIGH	:	300
FIRST READ TIME (SEC)	:	30
LAST READ TIME (SEC)	:	90
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0 TO 300
INITIAL AD	:	0.60
ABS LIMIT (AD)	:	20
REAGENT BLANK	:	NO
BEFORE WASH CYCLES	:	3
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/380	A	1.00	0.00	0.00	0.00
340/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **ABBOTT SPECTRUM**

Parameter	Part Number	Pack Size (mL)
URIC ACID	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters**

##### **URIC ACID**

ENTRY NAME	:	URIC
REPORT NAME	:	URIC ACID
RATIO REFERENCE	:	URIC
TEST NUMBER	:	**
TEST TYPE	:	CALIBRATED
MATH	:	LIN REG END PT
REACTION DIRECTION	:	UP
REAGENTS	:	1
TEMPERATURE (C)	:	37
SERUM BLANK	:	YES
CALIBRATOR	:	WATER
LEVEL (C)	:	0.00
SAMPLE (UL) NORMAL	:	6.00
LOW	:	3.00
HIGH	:	1.50
UNITS PRIM	:	MG/DL
UNITS SEC	:	
SEC. UNITS FACTOR	:	
PRINT DIGITS	:	1
INST MUL	:	1.00
INST INT	:	0.00
NORMAL (C)	:	2.4 TO 7.0
SAMP. DISP DELAY (SEC)	:	0
CAL MODE	:	CAL ON CMD
CAL LEVEL	:	0
CAL INTERVAL (HR)	:	USER DEF'D
REF CAL FACTOR	:	0
% TOL OF CAL	:	10
% TOL OF CAL FACTOR	:	10
INTCPT TOL (C)	:	-1000 TO 1000

## TEST PARAMETER FILE: REAGENT DEFINITION

REAGENT NAME	:	URIC
LOT ID	:	USER DEF'D
REAGENT VOL	:	(UL)
NORMAL	:	300
LOW	:	300
HIGH	:	300
FIRST READ TIME (SEC)	:	240
LAST READ TIME (SEC)	:	300
NUMBER OF READS	:	1
READ INTERVAL (SEC)	:	60.0
AUX REAG DISP (SEC)	:	0
LINEARITY (C)	:	0.1 TO 25.0
INITIAL AD	:	0.50
ABS LIMIT (AD)	:	2.00
REAGENT BLANK	:	YES
BEFORE WASH CYCLES	:	2
AFTER WASH CYCLES	:	5
MIX TIME (SEC)	:	1.00
COOLING	:	YES
CONSTANT INTERCEPT	:	0.00
CORRECTION LIMIT	:	0.00

SPECTRAL CORRECTION					
PRIM SEC	USE IN	CONST	E.F.	LOW	HIGH
516/636	A	1.00	0.00	0.00	0.00
516/636	A	1.00	0.00	0.00	0.00
516/636	A	1.00	0.00	0.00	0.00
516/636	A	1.00	0.00	0.00	0.00
516/636	A	1.00	0.00	0.00	0.00
516/MA	LE	1.00	0.00	0.00	0.00



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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
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Center Valley, PA 18034 U.S.A.



**Branch Office, EUROPE**  
**Avantor Performance Materials, B.V.**  
Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
7400 AA Deventer. The Netherlands.

#### Applicative Parameters ALBUMIN

TEST	ALB		
No.			
FULL NAME	Albumin		
STANDARD No.			
REACTION TYPE	End Point		
PRI. WAVE	630		
SEC. WAVE			
DIRECTION	Increasing		
REACTION TIME	1	-	3
INCUBATION TIME			
UNIT	g/dl		
PRECISION	0.1		
R 1	300		
R 2	0		
SAMPLE VOLUME	3		
R 1 BLANK			
MIXED RGT. BLANK			
LINEARITY RANGE	0	6	
LINEARITY LIMIT			
SUBSTRATE LIMIT			
FACTOR			
	<b>PROZONE CHECK</b>		
Q 1		Q 2	
Q 3		Q 4	
PC	Abs		

## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4 x 10, 1 x 10
	15000506	4 x 20, 1 x 20
	15000507	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



Manufactured by:  
**Avantor Performance Materials India Ltd.**  
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## APPLICATION INSERTS

### Calcium

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
CALCIUM	15000060	100

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
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#### Applicative Parameters CALCIUM

TEST	CAL				
No.					
FULL NAME	Calcium				
STANDARD No.					
REACTION TYPE	End Point				
PRI. WAVE	630				
SEC. WAVE					
DIRECTION	Increasing				
REACTION TIME	1	-	3		
INCUBATION TIME					
UNIT	mg/dl				
PRECISION	0.1				
R 1	300				
R 2	0				
SAMPLE VOLUME	3				
R 1 BLANK					
MIXED RGT. BLANK					
LINEARITY RANGE	0	16			
LINEARITY LIMIT					
SUBSTRATE LIMIT					
FACTOR					
<b>PROZONE CHECK</b>					
Q 1					
Q 3					
PC	Abs				

## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
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#### Applicative Parameters GLUCOSE

TEST	GLUC				
No.					
FULL NAME	Glucose				
STANDARD No.					
REACTION TYPE	End Point				
PRI. WAVE	510				
SEC. WAVE					
DIRECTION	Increasing				
REACTION TIME	1	-	34		
INCUBATION TIME					
UNIT	mg/dl				
PRECISION	Integer				
R 1	300				
R 2	0				
SAMPLE VOLUME	3				
R 1 BLANK					
MIXED RGT. BLANK					
LINEARITY RANGE	0	700			
LINEARITY LIMIT					
SUBSTRATE LIMIT					
FACTOR					
<b>PROZONE CHECK</b>					
Q 1					
Q 3					
PC	Abs				

## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
SGOT/AST	15000496	4x20, 1x20
	15000497	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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#### Applicative Parameters

#### SGPT/ALT

TEST	SGPT				
No.					
FULL NAME	SGPT/ALT				
STANDARD No.					
REACTION TYPE	Kinetic				
PRI. WAVE	340				
SEC. WAVE					
DIRECTION	Decreasing				
REACTION TIME	3	-	10		
INCUBATION TIME					
UNIT	u/l				
PRECISION	0.1				
R 1	200				
R 2	0				
SAMPLE VOLUME	20				
R 1 BLANK					
MIXED RGT. BLANK					
LINEARITY RANGE	0	350			
LINEARITY LIMIT	0.2				
SUBSTRATE LIMIT					
FACTOR					
		<b>PROZONE CHECK</b>			
Q 1					
Q 3					
PC	Abs				

## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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#### Applicative Parameters TOTAL PROTEIN

TEST	T.P.				
No.					
FULL NAME	Total Protein				
STANDARD No.					
REACTION TYPE	End Point				
PRI. WAVE	546				
SEC. WAVE					
DIRECTION	Increasing				
REACTION TIME	1	-	34		
INCUBATION TIME					
UNIT	gm/dl				
PRECISION	0.01				
R 1	300				
R 2	0				
SAMPLE VOLUME	3				
R 1 BLANK					
MIXED RGT. BLANK					
LINEARITY RANGE	0	10			
LINEARITY LIMIT					
SUBSTRATE LIMIT					
FACTOR					
<b>PROZONE CHECK</b>					
Q 1					
Q 3					
PC	Abs				

## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4 X 25
	15000393	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### TRIGLYCERIDES

TEST	TG		
No.			
FULL NAME	Triglycerides		
STANDARD No.			
REACTION TYPE	End Point		
PRI. WAVE	546		
SEC. WAVE			
DIRECTION	Increasing		
REACTION TIME	1	-	17
INCUBATION TIME			
UNIT	mg/dl		
PRECISION	Integer		
R 1	300		
R 2	0		
SAMPLE VOLUME	3		
R 1 BLANK			
MIXED RGT. BLANK			
LINEARITY RANGE	0	1000	
LINEARITY LIMIT			
SUBSTRATE LIMIT			
FACTOR			
	<b>PROZONE CHECK</b>		
Q 1		Q 2	
Q 3		Q 4	
PC	Abs		



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### FLEXOR JR

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **FLEXOR JR**

Parameter	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

Note : These suggested instructions and instrument parameters are to be use in conjunction with the reagent package insert and the instrument operation manual. Refer to these documents for complete instruction before performing the tests.

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
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TEST	UA		
No.			
FULL NAME	Uric Acid		
STANDARD No.			
REACTION TYPE	End Point		
PRI. WAVE	510		
SEC. WAVE			
DIRECTION	Increasing		
REACTION TIME	1	-	17
INCUBATION TIME			
UNIT	mg/dl		
PRECISION	0.1		
R 1	200		
R 2	0		
SAMPLE VOLUME	5		
R 1 BLANK			
MIXED RGT. BLANK			
LINEARITY RANGE	0	25	
LINEARITY LIMIT			
SUBSTRATE LIMIT			
FACTOR			
	<b>PROZONE CHECK</b>		
Q 1		Q 2	
Q 3		Q 4	
PC	Abs		

## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
ALBUMIN	15000000	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters ALBUMIN

No.	<Chemistry>	
1	Test Name	ALB
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	600
11	Sample Volume	3
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	3.2
55	Expect. Value (H)	5.5
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4x10, 1x10
	15000506	4x20, 1x20
	15000507	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters ALKALINE PHOSPHATASE

No.	<Chemistry>	
1	Test Name	ALKP
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	10
5	Assay Point 1	21
6	Assay Point 2	35
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	660
10	Wave Leng. (MAIN)	415
11	Sample Volume	4
12	R1 VOLUME	200
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	50
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	1000
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	13000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	110
55	Expect. Value (H)	310
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

#### **Hitachi 902**

Parameter	Part Number	Pack Size (mL)
<b>AMYLASE</b>	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### **Notes**

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- Manufacturer
- Σ Size

#### **Applicative Parameters AMYLASE**

No.	<Chemistry>	
1	Test Name	AMYL
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	13
6	Assay Point 2	17
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	415
11	Sample Volume	6
12	R1 VOLUME	250
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	25
55	Expect. Value (H)	140
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4X25
	15000389	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
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- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters CHOLESTEROL

No.	<Chemistry>	
1	Test Name	CHOL
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	505
11	Sample Volume	3
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	2000
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	0
55	Expect. Value (H)	200
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

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## APPLICATION INSERTS

### CK-NAC

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
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#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### CK-NAC

No.	<Chemistry>	
1	Test Name	CK-N
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	13
6	Assay Point 2	17
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	415
10	Wave Leng. (MAIN)	340
11	Sample Volume	12
12	R1 VOLUME	240
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	60
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	135
55	Expect. Value (H)	135
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
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#### Legend of the symbols used on the labels:

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- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters CREATININE

No.	<Chemistry>	
1	Test Name	CREA
2	Assay Code (Mthd)	2 POINT RATE
3	Assay Code (2. Test)	0
4	Reaction Time	4
5	Assay Point 1	10
6	Assay Point 2	13
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	505
11	Sample Volume	30
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	100
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	0.4
55	Expect. Value (H)	1.5
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
<b>GLUCOSE</b>	<b>15000390</b>	<b>4X250</b>
	<b>15000391</b>	<b>1X1000</b>

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
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#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters GLUCOSE

No.	<Chemistry>	
1	Test Name	GLUC
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	505
11	Sample Volume	3
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	2000
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	70
55	Expect. Value (H)	110
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
<b>SGOT/AST</b>	15000496	4x20, 1x20
	15000497	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
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#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### SGOT/AST

No.	<Chemistry>	
1	Test Name	AST/GOT
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	10
5	Assay Point 1	21
6	Assay Point 2	35
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	415
10	Wave Leng. (MAIN)	340
11	Sample Volume	15
12	R1 VOLUME	200
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	50
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	6000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	30
54	Expect. Value (L)	0
55	Expect. Value (H)	40
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
     RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### SGPT/ALT

No.	<Chemistry>	
1	Test Name	GPT/ALT
2	Assay Code (Mthd)	Rate A
3	Assay Code (2. Test)	0
4	Reaction Time	10
5	Assay Point 1	21
6	Assay Point 2	35
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	415
10	Wave Leng. (MAIN)	340
11	Sample Volume	15
12	R1 VOLUME	200
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	50
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	6000
50	ABS Limit (D/I)	Decrease
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	0
55	Expect. Value (H)	46
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters TOTAL PROTEIN

No.	<Chemistry>	
1	Test Name	TPRO
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	600
11	Sample Volume	6
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	2000
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	6
55	Expect. Value (H)	8.5
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
 RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters TRIGLYCERIDES

No.	<Chemistry>	
1	Test Name	TRIG
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	570
11	Sample Volume	3
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	40
55	Expect. Value (H)	165
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Hitachi 902

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Notes

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
     RFCL Limited, Diagnova Division

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### UREA - UV

No.	<Chemistry>	
1	Test Name	UREA
2	Assay Code (Mthd)	2 POINT RATE
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	10
6	Assay Point 2	15
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	415
10	Wave Leng. (MAIN)	340
11	Sample Volume	3
12	R1 VOLUME	240
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	60
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	10000
50	ABS Limit (D/I)	Decrease
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	15
55	Expect. Value (H)	45
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Hitachi 902**

Parameter	Part Number	Pack Size (mL)
<b>URIC ACID</b>	<b>15000394</b>	<b>4X25</b>
	<b>15000395</b>	<b>4X50</b>

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### **Notes**

1. Please refer to the package insert for Albumin (BCG) for the detailed information about the test on the following:  
     Test principle  
     Kit contents  
     Preparation of working reagent  
     Storage and stability  
     Specimen collection and storage  
     Precautions  
     Test Procedure  
     Calculations  
     Linearity  
     Clinical Significance  
     Interfering substances  
     References
2. The stability of the reagent on board of the analyser is at least one month provided that contamination and evaporation are avoided.
3. Manufactured by  
     RFCL Limited, Diagnova Division

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters URIC ACID**

No.	<Chemistry>	
1	Test Name	URIC
2	Assay Code (Mthd)	1 POINT
3	Assay Code (2. Test)	0
4	Reaction Time	5
5	Assay Point 1	17
6	Assay Point 2	0
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	505
11	Sample Volume	6
12	R1 VOLUME	300
13	R1 Pos.	#
14	R1 Bottle Size	Large
15	R2 VOLUME	0
16	R2 Pos.	#
17	R2 Bottle Size	Small
18	R3 VOLUME	0
19	R3 Pos.	#
20	R3 Bottle Size	Small
21	Calib. Type (Type)	Linear
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0
24	Calib. Pos. 1	#
25	Calib. Conc. 2	#
26	Calib. Pos. 2	#
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	0.1
45	Duplicate Limit	300
46	Sens. Limit	2000
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	20000
50	ABS Limit (D/I)	Increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower**
53	Prz. (End Point)	35
54	Expect. Value (L)	2.4
55	Expect. Value (H)	7
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	#

(#) Data entry by the user

(\*) Calculated by the analyzer



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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### ALBUMIN

No.	
Units	mg/dL
Sample Vol.	
Inc. Time	
R. Time	25
R1 blank	
L Limit	0
U Limit	0.3
Assay	CHOL Avantor
Precision	0
R1 Vol.	300
Substrate	0
Mix R. Blank	
L Limit	0
U Limit	0
Type	Endpoint
Prim. Wave.	510
R2 Vol.	0
Response	
L Limit	0
U Limit	0
Linearity	
L Limit	1
U Limit	750
Reaction	Ascending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	CHOL Avantor
Print No.	1



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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4 x 10, 1 x 10
	15000506	4 x 20, 1 x 20
	15000507	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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## APPLICATION INSERTS

### **$\alpha$ -Amylase**

For use on the automatic analyzer

#### **Mindray BS 300**

Parameter	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



Manufactured by:  
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 Plot No.-37, Pharma City,  
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**Corporate Headquarter**  
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 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
CHOLESTEROL TOTAL	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### CHOLESTEROL

No.	
Units	mg/dL
Sample Vol.	
Inc. Time	
R. Time	25
R1 blank	
L Limit	0
U Limit	0.3
Assay	CHOL Avantor
Precision	0
R1 Vol.	300
Substrate	0
Mix R. Blank	
L Limit	0
U Limit	0
Type	Endpoint
Prim. Wave.	510
R2 Vol.	0
Response	
L Limit	0
U Limit	0
Linearity	
L Limit	1
U Limit	750
Reaction	Ascending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	CHOL Avantor
Print No.	1



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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### GLUCOSE

No.	
Units	mg/dL
Sample Vol.	3
Inc. Time	0
R. Time	50
R1 blank	
L Limit	0
U Limit	0.3
Assay	GLU Avantor
Precision	0
R1 Vol.	300
Substrate	0
Mix R. Blank	
L Limit	0
U Limit	0
Type	Endpoint
Prim. Wave.	510
R2 Vol.	0
Response	
L Limit	0
U Limit	0
Linearity	
L Limit	1
U Limit	500
Reaction	Ascending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	GLU Avantor
Print No.	1



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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
SGOT/AST	15000496	4 x 20, 1 x 20
	15000497	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### SGPT/ALT

No.	
Units	mg/dL
Sample Vol.	25
Inc. Time	25
R. Time	5/15
<b>R1 blank</b>	
L Limit	0
U Limit	0
Assay	ALT(GPT) Avantor
Precision	0
R1 Vol.	200
Substrate	2.5
<b>Mix R. Blank</b>	
L Limit	0
U Limit	0
Type	Kinetic
Prim. Wave.	340
R2 Vol.	50
<b>Response</b>	
L Limit	0
U Limit	0
<b>Linearity</b>	
L Limit	1
U Limit	350
Reaction	Descending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	SGPT Avantor
Print No.	1



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4 X 25
	15000393	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### TRIGLYCERIDES

No.	
Units	mg/dL
Sample Vol.	3
Inc. Time	0
R. Time	25
R1 blank	
L Limit	0
U Limit	0.3
Assay	TRIG Avantor
Precision	0
R1 Vol.	300
Substrate	0
Mix R. Blank	
L Limit	0
U Limit	0
Type	Endpoint
Prim. Wave.	546
R2 Vol.	0
Response	
L Limit	0
U Limit	0
Linearity	
L Limit	1
U Limit	1000
Reaction	Ascending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	TRIG Avantor
Print No.	1

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Mindray BS 300

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### UREA-UV

No.	
Units	mg/dL
Sample Vol.	
Inc. Time	
R. Time	25
R1 blank	
L Limit	0
U Limit	0.3
Assay	CHOL Avantor
Precision	0
R1 Vol.	300
Substrate	0
Mix R. Blank	
L Limit	0
U Limit	0
Type	Endpoint
Prim. Wave.	510
R2 Vol.	0
Response	
L Limit	0
U Limit	0
Linearity	
L Limit	1
U Limit	750
Reaction	Ascending
Sec. Wave.	0
Lin. Limit	20
S. Volume	20
Ratio	5
Full name	CHOL Avantor
Print No.	1

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Mindray BS 300**

Parameter	Part Number	Pack Size (mL)
URIC ACID	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

#### **URIC ACID**

No.	
Units	mg/dL
Sample Vol.	6
Inc. Time	0
R. Time	25
<b>R1 blank</b>	
L Limit	0
U Limit	0.3
<b>Assay</b>	U A Avantor
<b>Precision</b>	0
<b>R1 Vol.</b>	300
<b>Substrate</b>	0
<b>Mix R. Blank</b>	
L Limit	0
U Limit	0
<b>Type</b>	Endpoint
<b>Prim. Wave.</b>	510
<b>R2 Vol.</b>	0
<b>Response</b>	
L Limit	0
U Limit	0
<b>Linearity</b>	
L Limit	1
U Limit	25
<b>Reaction</b>	Ascending
<b>Sec. Wave.</b>	0
<b>Lin. Limit</b>	20
<b>S. Volume</b>	20
<b>Ratio</b>	5
<b>Full name</b>	URIC ACID Avantor
<b>Print No.</b>	1

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
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- Manufacturer
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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

##### ALBUMIN

#### Test Information

Test : ALB  
 No. : 409  
 Std. No. :  
 Full Name :

#### Reagent Volume

R1 : 300  
 R2 :

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 3	15	10
Increased	:		
Decreased	:		

#### Reaction Parameters

Reac. Type	:	End-Point
Pri. Wave.	:	605
Sec. Wave.	:	700
Direction	:	Increase
Rgt. Blank	:	8 10
Reac. Time	:	14 16

#### Result Setup

Decimal	:	0.1
Unit	:	mg/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0 6
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4x10,1x10
	15000506	4x20,1x20
	15000507	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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#### Applicative Parameters ALKALINE PHOSPHATASE

#### Test Information

Test	:	ALP
No.	:	403
Std. No.	:	
Full Name	:	ALKALINE PHOSPHATASE

#### Reagent Volume

R1	:	240
R2	:	260

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	:	6	15
Increased	:	6	15
Decreased	:		

#### Reaction Parameters

Reac. Type	:	Kinetic
Pri. Wave.	:	412
Sec. Wave.	:	505
Direction	:	Increase
Rgt. Blank	:	0 0
Reac. Time	:	41 56

#### Result Setup

Decimal	:	0.1
Unit	:	U/L
Slope	:	0
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0 1500
Lin. Limit	:	0.20
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

#### **Mindray BS 380**

Parameter	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

#### **α- AMYLASE**

#### **Test Information**

Test	:	AMY
No.	:	428
Std. No.	:	
Full Name	:	ALPHA AMYLASE

#### **Reagent Volume**

R1	:	200
R2	:	

#### **Sample Volume**

	Disp.	Orig. Vol.	Ratio
Standard	: 5	15	10
Increased	: 5	15	10
Decreased	:		

#### **Reaction Parameters**

Reac. Type	:	KINETIC
Pri. Wave.	:	412
Sec. Wave.	:	
Direction	:	Increase
Rgt. Blank	:	0 0
Reac. Time	:	41 56

#### **Result Setup**

Decimal	:	0.1
Unit	:	U/L
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	5 2000
Lin. Limit	:	0.20
Subs. Limit	:	

#### **Prozone**

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### CHOLESTEROL

#### Test Information

Test : CHOL  
 No. : 416  
 Std. No. :  
 Full Name : CHOLESTEROL

#### Reagent Volume

R1 : 300  
 R2 :

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 3	15	10
Increased	:		
Decreased	:		

#### Reaction Parameters

Reac. Type	:	END-POINT
Pri. Wave.	:	505
Sec. Wave.	:	700
Direction	:	Increase
Rgt. Blank	:	8      10
Reac. Time	:	34      36

#### Result Setup

Decimal	:	1
Unit	:	mg/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0      0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0      750
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
CREATININE	15000004	4x 50
	15000005	4x 100

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### GLUCOSE

#### Test Information

Test : GLU-GOD  
 No. : 415  
 Std. No. :  
 Full Name :

#### Reagent Volume

R1 : 300  
 R2 :

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 3	15	10
Increased	:		
Decreased	:		

#### Reaction Parameters

Reac. Type	:	END-POINT
Pri. Wave.	:	505
Sec. Wave.	:	660
Direction	:	Increase
Rgt. Blank	:	8 10
Reac. Time	:	58 60

#### Result Setup

Decimal	:	1
Unit	:	mg/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0.3 500
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



Manufactured by:  
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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
SGOT/AST	15000496	4x20, 1x20
	15000497	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- Manufacturer
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### SGPT/ALT

#### Test Information

Test : SGPT  
 No. : 401  
 Std. No. :  
 Full Name :

#### Reagent Volume

R1 : 240  
 R2 : 60

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 30	20	10
Increased	: 30	20	10
Decreased	:		

#### Reaction Parameters

Reac. Type	:	KINETIC
Pri. Wave.	:	340
Sec. Wave.	:	412
Direction	:	Decrease
Rgt. Blank	:	0 0
Reac. Time	:	41 56

#### Result Setup

Decimal	:	0.1
Unit	:	U/L
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0 350
Lin. Limit	:	0.20
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
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- Manufacturer
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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### **TOTAL PROTEIN**

#### Test Information

Test	:	T PRO
No.	:	408
Std. No.	:	
Full Name	:	TOTAL PROTEIN

#### Reagent Volume

R1	:	250
R2	:	

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	:	5	15
Increased	:		10
Decreased	:		

#### Reaction Parameters

Reac. Type	:	END POINT
Pri. Wave.	:	546
Sec. Wave.	:	700
Direction	:	Increase
Rgt. Blank	:	8      10
Reac. Time	:	58      60

#### Result Setup

Decimal	:	0.1
Unit	:	gm/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0      0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0      10
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters

#### TRIGLYCERIDES

#### Test Information

Test : TRIG  
 No. : 417  
 Std. No. :  
 Full Name :

#### Reagent Volume

R1 : 200  
 R2 :

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 2	15	10
Increased	:		
Decreased	:		

#### Reaction Parameters

Reac. Type	:	END POINT
Pri. Wave.	:	505
Sec. Wave.	:	700
Direction	:	Increase
Rgt. Blank	:	8 10
Reac. Time	:	58 60

#### Result Setup

Decimal	:	1
Unit	:	mg/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0 500
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Mindray BS 380

Paramater	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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#### Applicative Parameters

##### UREA - UV

#### Test Information

Test : UREA  
 No. : 413  
 Std. No. :  
 Full Name :

#### Reagent Volume

R1	:	240
R2	:	60

#### Sample Volume

	Disp.	Orig. Vol.	Ratio
Standard	: 3	15	10
Increased	:		
Decreased	:		

#### Reaction Parameters

Reac. Type	:	Fixed-Time
Pri. Wave.	:	340
Sec. Wave.	:	700
Direction	:	Decrease
Rgt. Blank	:	0 0
Reac. Time	:	39 44

#### Result Setup

Decimal	:	0.1
Unit	:	mg/dL
Slope	:	1
Inter.	:	0
Absorbance	:	0 0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0 300
Lin. Limit	:	
Subs. Limit	:	

#### Prozone

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0

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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Mindray BS 380**

Paramater	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters**

##### **URIC ACID**

#### **Test Information**

Test	:	URIC
No.	:	412
Std. No.	:	
Full Name	:	URIC ACID

#### **Reagent Volume**

R1	:	250
R2	:	

#### **Sample Volume**

	Disp.	Orig. Vol.	Ratio
Standard	:	5	15
Increased	:		
Decreased	:		

#### **Reaction Parameters**

Reac. Type	:	END POINT
Pri. Wave.	:	505
Sec. Wave.	:	700
Direction	:	Increase
Rgt. Blank	:	8      10
Reac. Time	:	34      56

#### **Result Setup**

Decimal	:	0.1
Unit	:	mg/dL
Slope	:	0
Inter.	:	0
Absorbance	:	0      0
Incre. Test	:	0
Decre. Test	:	0
Lin. Range	:	0      25
Lin. Limit	:	
Subs. Limit	:	

#### **Prozone**

Q1	:	0
Q2	:	0
Q3	:	0
Q4	:	0
PC	:	0
ABS	:	0



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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4 x 10, 1 x 10
	15000506	4 x 20, 1 x 20
	15000507	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

△ Size



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## Applicative Parameters - Alkaline Phosphatase

Test No. #        Name ALKALINE PHOSPHATASE V Type Serum V Operational YES V Page 1/2

Sample Vol.	<u>4</u>	Dil. Vol	<u>0</u> uL	Pre-DilutionRate	Min. OD	Max. OD
Reagent 1 vol	<u>300</u>	Dil. Vol	<u>0</u> uL		L <u>0</u>	H <u>2.5</u>
Reagent 2 vol	<u>      </u>	Dil. Vol	<u>0</u> uL		Reagent OD limit	
				Fst. L <u>0</u>	Fst. H <u>1.5</u>	
Wavelength	Pri. <u>405</u> V	Sec. <u>480</u> V		Lst. L <u>0</u>	Lst. H <u>1.5</u>	
Method	<u>RATE</u> V					Dynamic range
Reaction	+ V					L # H #
Point 1	FST <u>3</u>	Lst <u>5</u>	Correlation factor	A: <u>1</u>	B: <u>0</u>	
Point 2	FST <u>      </u>	Lst <u>      </u>				
Linearity	FST <u>25</u> %	Sec. <u>      </u> %				
No-Lag-Time	<u>NO</u> V			ONBOARD STABILITY PERIOD	# <u>      </u>	

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Sex	Age L	Age H	L	H
1	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
2	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
3	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
4	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
5	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
6	V <u>      </u> Yr <u>      </u> Mo <u>      </u> Yr <u>      </u> Mo <u>      </u> ?	<u>      </u> #	<u>      </u> #	
7	None Selected	<u>      </u> ?	<u>      </u> #	<u>      </u> #
8	Out of Range	<u>      </u> ?	<u>      </u> #	<u>      </u> #
		I.	II	
Panic value	<u>      </u> ?	#	#	

### CALIBRATION SPECIFIC

Test No.        Name ALKALINE PHOSPHATASE V Type Serum V

Cal. Type MB V Counts 2

Formula Y-AX+B V Process CONC. V

#### Calibrator Selection

	Cal No.	OD	Conc	Factor/OD-L	Factor/OD-H
Point 1	<u>#</u> V	<u>      </u>	<u>      </u> #	<u>.9999999</u>	<u>.9999999</u>
Point 2	<u>#</u> V	<u>      </u>	<u>      </u>	<u>.9999999</u>	<u>.9999999</u>
Point 3	<u>#</u> V	<u>      </u>	<u>      </u>	<u>.9999999</u>	<u>.9999999</u>
Point 4	<u>#</u> V	<u>      </u>	<u>      </u>	<u>.9999999</u>	<u>.9999999</u>
Point 5	<u>#</u> V	<u>      </u>	<u>      </u>	<u>.9999999</u>	<u>.9999999</u>
Point 6	<u>#</u> V	<u>      </u>	<u>      </u>	<u>.9999999</u>	<u>.9999999</u>
Point 7	<u>      </u> V	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>

1-point cal. Point       

MB type Factor 2757

## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

### **Olympus AU 400**

Paramater	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

Test No.	#	Name	AMYLASE (CNPG3)	▼	Type	Serum	▼	Operational	YES	▼	Page	1/2
<hr/>												
Sample Vol.	3	Dil. Vol	0	uL	Pre-Dilution Rate		Min. OD		Max. OD			
Reagent 1 vol	150	Dil. Vol	0	uL		L	0,0000	H	2,5000			
Reagent 2 vol	0	Dil. Vol	0	uL		Reagent OD limit						
						Est. L.	0	Est. H	1,5000			
Wavelength	Pri.	405	▼	Sec.	520	▼		Est. L.	0	Est. H	1,5000	
Method	RATelu	▼					Dynamic range					
Reaction	+	▼				L	#	H	#			
Point 1	FST	3		Lst	7		Correlation factor	A:	1			
Point 2	FST	—		Lst	—			B:	0			
Linearity	FST	25	%	Sec.	—	%						
No-Lag-Time	NO	▼					ONBOARD STABILITY PERIOD	#	—			
NOTE: Reagent ID must be assigned a non-Olympus ID test code.												

#### **Legend of the symbols used on the labels:**

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

▼ Size



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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4X25
	15000389	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test No.	#	Name	CHOLESTEROL (CHOD-POD) V	Type	Serum V	Operational	YES V	Page	1/2
Sample Vol.	2	Dil. Vol	0 uL	Pre-DilutionRate		Min. OD		Max. OD	
Reagent 1 vol	200	Dil. Vol	0 uL		L	H			
Reagent 2 vol	0	Dil. Vol	0 uL						
Wavelength	Pri. 505 V	Sec.	660 V		Reagent OD limit				
Method	END V				Fst. L 0.0000	Fst. H 0.5000			
Reaction	+ V				Lst. L 0.0000	Lst. H 0.5000			
Point 1	FST 0	Lst	17	Correlation factor	A: 1				
Point 2	FST	Lst			B: 0				
Linearity	FST %	Sec.	%						
No-Lag-Time	NO V			ONBOARD STABILITY PERIOD	#				

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

#### Legend of the symbols used on the labels:

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

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**Corporate Headquarter**  
Avantor Performance Materials  
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Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### **CK-NAC**

For use on the automatic analyzer

#### **Olympus AU 400**

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

▽ Size

## Applicative Parameters - CK-NAC

SPECIFIC TEST PARAMETERS							
Test No.	#	Name	<u>CPK</u> ▼	Type	<u>Serum</u> ▼	Operational	<u>YES</u> ▼
Page	<u>1/2</u>						
Sample Vol.	<u>7</u>	Dil. Vol	<u>0</u> uL	Pre-DilutionRate	Min. OD	Max. OD	
Reagent 1 vol	<u>200</u>	Dil. Vol	<u>0</u> uL	L <u>0.0000</u>	H <u>2.5000</u>		
Reagent 2 vol	<u>50</u>	Dil. Vol	<u>0</u> uL	Reagent OD limit	Fst. L <u>0.0000</u>	Fst. H <u>1.5000</u>	
Wavelength	Pri. <u>340</u> ▼	Sec.	<u>380</u> ▼	Lst. L <u>0.0000</u>	Lst. H <u>1.5000</u>		
Method	<u>RATEV</u>				Dynamic range		
Reaction	<u>+V</u>				L #	H #	
Point 1	FST <u>7</u>	Lst	<u>17</u>	Correlation factor	A: <u>1</u>		
Point 2	FST <u>  </u>	Lst	<u>  </u>		B: <u>0</u>		
Linearity	FST <u>25</u> %	Sec.	<u>  </u> %	ONBOARD STABILITY PERIOD #			
No-Lag-Time	<u>NO</u> ▼						

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Test No.	#	Name	<u>CPK</u> ▼	Type	<u>Serum</u> ▼	Page	<u>2/2</u>
				Level L	Level H		
Value/Flag	#						
Normal ranges							
Sex	Age L	Age H	L		H		
1	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
2	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
3	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
4	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
5	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
6	<u>  </u> ▼	<u>  </u> Yr	Mo	<u>  </u> Yr	Mo	→ <u>  </u> #	<u>  </u> #
7	None Selected					→ <u>  </u> #	<u>  </u> #
8	Out of Range					→ <u>  </u> #	<u>  </u> #
Panic value			→	<u>  </u> L		<u>  </u> H	<u>  </u> #

### CALIBRATION SPECIFIC

Test No.	#	Name	<u>CPK</u> ▼	Type	<u>Serum</u> ▼
Cal. Type	<u>MB</u> ▼	Counts	<u>2</u>		
Formula	<u>Y=AX+B</u> ▼	Process	<u>CONC.</u> ▼		
Calibrator Selection					
Cal No.	OD	Conc	Factor/OD-L	Factor/OD-H	
Point 1	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 2	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 3	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 4	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 5	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 6	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
Point 7	<u>  </u> ▼	<u>  </u>	<u>-9999999</u>	<u>9999999</u>	
1-point cal. Point					
MB type Factor	<u>  </u> 7325				
CALIB. STBLTY PERIOD	<u>  </u> #				



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## APPLICATION INSERTS

### CK-MB

For use on the automatic analyzer

#### Olympus AU 400

Parameter	Part Number	Pack Size (mL)
CK-MB	15000586	50 ml
	15000587	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.  
Stable up to expiry date stated on the label.  
Stability of open vial on board of the  
analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- ▽ Size

## Applicative Parameters - CK-MB

SPECIFIC TEST PARAMETERS							
Test No.	#	Name	<u>CK-MB</u>	▀	Type	<u>Serum</u>	▀
Operational	YES	▀	Page	1/2			
Sample Vol.	7	Dil. Vol	0	uL	Pre-DilutionRate	Min. OD	Max. OD
Reagent 1 vol	150	Dil. Vol	0	uL	L 0.0000	H 2.5000	
Reagent 2 vol	0	Dil. Vol	0	uL	Reagent OD limit		
Wavelength	Pri. 340	▀	Sec.	380	▀	Fst. L 0.0000	Fst. H 2.0000
Method	RATE	▀				Lst. L 0.0000	Lst. H 2.0000
Reaction	+ ▽					Dynamic range	
Point 1	FST 17		Lst	24		A: 1	H #
Point 2	FST		Lst			B: 0	
Linearity	FST 25	%	Sec.		%	ONBOARD STABILITY PERIOD #	
No-Lag-Time	NO	▀					

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Test No.	#	Name	<u>CK-MB</u>	▀	Type	<u>Serum</u>	▀	Page	2/2
Value/Flag	#				Level L		Level H		
Normal ranges									
Sex	Age L		Age H		L		H		
1	Yr	Mo	Yr	Mo	-----►	#	#		
2	Yr	Mo	Yr	Mo	-----►	#	#		
3	Yr	Mo	Yr	Mo	-----►	#	#		
4	Yr	Mo	Yr	Mo	-----►	#	#		
5	Yr	Mo	Yr	Mo	-----►	#	#		
6	Yr	Mo	Yr	Mo	-----►	#	#		
7	None Selected				-----►	#	#		
8	Out of Range				-----►	#	#		
Panic value					-----►	L #	H #		

### CALIBRATION SPECIFIC

Test No.	#	Name	<u>CK-MB</u>	▀	Type	<u>Serum</u>	▀
Cal. Type	<u>MB</u>	▀			Counts	<u>2</u>	
Formula	<u>Y=AX+B</u>	▀			Process	<u>CONC.</u>	▀
Calibrator Selection							
Cal No.	OD	Conc		Factor/OD-L	Factor/OD-H		
Point 1	# ▽		#	-9999999	9999999		
Point 2	# ▽		#	-9999999	9999999		
Point 3	# ▽		#	-9999999	9999999		
Point 4	# ▽		#	-9999999	9999999		
Point 5	# ▽		#	-9999999	9999999		
Point 6	# ▽		#	-9999999	9999999		
Point 7	# ▽		#	-9999999	9999999		
1-point cal. Point							
MB type Factor	7212						
CALIB. STBLTY PERIOD	#						



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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

▽ Size

## Applicative Parameters - Creatinine

### SPECIFIC TEST PARAMETERS

Test No.	#	Name	CREATININE	∇	Type	Serum	∇	Operational	YES	∇	Page	1/2
Sample Vol.	<u>10</u>	Dil. Vol	<u>0</u>	uL	Pre-DilutionRate		Min. OD		Max. OD			
Reagent 1 vol	<u>250</u>	Dil. Vol	<u>0</u>	uL		L	<u>0</u>	H	<u>1.5</u>			
Reagent 2 vol	<u>50</u>	Dil. Vol	<u>0</u>	uL		Reagent OD limit						
Wavelength	Pri. <u>510</u> ∇	Sec.	<u>800</u>	∇		Fst. L	<u>-0.1000</u>	Fst. H	<u>0.6000</u>			
Method	FIXED∇					Lst. L	<u>-0.1000</u>	Lst. H	<u>0.6000</u>			
Reaction	+ ∇					Dynamic range						
Point 1	FST <u>2</u>	Lst	<u>7</u>		Correlation factor	L	#	H	#			
Point 2	FST <u>  </u>	Lst	<u>  </u>			A:	<u>1</u>	B:	<u>0</u>			
Linearity	FST <u>25</u> %	Sec.	<u>  </u>	%		ONBOARD STABILITY PERIOD	#					
No-Lag-Time	NO ∇											

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Test No.	#	Name	CREATININE	∇	Type	Serum	∇	Page	2/2
Value/Flag	#				Level L		Level H		
Normal ranges									
Sex	Age L		Age H		L		H		
1	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
2	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
3	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
4	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
5	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
6	<u>  </u> ∇ <u>  </u> Yr <u>  </u> Mo- <u>  </u>		<u>  </u> Yr <u>  </u> Mo- <u>  </u>		Mo -----►	<u>  </u> #	<u>  </u> #		
7	None Selected				-----►	<u>  </u> #	<u>  </u> #		
8	Out of Range				-----►	<u>  </u> #	<u>  </u> #		
Panic value						L	H		

### CALIBRATION SPECIFIC

Test No.	#	Name	CREATININE	∇	Type	Serum	∇
Cal. Type	<u>AB</u> ∇				Counts	<u>2</u>	
Formula	<u>Y=AX+B</u> ∇				Process	<u>CONC.</u> ∇	
Calibrator Selection							
Cal No.	OD	Conc		Factor/OD-L		Factor/OD-H	
Point 1	<u>  </u> ∇	<u>  </u>	<u>  </u> #	<u>-9999999</u>		<u>9999999</u>	
Point 2	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
Point 3	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
Point 4	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
Point 5	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
Point 6	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
Point 7	<u>  </u> ∇	<u>  </u>	<u>  </u>	<u>-9999999</u>		<u>9999999</u>	
1-point cal. Point	<u>  </u>						
MB type Factor	<u>  </u>						
CALIB. STBLTY PERIOD	<u>  </u> #						



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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test No.	#	Name	GLUCOSE (GOD-POD) V	Type	Serum V	Operational	YES V	Page	1/2
Sample Vol.	2	Dil. Vol	0 uL	Pre-DilutionRate	Min. OD	Max. OD			
Reagent 1 vol	200	Dil. Vol	0 uL		L	H			
Reagent 2 vol	0	Dil. Vol	0 uL	Reagent OD limit	Fst. L 0.0000	Fst. H 0.5000			
Wavelength	Pri. 505 V	Sec.	660 V		Lst. L 0.0000	Lst. H 0.5000			
Method	END V				Dynamic range				
Reaction	+ V				L #	H #			
Point 1	FST 0	Lst	17	Correlation factor	A: 1				
Point 2	FST	Lst			B: 0				
Linearity	FST %	Sec.	%						
No-Lag-Time	NO V			ONBOARD STABILITY PERIOD	#				

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

#### Legend of the symbols used on the labels:

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

△ Size



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## APPLICATION INSERTS

### **SGPT/ALT**

For use on the automatic analyzer

#### **Olympus AU 400**

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

△ Size



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## Applicative Parameters - SGPT/ALT

Test No. # Name ALT V Type Serum V Operational YES V Page 1/2

Sample Vol.	12	Dil. Vol	0 uL	Pre-DilutionRate	Min. OD	Max. OD
Reagent 1 vol	300	Dil. Vol	0 uL		L 0.300	H 2.5
Reagent 2 vol	0	Dil. Vol	0 uL		Reagent OD limit	
					Fst. L 0.6000	Fst. H 2.5
Wavelength	Pri. 340 V	Sec.	380 V		Lst. L 0.6000	Lst. H 2.5
Method	RATE V				Dynamic range	
Reaction	- V				L #	H #
Point 1	FST 3	Lst	10	Correlation factor	A: 1	
Point 2	FST	Lst			B: 0	
Linearity	FST 25 %	Sec.				
No-Lag-Time	NO V			ONBOARD STABILITY PERIOD	#	

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Sex	Age L	Age H	L	H
1	V Yr Mo Yr Mo ----?		#	#
2	V Yr Mo Yr Mo ----?		#	#
3	V Yr Mo Yr Mo ----?		#	#
4	V Yr Mo Yr Mo ----?		#	#
5	V Yr Mo Yr Mo ----?		#	#
6	V Yr Mo Yr Mo ----?		#	#
7	None Selected	-----?	#	#
8	Out of Range	-----?	#	#
			L	H
Panic value	-----?	#	#	

---

Test No. # Name ALKALINE PHOSPHATASE V Type Serum V

---

Cal. Type	MB V	Counts	2		
Formula	Y=AX+B V	Process	CONC V		
Calibrator Selection					
Cal No.	OD	Cone	Factor/OD-L	Factor/OD-H	
Point 1	# V		#	.9999999	9999999
Point 2	# V			.9999999	9999999
Point 3	# V			.9999999	9999999
Point 4	# V			.9999999	9999999
Point 5	# V			.9999999	9999999
Point 6	# V			.9999999	9999999
Point 7	V				
1-point cal. Point	-----				
MB type Factor	1746				

## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
TOTAL PROTEIN	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- ▽ Size

## Applicative Parameters - Total Protein

SPECIFIC TEST PARAMETERS								
Test No.	#	Name	TOTAL PROTEIN	V	Type	Serum	V	Operational
Sample Vol.	4	Dil. Vol	0	uL	Pre-DilutionRate	Min. OD		Max. OD
Reagent 1 vol	200	Dil. Vol	0	uL		L	H	
Reagent 2 vol	0	Dil. Vol	0	uL		Reagent OD limit		
Wavelength	Pri. 546	V	Sec. 800	V		Fst. L -0.1000	Fst. H 0.9000	
Method	ENDV					Lst. L -0.1000	Lst. H 0.9000	
Reaction	+ V					Dynamic range		
Point 1	FST 0		Lst 27		Correlation factor	L #	H #	
Point 2	FST —		Lst —			A: 1	B: 0	
Linearity	FST —	%	Sec. —	%		ONBOARD STABILITY PERIOD #		
No-Lag-Time	NO	V						

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

Test No.	#	Name	TOTAL PROTEIN	V	Type	Serum	V	Page	2/2
Value/Flag	#				Level L		Level H		
Normal ranges									
Sex	Age L		Age H		L		H		
1	Yr	Mo	Yr	Mo	→	#		#	
2	Yr	Mo	Yr	Mo	→	#		#	
3	Yr	Mo	Yr	Mo	→	#		#	
4	Yr	Mo	Yr	Mo	→	#		#	
5	Yr	Mo	Yr	Mo	→	#		#	
6	Yr	Mo	Yr	Mo	→	#		#	
7	None Selected				→	#		#	
8	Out of Range				→	#		#	
Panic value					→	6.0		8.5	

CALIBRATION SPECIFIC								
Test No.	#	Name	TOTAL PROTEIN	V	Type	Serum	V	
Cal. Type	AB	V			Counts	2		
Formula	Y=AX+B	V			Process	CONC.	V	
Calibrator Selection								
Cal No.	OD	Conc		Factor/OD-L	Factor/OD-H			
Point 1	#	#		-9999999	9999999			
Point 2	#	#		-9999999	9999999			
Point 3	#	#		-9999999	9999999			
Point 4	#	#		-9999999	9999999			
Point 5	#	#		-9999999	9999999			
Point 6	#	#		-9999999	9999999			
Point 7	#	#		-9999999	9999999			
1-point cal. Point								
MB type Factor								
CALIB. STBLTY PERIOD	#							



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

### Olympus AU 400

Paramater	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test No.	#	Name	TRIGLYCERIDE (GPO)	V	Type	Serum	▼	Operational	YES	▼	Page	1/2
Sample Vol.	2			Dil. Vol	0	uL	Pre-DilutionRate	Min. OD		Max. OD		
Reagent 1 vol	200			Dil. Vol	0	uL		L		H		
Reagent 2 vol	0			Dil. Vol	0	uL		Reagent OD limit				
							Fst. L	0.0000	Fst. H	0.5000		
Wavelength		Pri.	546	▼	Sec.	660	▼	Lst. L	0.0000	Lst. H	0.5000	
Method		END	V					Dynamic range				
Reaction		+	▼					L #		H #		
Point 1		FST	0		Lst	17		Correlation factor	A:	1		
Point 2		FST	—		Lst	—			B:	0		
Linearity		FST	— %		Sec.	— %						
No-Lag-Time		NO	▼					ONBOARD STABILITY PERIOD	#			

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

#### Legend of the symbols used on the labels:

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

▼ Size



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

### Olympus AU 400

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4x10,1x10
	15000503	4x20,1x20
	15000504	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test No. # Name UREA V Type Serum V Operational YES V Page 1/2

Sample Vol.	3	Dil. Vol	0 uL	Pre-DilutionRate	Min. OD	Max. OD
Reagent 1 vol	300	Dil. Vol	0 uL		L 0.6000	H 2.5000
Reagent 2 vol	-	Dil. Vol	0 uL		Reagent OD limit	
					Fst. L 0.8000	Fst. H 2.5000
Wavelength	Pri. 340 V	Sec.	380 V		Lst. L 0.8000	Lst. H 2.5000
Method	RATE V				Dynamic range	
Reaction	- V				L #	H #
Point 1	FST 2	Lst	4	Correlation factor	A: 1	
Point 2	FST	Lst			B: 0	
Linearity	FST 25 %	Sec.				
No-Lag-Time	NO V			ONBOARD STABILITY PERIOD	#	

NOTE: Reagent ID must be assigned a non - Olympus ID test code

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

### **Olympus AU 400**

Paramater	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

Test No. # Name URIC ACID ▽ Type Serum ▽ Operational YES ▽ Page 1/2

Sample Vol.	3	Dil. Vol	0 uL	Pre-DilutionRate	Min. OD	Max. OD
Reagent 1 vol	150	Dil. Vol	0 uL		L	H
Reagent 2 vol	0	Dil. Vol	0 uL		Reagent OD limit	
				Fst. L 0.0000	Fst. H 0.6000	
Wavelength	Pri. 505 ▽	Sec.	660 ▽	Lst. L 0.0000	Lst. H 0.6000	
Method	END ▽				Dynamic range	
Reaction	+ ▽			L #	H #	
Point 1	FST 0	Lst	17	Correlation factor	A: 1	
Point 2	FST	Lst			B: 0	
Linearity	FST %	Sec.	%			
No-Lag-Time	NO ▽			ONBOARD STABILITY PERIOD	#	

NOTE: Reagent ID must be assigned a non - Olympus ID test code.

#### **Legend of the symbols used on the labels:**

H CE Mark (requirement of 98/79/CE regulation)

F For in vitro diagnostic use

C Batch code

B Catalogue number

I Storage temperature

K Expiry date (year-month)

J Consult accompanying documents

L consult operating instructions

A Bio-hazard

■ Manufacturer

▽ Size



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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### ALBUMIN

Test	:	Alb
No.	:	x
Full Name	:	Albumin
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	630
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1      3
Unit	:	g/dl
Precision	:	0.1
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x      x
Mixed Rgt. Blank	:	x      x
Linearity Range	:	0      6
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
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- J Consult accompanying documents
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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4x10,1x10
	15000506	4x20,1x20
	15000507	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters ALKALINE PHOSPHATASE

Test	:	Alp
No.	:	x
Full Name	:	Alkaline Phosphatase
Standard No.	:	x
Reaction Type	:	Kinetic
Pri. Wavelength	:	405
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	3      10
Unit	:	u/l
Precision	:	Integer
R1	:	200
R2	:	x
Sample Volume	:	4
R1 Blank	:	x      x
Mixed Rgt. Blank	:	x      x
Linearity Range	:	0      1500
Linearity Limit	:	0.2
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### Calcium

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
CALCIUM	15000060	100

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### CALCIUM

Test	:	Cal
No.	:	x
Full Name	:	Calcium
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	630
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	x 3
Unit	:	mg/dl
Precision	:	0.1
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 16
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4X25
	15000389	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters **CHOLESTEROL**

Test	:	Chol
No.	:	x x
Full Name	:	Cholesterol
Standard No.	:	x x
Reaction Type	:	End Point
Pri. Wavelength	:	10
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1 17
Unit	:	mg/dl
Precision	:	Integer
R1	:	300
R2	:	x
Sample Volume	:	x
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	500
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### CREATININE

Test	:	Creat
No.	:	x
Full Name	:	Creatinine
Standard No.	:	x
Reaction Type	:	Fixed Time
Pri. Wavelength	:	510
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1      3
Unit	:	mg/dl
Precision	:	0.01
R1	:	200
R2	:	200
Sample Volume	:	20
R1 Blank	:	x      x
Mixed Rgt. Blank	:	x      x
Linearity Range	:	0      20
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters **GLUCOSE**

Test	:	GLUC
No.	:	x
Full Name	:	Glucose
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	510
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1      34
Unit	:	mg/dl
Precision	:	Integer
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x      x
Mixed Rgt. Blank	:	x      x
Linearity Range	:	0      700
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
SGOT/AST	15000496	4x20,1x20
	15000497	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGOT/AST

Test	:	SGOT
No.	:	x
Full Name	:	SGOT
Standard No.	:	x
Reaction Type	:	Kinetic
Pri. Wavelength	:	340
Sec. Wavelength	:	x
Direction	:	Decreasing
Incubation Time	:	3 10
Unit	:	u/l
Precision	:	Integer
R1	:	200
R2	:	x
Sample Volume	:	x
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 350
Linearity Limit	:	0.2
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGPT/ALT

Test	:	SGPT
No.	:	x
Full Name	:	SGPT
Standard No.	:	x
Reaction Type	:	Kinetic
Pri. Wavelength	:	350
Sec. Wavelength	:	x
Direction	:	Decreasing
Incubation Time	:	3 10
Unit	:	u/l
Precision	:	Integer
R1	:	200
R2	:	x
Sample Volume	:	20
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 350
Linearity Limit	:	0.2
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### **TOTAL PROTEIN**

Test	:	TP
No.	:	x
Full Name	:	Total Protein
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	456
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1      34
Unit	:	mg/dl
Precision	:	0.01
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x      x
Mixed Rgt. Blank	:	x      x
Linearity Range	:	0      10
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### TRIGLYCERIDES

Test	:	TG
No.	:	x
Full Name	:	Triglycerides
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	546
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1 17
Unit	:	mg/dl
Precision	:	Integer
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 1000
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- △ Size



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### ROBOCHEM

Paramater	Part Number	Pack Size (mL)
UREA UV	15000502	4x10,1x10
	15000503	4x20,1x20
	15000504	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### UREA-UV

Test	:	Urea
No.	:	x
Full Name	:	Urea-UV
Standard No.	:	x
Reaction Type	:	Fixed Time
Pri. Wavelength	:	340
Sec. Wavelength	:	x
Direction	:	Decreasing
Incubation Time	:	2 5
Unit	:	mg/dl
Precision	:	0.1
R1	:	300
R2	:	x
Sample Volume	:	3
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 300
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
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- J Consult accompanying documents
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **ROBOCHEM**

Paramater	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

#### **URIC ACID**

Test	:	UA
No.	:	x
Full Name	:	Uric Acid
Standard No.	:	x
Reaction Type	:	End Point
Pri. Wavelength	:	630
Sec. Wavelength	:	x
Direction	:	Increasing
Incubation Time	:	1 17
Unit	:	mg/dl
Precision	:	0.1
R1	:	200
R2	:	x
Sample Volume	:	5
R1 Blank	:	x x
Mixed Rgt. Blank	:	x x
Linearity Range	:	0 25
Linearity Limit	:	x
Substrate Limit	:	x
Factor	:	x
Prozone Check	:	x

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### ALBUMIN

PARAMETER	
TEST	ALB
Test BAR CODE	0010/**
TEST TYPE	End Point
CURVE TYPE	BLANKED LINEAR
UNITS	g/dl
NO. OF DECIMALS	2
PRIMARY WAVELENGTH	600
SECONDARY WAVE LENGTH	NONE
READ TIME / INTERVAL	20
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW -0.1 HIGH 2.0
A LIMIT	LOW 0.0 HIGH 2.5
NORMAL LIMIT	LOW 3.20 HIGH 5.50
LINERITY LIMIT	6.00
CURVE SD LIMIT	—

TEST	ALB
Test BAR CODE	0010/**
SAMPLE VOLUME (ul.)	3
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME (sec) BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME BOTTLE TYPE

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4x10,1x10
	15000506	4x20,1x20
	15000507	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters ALKALINE PHOSPHATASE

PARAMETER	
TEST	ALKP
Test BAR CODE	007/**
TEST TYPE	KINETIC
CURVE TYPE	BLANKED LINEAR
UNITS	IU/L
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	405
SECONDARY WAVE LENGTH	600
READ TIME / INTERVAL	60
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW -0.1 HIGH 2.0
A LIMIT	LOW 0.0 HIGH 2.5
NORMAL LIMIT	LOW 110 HIGH 310
LINERITY LIMIT	1500
CURVE SD LIMIT	—

TEST	ALKP
Test BAR CODE	007/**
SAMPLE VOLUME (ul.)	6
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME (sec) BOTTLE TYPE
	240 ** 60 GLASS
REAGENT 2	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME BOTTLE TYPE
	60 ** 60 GLASS



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## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

### **Siemens Express Plus/Express 550**

Paramater	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### **Applicative Parameters**

#### **α- AMYLASE**

PARAMETER	AMYLASE
TEST	AMYL
Test BAR CODE	009/**
TEST TYPE	KINETIC
CURVE TYPE	BLANKED LINEAR
UNITS	IU/L
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	405
SECONDARY WAVE LENGTH	600
READ TIME / INTERVAL	60
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW -0.1 HIGH 2.0
A LIMIT	LOW 0.0 HIGH 2.5
NORMAL LIMIT	LOW 45 HIGH 140
LINERITY LIMIT	2000
CURVE SD LIMIT	—

TEST	AMYL
Test BAR CODE	009/**
SAMPLE VOLUME (ul.)	6
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) 300 BAR CODE ** DILUENT VOLUME (ul.) LAG TIME (sec) BOTTLE TYPE GLASS
REAGENT 2	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME BOTTLE TYPE



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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### CHOLESTEROL

PARAMETER		CHOLESTEROL
TEST		CHOL
Test BAR CODE		002/**
TEST TYPE		ENDPOINT
CURVE TYPE		BLANKED LINEAR
UNITS		mg/dl
NO. OF DECIMALS		1
PRIMARY WAVELENGTH		510
SECONDARY WAVE LENGTH		600
READ TIME / INTERVAL		20
SAMPLE BLANK		NO
FACTOR		-
CALIBRATION INTERVAL		**
NORM. / REBLANK INTERVAL		**
NO. OF CALIBRATOR		2
NO. OF REPLICATES		2
BLANK A LIMIT	LOW	-0.1
	HIGH	2.0
A LIMIT	LOW	0.0
	HIGH	2.5
NORMAL LIMIT	LOW	0
	HIGH	200
LINERITY LIMIT		750
CURVE SD LIMIT		—

TEST		CHOL
Test BAR CODE		022/**
SAMPLE VOLUME (ul.)		3
RERUN DILUTION RATIO		
PRERUN DILUTION RATIO		
REAGENT DILUENT		
REAGENT 1	REAGENT VOLUME (ul.)	300
	BAR CODE	**
	DILUENT VOLUME (ul.)	
	LAG TIME (sec)	
	BOTTLE TYPE	GLASS
REAGENT 2	REAGENT VOLUME (ul.)	
	BAR CODE	
	DILUENT VOLUME (ul.)	
	LAG TIME	
	BOTTLE TYPE	

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
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## APPLICATION INSERTS

### CK-NAC

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### CK-NAC

PARAMETER	CK-NCK
TEST	CK-N
Test BAR CODE	0013/**
TEST TYPE	KINETIC
CURVE TYPE	BLANKED LINEAR
UNITS	IU/L
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	340
SECONDARY WAVE LENGTH	380
READ TIME / INTERVAL	120
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW HIGH
A LIMIT	LOW HIGH
NORMAL LIMIT	LOW HIGH
LINERITY LIMIT	1000
CURVE SD LIMIT	—

TEST	CK-N
Test BAR CODE	0013/**
SAMPLE VOLUME (ul.)	12
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME (sec) BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME BOTTLE TYPE

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### CREATININE

PARAMETER	CREATININE
TEST	CREA
Test BAR CODE	0012/**
TEST TYPE	TWO POINT
CURVE TYPE	BLANKED LINEAR
UNITS	mg/dl
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	510
SECONDARY WAVE LENGTH	600
READ TIME / INTERVAL	120
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW
	HIGH
A LIMIT	LOW
	HIGH
NORMAL LIMIT	LOW
	HIGH
LINERITY LIMIT	300
CURVE SD LIMIT	

TEST	CREA
Test BAR CODE	0012/**
SAMPLE VOLUME (ul.)	30
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.)
	BAR CODE
	DILUENT VOLUME (ul.)
	LAG TIME (sec)
	BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.)
	BAR CODE
	DILUENT VOLUME (ul.)
	LAG TIME
	BOTTLE TYPE

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### GLUCOSE

PARAMETER		GLUCOSE
TEST		GLUC
Test BAR CODE		001/**
TEST TYPE		ENDPOINT
CURVE TYPE		BLANKED LINEAR
UNITS		mg/dl
NO. OF DECIMALS		1
PRIMARY WAVELENGTH		510
SECONDARY WAVE LENGTH		600
READ TIME / INTERVAL		20
SAMPLE BLANK		NO
FACTOR		-
CALIBRATION INTERVAL		**
NORM. / REBLANK INTERVAL		**
NO. OF CALIBRATOR		2
NO. OF REPLICATES		2
BLANK A LIMIT	LOW	-0.1
	HIGH	2.0
A LIMIT	LOW	0.0
	HIGH	2.5
NORMAL LIMIT	LOW	70
	HIGH	110
LINERITY LIMIT		500
CURVE SD LIMIT		—

TEST		GLUC
Test BAR CODE		001/**
SAMPLE VOLUME (ul.)		3
RERUN DILUTION RATIO		
PRERUN DILUTION RATIO		
REAGENT DILUENT		
REAGENT 1	REAGENT VOLUME (ul.)	300
	BAR CODE	**
	DILUENT VOLUME (ul.)	
	LAG TIME (sec)	
	BOTTLE TYPE	GLASS
REAGENT 2	REAGENT VOLUME (ul.)	
	BAR CODE	
	DILUENT VOLUME (ul.)	
	LAG TIME	
	BOTTLE TYPE	

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
- K Expiry date (year-month)
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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
SGOT/AST	15000496	4 x 20, 1 x 20
	15000497	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGOT/AST

PARAMETER		SGOT/AST
TEST		SGOT
Test BAR CODE		005/**
TEST TYPE		KINETIC
CURVE TYPE		BLANKED LINEAR
UNITS		IU/L
NO. OF DECIMALS		1
PRIMARY WAVELENGTH		340
SECONDARY WAVE LENGTH		380
READ TIME / INTERVAL		60
SAMPLE BLANK		NO
FACTOR		-
CALIBRATION INTERVAL		**
NORM. / REBLANK INTERVAL		**
NO. OF CALIBRATOR		2
NO. OF REPLICATES		2
BLANK A LIMIT	LOW	0.5
	HIGH	2.0
A LIMIT	LOW	0.5
	HIGH	2.5
NORMAL LIMIT	LOW	0
	HIGH	46
LINERITY LIMIT		350
CURVE SD LIMIT		—

TEST		SGOT
Test BAR CODE		005/**
SAMPLE VOLUME (ul.)		30
RERUN DILUTION RATIO		
PRERUN DILUTION RATIO		
REAGENT DILUENT		
REAGENT 1	REAGENT VOLUME (ul.)	240
	BAR CODE	**
	DILUENT VOLUME (ul.)	
	LAG TIME (sec)	60
	BOTTLE TYPE	GLASS
REAGENT 2	REAGENT VOLUME (ul.)	60
	BAR CODE	
	DILUENT VOLUME (ul.)	
	LAG TIME	60
	BOTTLE TYPE	GLASS

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- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



Manufactured by:  
**Avantor Performance Materials India Ltd.**  
 Plot No.-37, Pharma City,  
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**Corporate Headquarter**  
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGPT/ALT

SGPT/ALT
AGPT
006/**
KINETIC
BLANKED LINEAR
IU/L
1
340
380
60
NO
-
**
**
2
2
0.5
2.0
0.5
2.5
0
49
350
—

TEST	SGPT
Test BAR CODE	006/**
SAMPLE VOLUME (ul.)	30
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.)
	BAR CODE
	DILUENT VOLUME (ul.)
	LAG TIME (sec)
	BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.)
	BAR CODE
	DILUENT VOLUME (ul.)
	LAG TIME
	BOTTLE TYPE

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
TOTAL PROTEIN	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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#### Applicative Parameters

#### TOTAL PROTEIN

PARAMETER		TOTAL PROTEIN
TEST		TPRO
Test BAR CODE		0011/**
TEST TYPE		ENDPOINT
CURVE TYPE		BLANKED LINEAR
UNITS		g/dl
NO. OF DECIMALS		2
PRIMARY WAVELENGTH		540
SECONDARY WAVE LENGTH		600
READ TIME / INTERVAL		00
SAMPLE BLANK		NO
FACTOR		-
CALIBRATION INTERVAL		**
NORM. / REBLANK INTERVAL		**
NO. OF CALIBRATOR		2
NO. OF REPLICATES		2
BLANK A LIMIT	LOW	-0.1
	HIGH	2.0
A LIMIT	LOW	0.0
	HIGH	2.5
NORMAL LIMIT	LOW	6.00
	HIGH	8.50
LINERITY LIMIT		10.00
CURVE SD LIMIT		—

TEST		TPRO
Test BAR CODE		0011/**
SAMPLE VOLUME (ul.)		6
RERUN DILUTION RATIO		
PRERUN DILUTION RATIO		
REAGENT DILUENT		
REAGENT 1	REAGENT VOLUME (ul.)	300
	BAR CODE	**
	DILUENT VOLUME (ul.)	600
	LAG TIME (sec)	
	BOTTLE TYPE	GLASS
REAGENT 2	REAGENT VOLUME (ul.)	
	BAR CODE	
	DILUENT VOLUME (ul.)	
	LAG TIME	
	BOTTLE TYPE	



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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramater	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### TRIGLYCERIDES

PARAMETER	TRIGLYCERIDES
TEST	TRIG
Test BAR CODE	003/**
TEST TYPE	ENDPOINT
CURVE TYPE	BLANKED LINEAR
UNITS	mg/dl
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	540
SECONDARY WAVE LENGTH	600
READ TIME / INTERVAL	20
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW -0.1 HIGH 2.0
A LIMIT	LOW 0.0 HIGH 2.5
NORMAL LIMIT	LOW 40 HIGH 165
LINERITY LIMIT	1000
CURVE SD LIMIT	—

TEST	TRIG
Test BAR CODE	003/**
SAMPLE VOLUME (ul.)	3
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) 300
	BAR CODE **
	DILUENT VOLUME (ul.) 300
	LAG TIME (sec) GLASS
	BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.)
	BAR CODE
	DILUENT VOLUME (ul.)
	LAG TIME
	BOTTLE TYPE

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Siemens Express Plus/Express 550

Paramter	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

##### UREA - UV

PARAMETER	UREA
TEST	UREA
Test BAR CODE	008/**
TEST TYPE	TWOPONT
CURVE TYPE	BLANKED LINEAR
UNITS	IU/L
NO. OF DECIMALS	1
PRIMARY WAVELENGTH	340
SECONDARY WAVE LENGTH	380
READ TIME / INTERVAL	60
SAMPLE BLANK	NO
FACTOR	-
CALIBRATION INTERVAL	**
NORM. / REBLANK INTERVAL	**
NO. OF CALIBRATOR	2
NO. OF REPLICATES	2
BLANK A LIMIT	LOW HIGH
A LIMIT	LOW HIGH
NORMAL LIMIT	LOW HIGH
LINERITY LIMIT	300
CURVE SD LIMIT	—

TEST	UREA
Test BAR CODE	008/**
SAMPLE VOLUME (ul.)	3
RERUN DILUTION RATIO	
PRERUN DILUTION RATIO	
REAGENT DILUENT	
REAGENT 1	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME (sec) BOTTLE TYPE
REAGENT 2	REAGENT VOLUME (ul.) BAR CODE DILUENT VOLUME (ul.) LAG TIME BOTTLE TYPE

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

### **Siemens Express Plus/Express 550**

Paramater	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Legend of the symbols used on the labels:**

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#### **Applicative Parameters**

#### **URIC ACID**

PARAMETER		URIC ACID
TEST		URIC
Test BAR CODE		004/**
TEST TYPE		ENDPOINT
CURVE TYPE		BLANKED LINEAR
UNITS		mg/dl
NO. OF DECIMALS		2
PRIMARY WAVELENGTH		510
SECONDARY WAVE LENGTH		600
READ TIME / INTERVAL		20
SAMPLE BLANK		NO
FACTOR		-
CALIBRATION INTERVAL		**
NORM. / REBLANK INTERVAL		**
NO. OF CALIBRATOR		2
NO. OF REPLICATES		2
BLANK A LIMIT	LOW	-0.1
	HIGH	2.0
A LIMIT	LOW	0.0
	HIGH	2.5
NORMAL LIMIT	LOW	2.4
	HIGH	7.0
LINERITY LIMIT		25
CURVE SD LIMIT		—

TEST		URIC
Test BAR CODE		004/**
SAMPLE VOLUME (ul.)		6
RERUN DILUTION RATIO		
PRERUN DILUTION RATIO		
REAGENT DILUENT		
REAGENT 1	REAGENT VOLUME (ul.)	300
	BAR CODE	**
	DILUENT VOLUME (ul.)	
	LAG TIME (sec)	
	BOTTLE TYPE	GLASS
REAGENT 2	REAGENT VOLUME (ul.)	
	BAR CODE	
	DILUENT VOLUME (ul.)	
	LAG TIME	
	BOTTLE TYPE	



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## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

#### **Transasia - EM 200**

Parameter	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

##### **α- AMYLASE**

###### PROGRAMME SHEET FOR AMY ON EM-200

###### 1) TEST DETAILS

Test : AMY	Auto Rerun : Yes	
Report Name : AMY RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 405	Secondary :	Reagent R1 : AMY
Assay Type : Rate-A	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 3	M2 End : 7	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.62	
Technical Minimum : 0.0	Technical Maximum : 2000	
Y=aX+b	a= 1.0	

###### 2) TEST VOLUMES

Normal : 5.0 (micro)	Dilution Ratio : 1X
Increase : 10.0 (micro)	Dilution Ratio : 1X
Decrease : 5.0 (micro)	Dilution Ratio : 5X
Standard Volume : 5.0 (micro)	

###### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 200.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	20	140
Panic :	15	200

#### **Legend of the symbols used on the labels:**

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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### ALBUMIN

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : ALB	Auto Rerun : Yes	
Report Name : ALBUMIN RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 630	Secondary : 660	Reagent R1 : ALB
Assay Type : 1 - POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 3	M2 End : 5	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0	
Technical Minimum : 0.0	Technical Maximum : 6	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 3.0 (micro)	Dilution Ratio : 1X
Increase : 6.0 (micro)	Dilution Ratio : 1X
Decrease : 3.0 (micro)	Dilution Ratio : 5X
Standard Volume : 3.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	3.5	5.5
Panic :	2.5	5.5

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Alkaline Phosphatase

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
ALKALINE PHOSPHATE	15000505	4 x 10, 1 x 10
	15000506	4 x 20, 1 x 20
	15000507	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters ALKALINE PHOSPHATASE

##### PROGRAMME SHEET FOR AMY ON EM-200

###### 1) TEST DETAILS

Test : ALP	Auto Rerun : Yes	
Report Name : ALP RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 2
Wavelength Primary : 405	Secondary :	Reagent R1 : ALP
Assay Type : Rate-A	Curve Type : Linear	Reagent R2 : ALP
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.54	
Technical Minimum : 0.0	Technical Maximum : 1500	
Y=aX+b	a= 1.0	

###### 2) TEST VOLUMES

Normal : 6.0 (micro)	Dilution Ratio : 1X
Increase : 12.0 (micro)	Dilution Ratio : 1X
Decrease : 6.0 (micro)	Dilution Ratio : 5X
Standard Volume : 6.0 (micro)	

###### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	RGT-2 Volume : 60 micro	Stirrer Speed : High
PERFORMANCE RANGE	Lower	Upper
Normal :	110	810
Panic :	80	900

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4 X 25
	15000389	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters **CHOLESTEROL**

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : GLU	Auto Rerun : Yes	
Report Name : CHOL RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 505	Secondary : 660	Reagent R1 : CHOL
Assay Type : 1-POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0	
Technical Minimum : 0.0	Technical Maximum : 750	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 3.0 (micro)	Dilution Ratio : 1X
Increase : 6.0 (micro)	Dilution Ratio : 1X
Decrease : 3.0 (micro)	Dilution Ratio : 5X
Standard Volume : 3.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	0	200
Panic :	100	300

#### Legend of the symbols used on the labels:

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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
GLUCOSE	15000390	4 X 250
	15000391	1 X 1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### GLUCOSE

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : GLU	Auto Rerun : Yes	
Report Name : GLUCOSE RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 505	Secondary : 0	Reagent R1 : GLU
Assay Type : 1-POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0	
Technical Minimum : 0.0	Technical Maximum : 100	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 3.0 (micro)	Dilution Ratio : 1X
Increase : 6.0 (micro)	Dilution Ratio : 1X
Decrease : 3.0 (micro)	Dilution Ratio : 5X
Standard Volume : 3.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	70	110
Panic :	60	120

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



Manufactured by:  
**Avantor Performance Materials India Ltd.**  
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 Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
SGOT/AST	15000496	4 x 20, 1 x 20
	15000497	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGOT/AST

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : AST (GOT)	Auto Rerun : Yes	
Report Name : AST RFCL	Online Calibration :-	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 2
Wavelength Primary : 345	Secondary :	Reagent 1 : AST (GOT)
Assay Type : Rate-A	Curve Type : Linear	Reagent 1 : AST (GOT)
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 27	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Decreasing	React. Abs. Limit : 0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.20	
Technical Minimum : 0.0	Technical Maximum : 350	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 30.0 (micro)	Dilution Ratio : 1X
Increase : 30.0 (micro)	Dilution Ration : 1X
Decrease : 30.0 (micro)	Dilution Ration : 5X
Standard Volume : 30.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 240.0 (micro)	R1 Stirrer Speed : High	
RGT-2 Volume : 60.0 (micro)		
PERFORMANCE RANGE	Lower	Upper
Normal :	0	49
Panic :	10	200

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### SGPT/ALT

##### PROGRAMME SHEET FOR AMY ON EM-200

###### 1) TEST DETAILS

Test : ALT (GPT)	Auto Rerun : Yes	
Report Name : ALT RFCL	Online Calibration :-	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 2
Wavelength Primary : 340	Secondary :	Reagent R1 : ALT (GPT)
Assay Type : Rate-A	Curve Type : Linear	Reagent R1 : ALT (GPT)
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 27	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Decreasing	React. Abs. Limit : 0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.20	
Technical Minimum : 0.0	Technical Maximum : -350	
Y=aX+b	a= 1.0	

###### 2) TEST VOLUMES

Normal : 30.0 (micro)	Dilution Ratio : 1X
Increase : 30.0 (micro)	Dilution Ration : 1X
Decrease : 30.0 (micro)	Dilution Ration : 5X
Standard Volume : 30.0 (micro)	

###### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 240.0 (micro)	R1 Stirrer Speed : High	
RGT-2 Volume : 60.0 (micro)		
PERFORMANCE RANGE	Lower	Upper
Normal :	0	49
Panic :	10	200

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### **TOTAL PROTEIN**

##### PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : T PROTEIN	Auto Rerun : Yes
Report Name : T PROTEIN RFCL	Online Calibration :-
Unit : mg/dl	Decimal Planet : 1 Total Reagent : 1
Wavelength Primary : 546	Secondary : 660 Reagent R1 : T-Protein
Assay Type : 1-POINT	Curve Type : Linear
M1 Start : 0	M1 End : 0
M2 Start : 34	M2 End : 36
Sample Replicates : 1	Standard Replicates : 3
Control Replicates : 1	Control Interval : 0
Reaction Direction : Increasing	React. Abs. Limit : 0.0
Prozone Limit % : 0	Prozone Check : Lower
Linearity Limit : 0	Delta Abs/Min : 0
Technical Minimum : 0.0	Technical Maximum : 10
Y=aX+b	a= 1.0

##### 2) TEST VOLUMES

Normal : 6.0 (micro)	Dilution Ratio : 1X
Increase : 12.0 (micro)	Dilution Ration : 1X
Decrease : 6.0 (micro)	Dilution Ration : 5X
Standard Volume : 6.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High
PERFORMANCE RANGE	Lower      Upper
Normal :	6.0      8.5
Panic :	

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4 X 25
	15000393	4 X 50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### TRIGLYCERIDES

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : GLU	Auto Rerun : Yes	
Report Name : TRIG RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 556	Secondary : 660	Reagent R1 : TRIG
Assay Type : 1-POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0	
Technical Minimum : 0.0	Technical Maximum : 1000	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 3.0 (micro)	Dilution Ratio : 1X
Increase : 6.0 (micro)	Dilution Ration : 1X
Decrease : 3.0 (micro)	Dilution Ration : 5X
Standard Volume : 3.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	40	165
Panic :	30	200

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Transasia - EM 200

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4x10,1x10
	15000503	4x20,1x20
	15000504	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

#### UREA-UV

PROGRAMME SHEET FOR AMY ON EM-200

##### 1) TEST DETAILS

Test : UREA	Auto Rerun : Yes	
Report Name : UREA RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 340	Secondary :	Reagent R1 : AMY
Assay Type : Rate-A	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Decreasing	React. Abs. Limit : 0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.20	
Technical Minimum : 0.0	Technical Maximum : 350	
Y=aX+b	a= 1.0	

##### 2) TEST VOLUMES

Normal : 30.0 (micro)	Dilution Ratio : 1X
Increase : 30.0 (micro)	Dilution Ratio : 1X
Decrease : 30.0 (micro)	Dilution Ratio : 5X
Standard Volume : 30.0 (micro)	

##### 3) REAGENT VOLUME & STIRRER SPEED

RGT-1 Volume : 240.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	15	45
Panic :	10	100

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Transasia - EM 200**

Parameter	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4 X 25
	15000395	4 X 50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

#### **URIC ACID**

PROGRAMME SHEET FOR AMY ON EM-200

##### **1) TEST DETAILS**

Test : UA	Auto Rerun : Yes	
Report Name : URIC AC RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 505	Secondary : 660	Reagent R1 : UA
Assay Type : 1-POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.62	
Technical Minimum : 0.0	Technical Maximum : 25	
Y=aX+b	a= 1.0	

##### **2) TEST VOLUMES**

Normal : 6.0 (micro)	Dilution Ratio : 1X
Increase : 12.0 (micro)	Dilution Ratio : 1X
Decrease : 6.0 (micro)	Dilution Ratio : 5X
Standard Volume : 6.0 (micro)	

##### **3) REAGENT VOLUME & STIRRER SPEED**

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	2.4	7.0
Panic :	2.0	7.5

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
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- I Storage temperature
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Transasia - EM 200**

Parameter	Part Number	Pack Size (mL)
<b>URIC ACID</b>	15000394	4 X 25
	15000395	4 X 50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

#### **URIC ACID**

PROGRAMME SHEET FOR AMY ON EM-200

##### **1) TEST DETAILS**

Test : UA	Auto Rerun : Yes	
Report Name : URIC AC RFCL	Online Calibration : --	
Unit : mg/dl	Decimal Planet : 1	Total Reagent : 1
Wavelength Primary : 505	Secondary : 660	Reagent R1 : UA
Assay Type : 1-POINT	Curve Type : Linear	
M1 Start : 0	M1 End : 0	
M2 Start : 17	M2 End : 19	
Sample Replicates : 1	Standard Replicates : 3	
Control Replicates : 1	Control Interval : 0	
Reaction Direction : Increasing	React. Abs. Limit : 0.0	
Prozone Limit % : 0	Prozone Check : Lower	
Linearity Limit : 0	Delta Abs/Min : 0.62	
Technical Minimum : 0.0	Technical Maximum : 25	
Y=aX+b	a= 1.0	

##### **2) TEST VOLUMES**

Normal : 6.0 (micro)	Dilution Ratio : 1X
Increase : 12.0 (micro)	Dilution Ratio : 1X
Decrease : 6.0 (micro)	Dilution Ratio : 5X
Standard Volume : 6.0 (micro)	

##### **3) REAGENT VOLUME & STIRRER SPEED**

RGT-1 Volume : 300.0 (micro)	R1 Stirrer Speed : High	
PERFORMANCE RANGE	Lower	Upper
Normal :	2.4	7.0
Panic :	2.0	7.5

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
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## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Paramater	Part Number	Pack Size (mL)
<b>CHOLESTEROL TOTAL</b>	15000388	4X25
	15000389	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	32	Test	CHOR
Assay Type	1 POINT		
Wave Length	Primary 505	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 3	PostDil 0	Diluent 0
S Vol. Decr	50	3	150
S Vol. Incr	6	0	0
Standard Vol	3	0	0
React. Abs Lim	0		
React. Dir.	Decr		
Prozone Limit	0	Upper	
Unit	mg/dl	Decimal Point	0
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values			
		Male	Female
		Min 65	Max 200
		0	0
		0	0
		Min	0
		Max.	

## Applicative Parameters

Report Name	Cholesterol AMP			
Assay Points	M1Start	M1End	M2Start	M2End
	0	0	30	32
Con. Interval	0	Samp Repl.	0	
R1	Vol.	Pos	Size	Multiple Positions
	0	0	30	
R2	0	0	30	Reagent Stability
		Min.	Max.	
Reagent ABS		0	0.3	
Tech. Serum Limits		0	350	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	200	
Auto Rerun		Yes		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### **Transasia-ERBA EM 360/XL 300**

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	03	Test	GLUR
Assay Type	1 POINT		
Wave Length	Primary 505	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 3	PostDil 0	Diluent 0
S Vol. Decr	50	3	150
S Vol. Incr	6	0	0
Standard Vol	3	0	0
React. Abs Lim	0		
React. Dir.	Incr		
Prozone Limit	0	Upper	
Unit	mg/dl	Decimal Point	0
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values			
		Male	Female
		Min 70	Max 110
		0	0
		0	0
		Min	0
		Max.	

## Applicative Parameters

Report Name	GLU AMP			
Assay Points	M1Start 0	M1End 0	M2Start 48	M2End 51
Con. Interval	0	Samp Repl.	1	
R1	Vol. 300	Pos. 43	Size L	Multiple Positions
R2	0	0		Reagent Stability
		Min.	Max.	
Reagent ABS		0	0.3	
Tech. Serum Limits		0	500	
Tech. Urine Limits		0	0	
Serum Panic Limits		30	250	
Auto Rerun		Yes		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Paramater	Part Number	Pack Size (mL)
SGOT/AST	15000496	4x20,1x20
	15000497	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	44	Test	RGOT
Assay Type	RATE-A		
Wave Length	Primary 340	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 25	PostDil 0	Diluent 0
S Vol. Decr	Sample 20	PostDil 20	Diluent 180
S Vol. Incr	Sample 25	PostDil 0	Diluent 0
Standard Vol	Sample 25	PostDil 0	Diluent 0
React. Abs Lim	0		
React. Dir.	Decr		
Prozone Limit	0	Upper	
Unit	IU/L	Decimal Point	0
Normal Values	Age	Male	Female
Serum	Default	Min 0	Max 0
Serum	11 Month	Min 0	Max 0
Serum	29 Days	Min 0	Max 0
Urine Values		Min 0	Max. 0

## Applicative Parameters

Report Name	SGOT RFCL			
Assay Points	M1Start	M1End	M2Start	M2End
	0	0	21	30
Con. Interval	0	Samp Repl.	1	
R1	Vol.	Pos	Size	Multiple Positions
	200	1	L	
R2	50	2	S	Reagent Stability
		Min.	Max.	
Reagent ABS		0.8	2.5	
Tech. Serum Limits		0	0.2	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		Yes		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size



Manufactured by:  
**Avantor Performance Materials India Ltd.**  
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**Branch Office, EUROPE**  
**Avantor Performance Materials, B.V.**  
 Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4x20, 1x20
	15000499	4x40, 1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	45	Test	RGPT
Assay Type	RATE-A		
Wave Length	Primary 340	Secondary 0	
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 25	PostDil 0	Diluent 0
S Vol. Decr	Sample 20	PostDil 20	Diluent 180
S Vol. Incr	Sample 25	PostDil 0	Diluent 0
Standard Vol	Sample 25	PostDil 0	Diluent 0
React. Abs Lim	0		
React. Dir.	Decr		
Prozone Limit	0	Upper	
Unit	IU/L	Decimal Point	0
Normal Values	Age	Male	Female
Serum	Default	Min 0	Max 0
Serum	11 Month	Min 0	Max 0
Serum	29 Days	Min 0	Max 0
Urine Values		Min 0	Max 0

## Applicative Parameters

Report Name	SGPT RFCL			
Assay Points	M1Start	M1End	M2Start	M2End
	0	0	21	30
Con. Interval	0	Samp Repl.	1	
R1	Vol. 200	Pos. 2	Size S	Multiple Positions
R2	50	3	S	Reagent Stability
		Min.	Max.	
Reagent ABS		0.8	2.5	
Tech. Serum Limits		0	0.2	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		NO		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
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- I Storage temperature
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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### **Transasia-ERBA EM 360/XL 300**

Paramater	Part Number	Pack Size (mL)
<b>TOTAL PROTEIN</b>	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	21	Test	PROR
Assay Type	1 POINT		
Wave Length	Primary 546	Secondary 0	
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 4	PostDil 0	Diluent 0
S Vol. Decr	50	4	150
S Vol. Incr	8	0	0
Standard Vol	4	0	0
React. Abs Lim	0		
React. Dir.	Incr		
Prozone Limit	0	Upper	
Unit	g/dl	Decimal Point	2
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values	Min	0	Max.

## Applicative Parameters

Report Name	Tot.Pro.RFCL			
Assay Points	M1Start 0	M1End 0	M2Start 48	M2End 51
Con. Interval	0	Samp Repl.	1	
R1	Vol. 200	Pos. 10	Size T	Multiple Positions
R2	0	0		Reagent Stability
		Min.	Max.	
Reagent ABS		0	0.4	
Tech. Serum Limits		0	10	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		Yes		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Paramater	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	30	Test	TRIR
Assay Type	1 POINT		
Wave Length	Primary 546	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 3	PostDil 0	Diluent 0
S Vol. Decr	50	3	150
S Vol. Incr	6	0	0
Standard Vol	3	0	0
React. Abs Lim	0		
React. Dir.	Incr		
Prozone Limit	0	Upper	
Unit	mg/dl	Decimal Point	0
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values			
		Male	Female
		Min 35	Max 165
		0	0
		0	0
		Min	0
		Max.	

## Applicative Parameters

Report Name	TG RFCL			
Assay Points	M1Start	M1End	M2Start	M2End
	0	0	30	32
Con. Interval	0	Samp Repl.	1	
R1	Vol.	Pos	Size	Multiple Positions
	300	34	T	
R2	0	0		Reagent Stability
		Min.	Max.	
Reagent ABS		0	0	
Tech. Serum Limits		40	1000	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	200	
Auto Rerun		Yes		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

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- C Batch code
- B Catalogue number
- I Storage temperature
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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Paramater	Part Number	Pack Size (mL)
UREA UV	15000502	4x10,1x10
	15000503	4x20,1x20
	15000504	4x40,1x40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	47	Test	RURE
Assay Type	1 POINT		
Wave Length	Primary 340	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 3	PostDil 0	Diluent 0
S Vol. Decr	20	3	180
S Vol. Incr	4	0	0
Standard Vol	3	0	0
React. Abs Lim	0		
React. Dir.	Decr		
Prozone Limit	0	Upper	
Unit	IU/L	Decimal Point	0
Normal Values	Age	Male	
Serum	Default	Min	Max
Serum	11 Month	0	0
Serum	29 Days	0	0
Urine Values	Min	0	Max. 0

## Applicative Parameters

Report Name	UREA RFCL			
Assay Points	M1Start 0	M1End 0	M2Start 19	M2End 25
Con. Interval	0	Samp Repl.	1	
R1	Vol. 240	Pos. 5	Size L	Multiple Positions
R2	60	6	S	Reagent Stability
		Min.	Max.	
Reagent ABS		0	0	
Tech. Serum Limits		0	0.2	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		NO		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

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- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
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## APPLICATION INSERTS

### **Uric Acid**

For use on the automatic analyzer

#### **Transasia-ERBA EM 360/XL 300**

Paramater	Part Number	Pack Size (mL)
URIC ACID	15000394	4X25
	15000395	4X50

#### **Reagent preparation and stability**

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters**

Test Code	33	Test	UACR
Assay Type	1 POINT		
Wave Length	Primary 505	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 6	PostDil 0	Diluent 0
S Vol. Decr	Sample 50	PostDil 6	Diluent 150
S Vol. Incr	Sample 12	PostDil 0	Diluent 0
Standard Vol	Sample 6	PostDil 0	Diluent 0
React. Abs Lim	0		
React. Dir.	Incr		
Prozone Limit	0	Upper	
Unit	mg/dl	Decimal Point	2
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values	Min	0	Max.

## Applicative Parameters

Report Name	Uric Acid A M P			
Assay Points	M1Start 0	M1End 0	M2Start 30	M2End 32
Con. Interval	0	Samp Repl.	1	
R1	Vol. 300	Pos. 36	Size T	Multiple Positions
R2	0	0		Reagent Stability
		Min.	Max.	
Reagent ABS		0	0.3	
Tech. Serum Limits		0	25	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		NO		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
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## APPLICATION INSERTS

### CK-NAK

For use on the automatic analyzer

#### Transasia-ERBA EM 360/XL 300

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C. : 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters

Test Code	12	Test	CK-N
Assay Type	Rate A		
Wave Length	Primary 340	Secondary	0
Serum Volume		Urine Volumes	
S Vol. Normal	Sample 3	PostDil 0	Diluent 0
S Vol. Decr	50	3	150
S Vol. Incr	6	0	0
Standard Vol	3	0	0
React. Abs Lim	0		
React. Dir.	Decr		
Prozone Limit	0	Upper	
Unit	mg/dl	Decimal Point	0
Normal Values	Age		
Serum	Default		
Serum	11 Month		
Serum	29 Days		
Urine Values			
		Male	Female
		Min 65	Max 200
		0	0
		0	0
		Min	0
		Max.	

## Applicative Parameters

Report Name	Uric Acid A M P			
Assay Points	M1Start	M1End	M2Start	M2End
	0	0	30	32
Con. Interval	0	Samp Repl.	1	
R1	Vol.	Pos	Size	Multiple Positions
	300	36	T	
R2	0	0		Reagent Stability
		Min.	Max.	
Reagent ABS		0	0.3	
Tech. Serum Limits		0	25	
Tech. Urine Limits		0	0	
Serum Panic Limits		0	0	
Auto Rerun		NO		
Y=ax+b		a= 1	b= 0	

### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
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- C Batch code
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## APPLICATION INSERTS

### Albumin

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Paramater	Part Number	Pack Size (mL)
ALBUMIN	15000000	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters ALBUMIN

PARAMETER	ENZO L ALBUMIN
MONO MODE PARAMETERS	
TEST NAME	ALBUMIN
ABBREVIATED NAME	ALBU
MODE	END POINT MONOCHROMATIC
WAVELENGTH	620
UNITS	G/DL
DECIMALS	2
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	6
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	3
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	4.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

UD - User Defined



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## APPLICATION INSERTS

### **α-Amylase**

For use on the automatic analyzer

#### **Vital Scientific/Flexor XL**

Paramater	Part Number	Pack Size (mL)
AMYLASE	15000387	1X10
	15000386	2X30

#### **Reagent preparation and stability**

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### **Applicative Parameters α- AMYLASE**

PARAMETER	ENZO L AMYLASE
MONO MODE PARAMETERS	
TEST NAME	AMYLASE
ABBREVIATED NAME	AMYL
MODE	KINETIC
WAVELENGTH	450
UNITS	U/L
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	2000
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### **Legend of the symbols used on the labels:**

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	8
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	77
MIN. TIME (SEC)	132
LINEARITY LIMIT (%)	15
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	3.000

UD - User Defined



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 Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### Cholesterol

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
CHOLESTEROL TOTAL	15000388	4X25
	15000389	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters CHOLESTEROL

PARAMETER	ENZO L CHOLESTEROL
MONO MODE PARAMETERS	
TEST NAME	CHOLESTEROL
ABBREVIATED NAME	CHOL
MODE	END POINT MONOCHROMATIC
WAVELENGTH	505
UNITS	mG/DL
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	500
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	3
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	4.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

UD - User Defined



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## APPLICATION INSERTS

### CK-NAC

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
CK-NAC	15000588	50 ml
	15000589	100 ml

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters CK-NAC

PARAMETER	ENZO L CK-NAC
MONO MODE PARAMETERS	
TEST NAME	CK-NAC
ABBREVIATED NAME	CK
MODE	KINETIC
WAVELENGTH	340
UNITS	IU/L
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	1000
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### Legend of the symbols used on the labels:

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- C Batch code
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- I Storage temperature
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- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicative Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	240
RERUN (ul.)	240
SAMPLE (ul.)	12
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	60
NORMAL (ul.)	60
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	132
MIN. TIME (SEC)	132
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	3.000

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## APPLICATION INSERTS

### Creatinine

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Paramater	Part Number	Pack Size (mL)
CREATININE	15000004	4x50
	15000005	4x100

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters **CREATININE**

PARAMETER	ENZO L CREATININE
MONO MODE PARAMETERS	
TEST NAME	CREATININE
ABBREVIATED NAME	CRTN
MODE	TWO POINT
WAVELENGTH	505
UNITS	Mg/DL
DECIMALS	2
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	25
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

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- C Batch code
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- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	30
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	24
POINT 2 ( TWO POINT ) (SEC)	102
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	3.000
Rabs. Deviation	

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## APPLICATION INSERTS

### Glucose

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Paramater	Part Number	Pack Size (mL)
GLUCOSE	15000390	4X250
	15000391	1X1000

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

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- C Batch code
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- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters GLUCOSE

PARAMETER	ENZO L GLUCOSE
MONO MODE PARAMETERS	
TEST NAME	GLUCOSE
ABBREVIATED NAME	GLUC
MODE	END POINT MONOCHROMATIC
WAVELENGTH	505
UNITS	mG/DL
DECIMALS	2
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	700
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	3
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	11.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

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## APPLICATION INSERTS

### SGOT/AST

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
SGOT/AST	15000496	4 x 20, 1 x 20
	15000497	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters SGOT/AST

PARAMETER	ENZO L SGOT
MONO MODE PARAMETERS	
TEST NAME	SGOT
ABBREVIATED NAME	SGOT
MODE	KINETIC
WAVELENGTH	340
UNITS	U/L
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	350
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

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- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	30
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	77
MIN. TIME (SEC)	132
LINEARITY LIMIT (%)	15
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	0.100

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## APPLICATION INSERTS

### SGPT/ALT

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Paramater	Part Number	Pack Size (mL)
SGPT/ALT	15000498	4 x 20, 1 x 20
	15000499	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters SGPT/AST

PARAMETER	ENZO L SGPT
MONO MODE PARAMETERS	
TEST NAME	SGPT
ABBREVIATED NAME	SGPT
MODE	KINETIC
WAVELENGTH	340
UNITS	U/L
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	350
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

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- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	30
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	77
MIN. TIME (SEC)	132
LINEARITY LIMIT (%)	15
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	0.100

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## APPLICATION INSERTS

### Total Protein

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
TOTAL PROTEIN	15000011	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters TOTAL PROTEIN

PARAMETER	ENZO L TOTAL PROTEIN
MONO MODE PARAMETERS	
TEST NAME	TOTAL PROTEIN
ABBREVIATED NAME	TPRO
MODE	END POINT MONOCHROMATIC
WAVELENGTH	546
UNITS	G/DL
DECIMALS	2
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	10
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	6
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	11.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

UD - User Defined



Manufactured by:  
**Avantor Performance Materials India Ltd.**  
 Plot No.-37, Pharma City,  
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**Branch Office, EUROPE**  
**Avantor Performance Materials, B.V.**  
 Teugseweg 20, 7418 AM Deventer. P.O. Box 1,  
 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### Triglycerides

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
TRIGLYCERIDES	15000392	4X25
	15000393	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters TRIGLYCERIDES

PARAMETER	ENZO L TRIGYCERIDES
MONO MODE PARAMETERS	
TEST NAME	TRIGYCERIDES
ABBREVIATED NAME	TRIG
MODE	END POINT MONOCHROMATIC
WAVELENGTH	546
UNITS	mG/DL
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	1000
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	3
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	4.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

UD - User Defined



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## APPLICATION INSERTS

### Urea-UV

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
UREA UV	15000502	4 x 10, 1 x 10
	15000503	4 x 20, 1 x 20
	15000504	4 x 40, 1 x 40

#### Reagent preparation and stability

Ready to use liquid reagents.

Stable up to expiry date stated on the label.

Stability of open vial on board of the analyzer at 2-12°C.: 1 month

Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Applicative Parameters UREA - UV

PARAMETER	ENZO L UREA
MONO MODE PARAMETERS	
TEST NAME	UREA
ABBREVIATED NAME	UREA
MODE	TWO POINT
WAVELENGTH	340
UNITS	mG/DL
DECIMALS	1
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	300
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	3
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	
POINT 1 ( TWO POINT ) (SEC)	24
POINT 2 ( TWO POINT ) (SEC)	77
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	0.100

UD - User Defined



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 7400 AA Deventer. The Netherlands.

## APPLICATION INSERTS

### Uric Acid

For use on the automatic analyzer

#### Vital Scientific/Flexor XL

Parameter	Part Number	Pack Size (mL)
URIC ACID	15000394	4X25
	15000395	4X50

#### Reagent preparation and stability

Ready to use liquid reagents.  
 Stable up to expiry date stated on the label.  
 Stability of open vial on board of the analyzer at 2-12°C.: 1 month

#### Note:

It is recommended that each laboratory confirm the validity of the application parameters through its Quality Control procedures.

For further information regarding the product refer to the package insert PN

#### Legend of the symbols used on the labels:

- H CE Mark (requirement of 98/79/CE regulation)
- F For in vitro diagnostic use
- C Batch code
- B Catalogue number
- I Storage temperature
- K Expiry date (year-month)
- J Consult accompanying documents
- L consult operating instructions
- A Bio-hazard
- Manufacturer
- Σ Size

#### Applicative Parameters URIC ACID

PARAMETER	ENZO L URIC ACID
MONO MODE PARAMETERS	
TEST NAME	URIC ACID
ABBREVIATED NAME	URIC
MODE	END POINT MONOCHROMATIC
WAVELENGTH	505
UNITS	mG/DL
DECIMALS	2
REPEATS	1
LOW CONCENTRATION	0
HIGH CONCENTRATION	25
CALIBRATOR NAME	UD
NUMBER OF STANDARDS	1
CALIBRATION ACCEPTED	YES
NUMBER OF POINTS	1
REPEATS	1
INTERVAL	UD
AUTO ACCEPT CALIBRATION	NO
LAST MEASURED	
AUTO PREDILUTION	NO
CUT OFF	NO
STANDARD	
PREDILUTION	NONE
CONCENTRATION	
ABSORBANCE	
ABSORBANCE - LOW LIMIT	0.0000
ABSORBANCE - HIGH LIMIT	0.0000
DUP-DIFF.	0.0000
PROZONE CHECK	NONE
REF. MALE LOW	UD
REF. MALE HIGH	UD
REF. FEMALE LOW	UD
REF. FEMALE HIGH	UD
REF. PED. LOW	UD
REF. PED. HIGH	UD
REF. PANIC LOW	UD
REF. PANIC HIGH	UD
CONTROL 1	UD
TARGET	UD
STANDARD DEVIATION	UD

## Applicable Parameters

LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 2	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	UD
CONTROL 3	UD
TARGET	UD
STANDARD DEVIATION	UD
LOW LIMIT	UD
HIGH LIMIT	UD
WESTGARD	YES
CORRELATION FACTOR	1.000
CORRELATION OFFSET	0
DUAL MODE PARAMETERS	
SAMPLE BLANK	NO
REAGENT BLANK	YES
BUFFER REAGENT (ul.)	NO
REAGENT 1 (ul.)	
NORMAL (ul.)	300
RERUN (ul.)	300
SAMPLE (ul.)	7
NORMAL (ul.)	3
RERUN (ul.)	
REAGENT 2 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
REAGENT 3 (ul.)	
NORMAL (ul.)	
RERUN (ul.)	
PRE DILUTION	NO
SLOPE BLANK	NO
INCUBATION TIME (Min)	4.5
POINT 1 ( TWO POINT ) (SEC)	
POINT 2 ( TWO POINT ) (SEC)	
DEALY ( SEC )	
MIN. TIME (SEC)	
LINEARITY LIMIT (%)	
FACTOR	
REAGENT BLANK	0.000
LOW ABSORBANCE	-0.100
HIGH ABSORBANCE	3.000
Rabs. L. limit	-0.100
Rabs. H. limit	3.000
SUBSTRATE DEPLETION	
Rabs. Deviation	

UD - User Defined



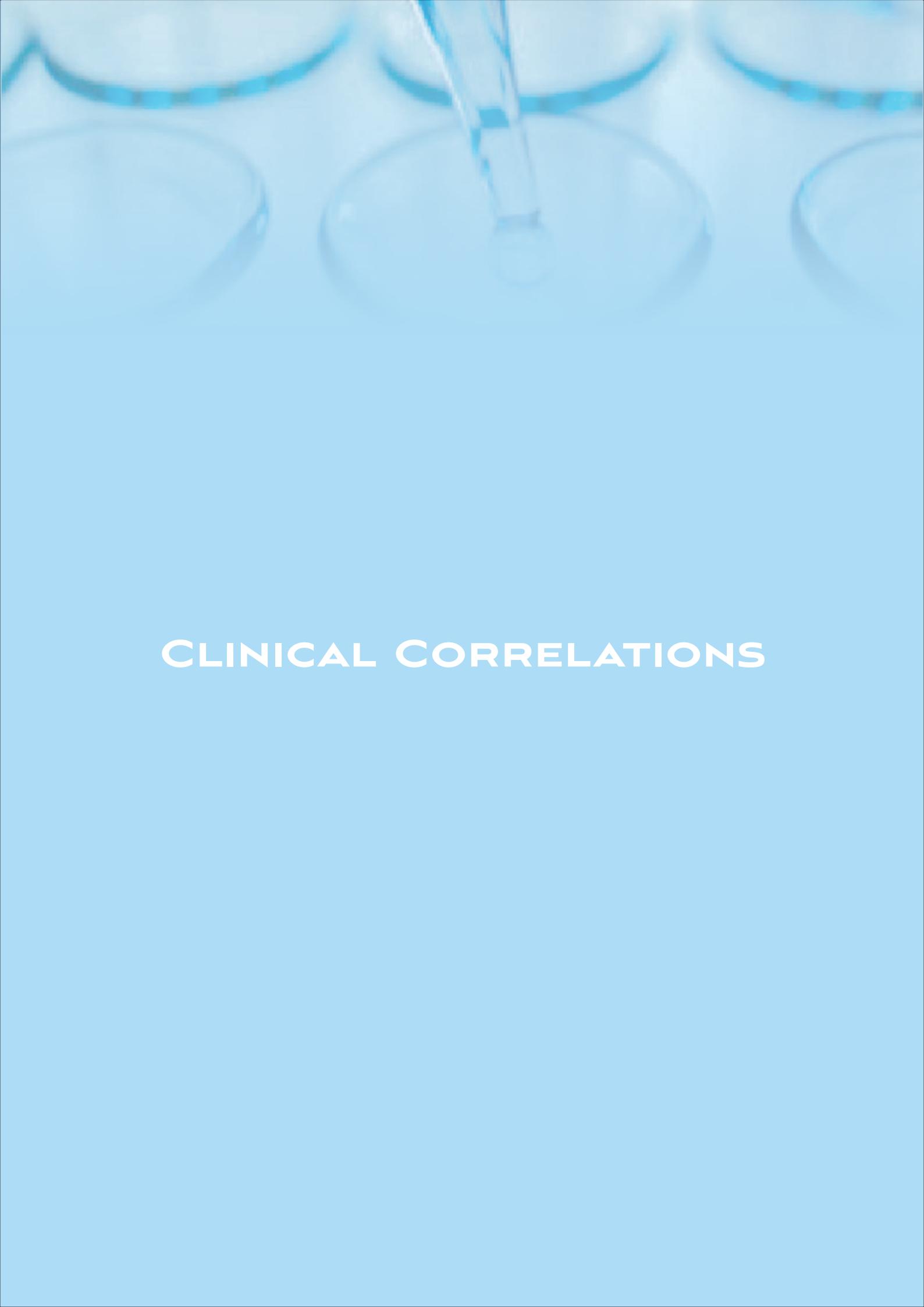
Manufactured by:  
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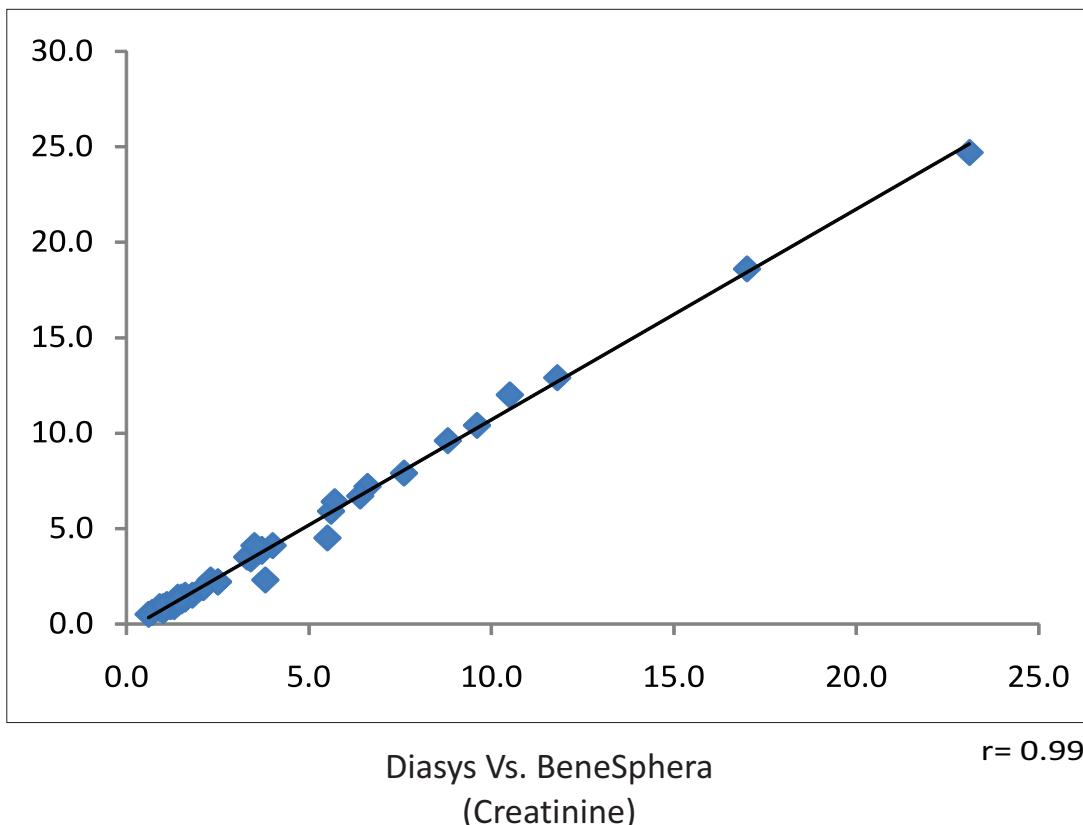
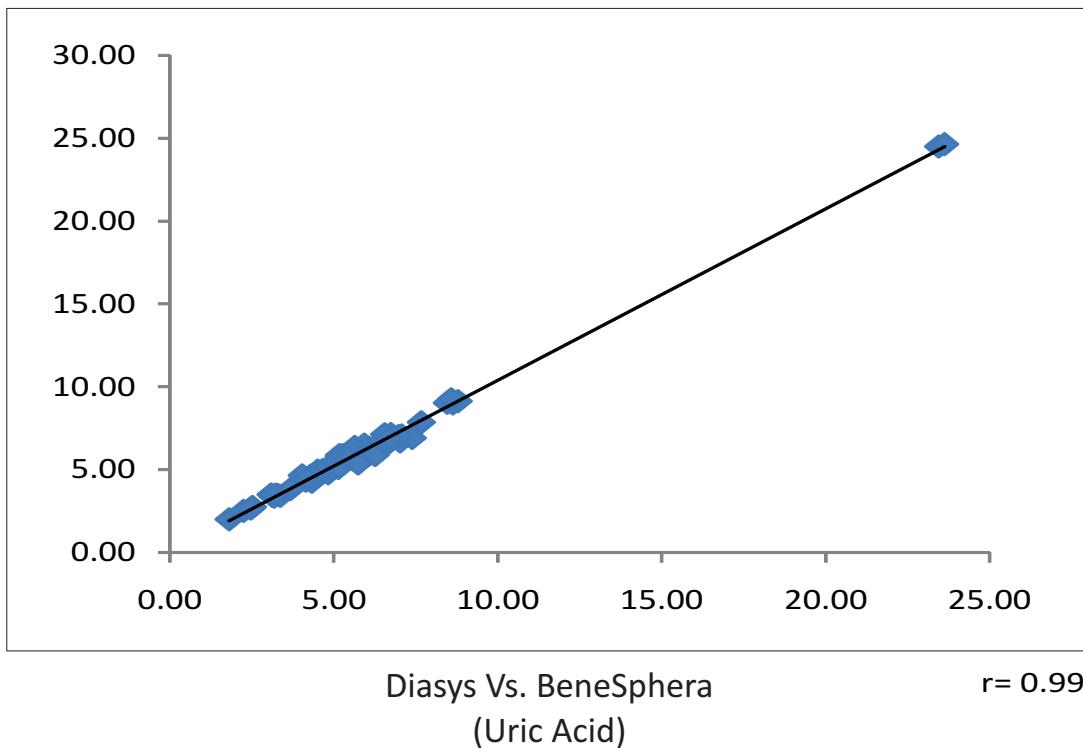


## **CLINICAL CORRELATIONS**



## Clinical Correlation

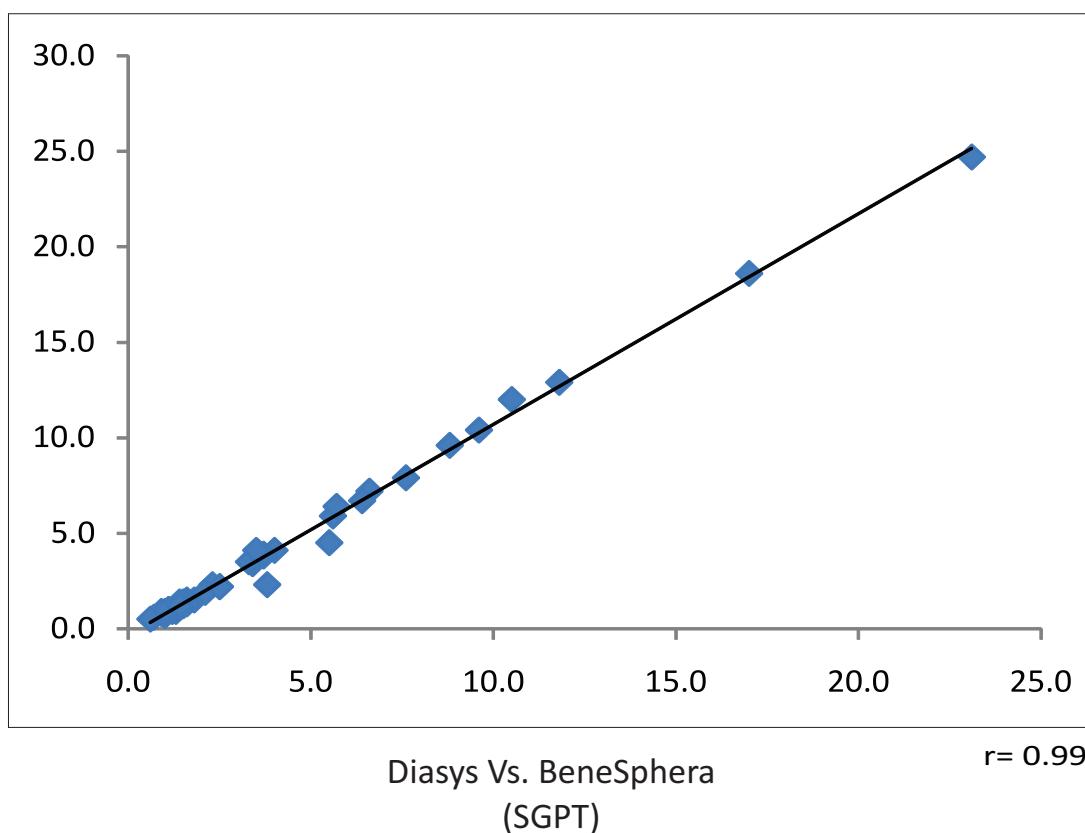
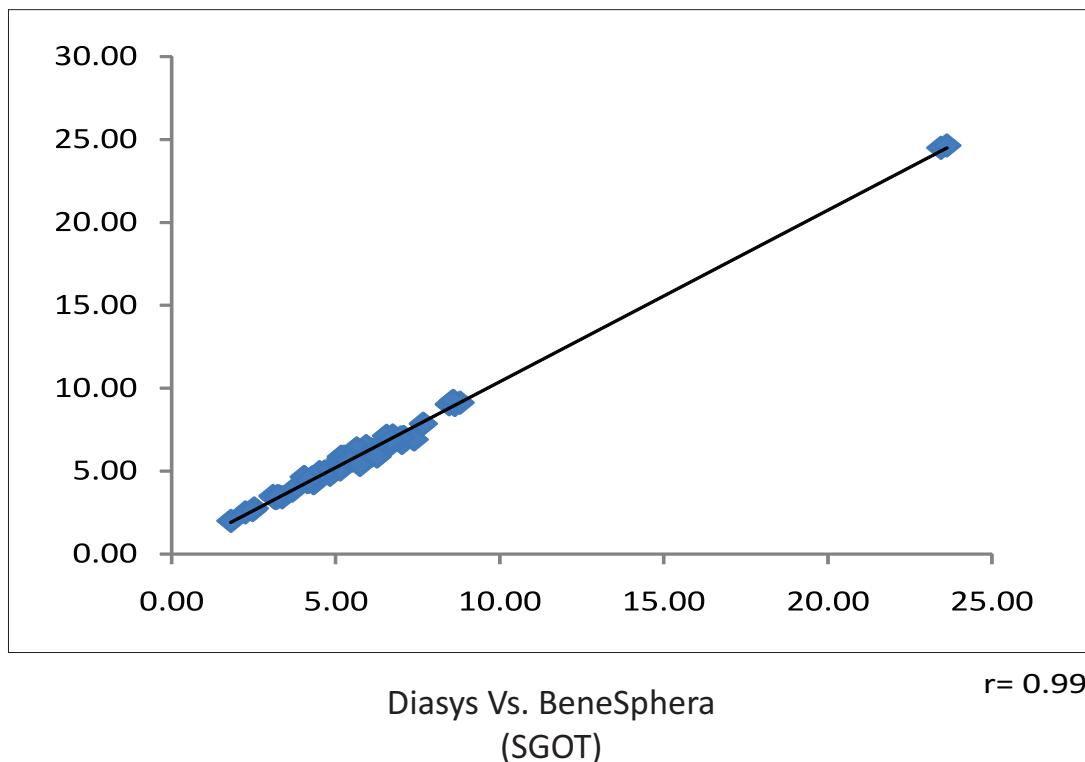
### Diasys Vs. BeneSphera™



Note: Data available in company records

## Clinical Correlation

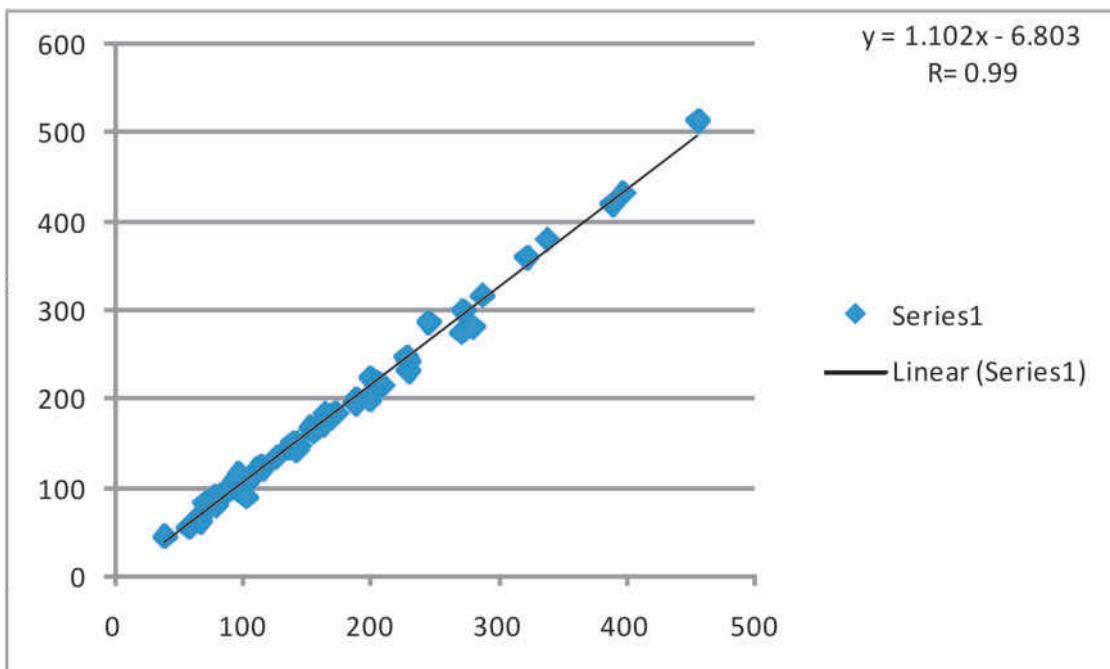
### Diasys Vs. BeneSphera



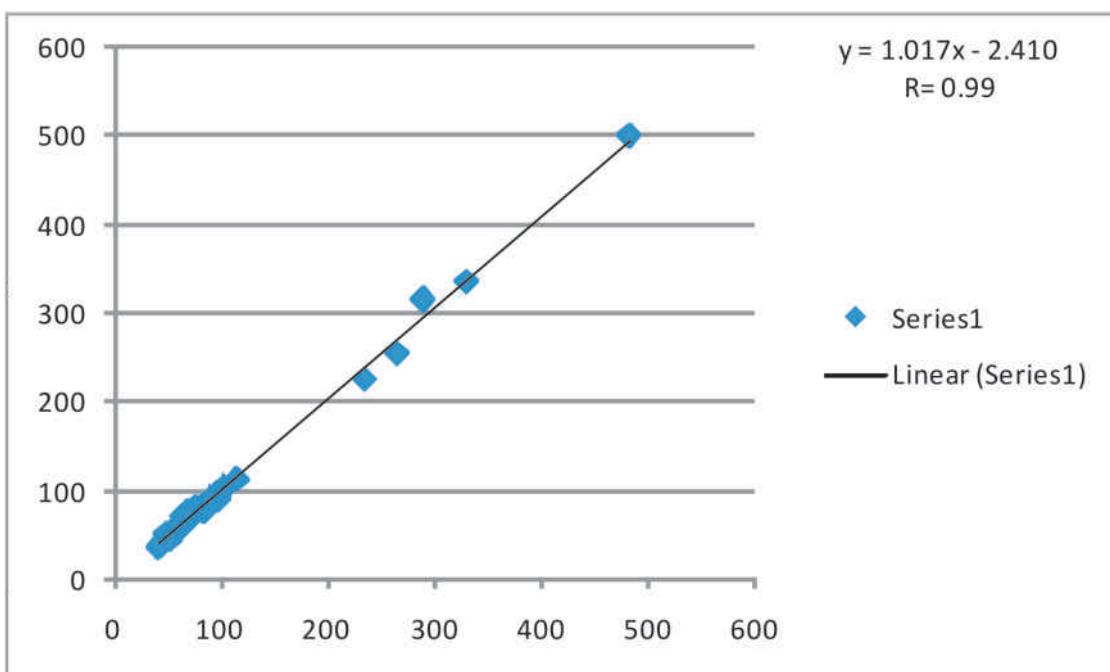
Note: Data available in company records

## Clinical Correlation

### Diasys Vs. BeneSphera



Diasys Vs. BeneSphera  
(Triglyceride)

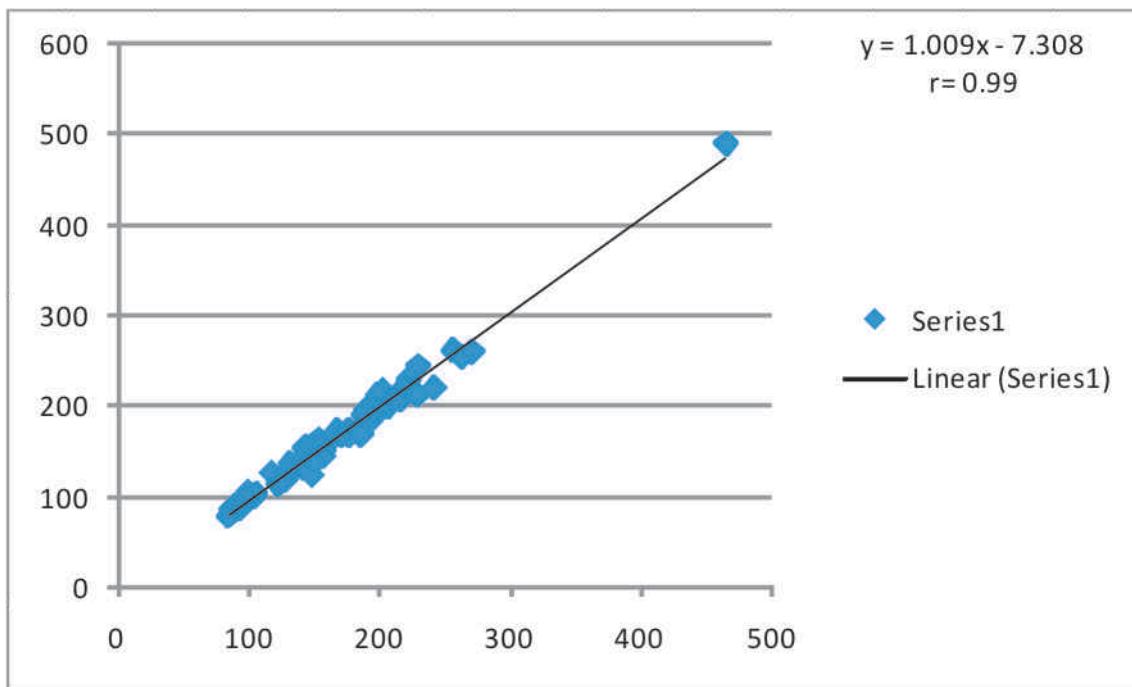


Diasys Vs. BeneSphera  
(Glucose)

Note: Data available in company records

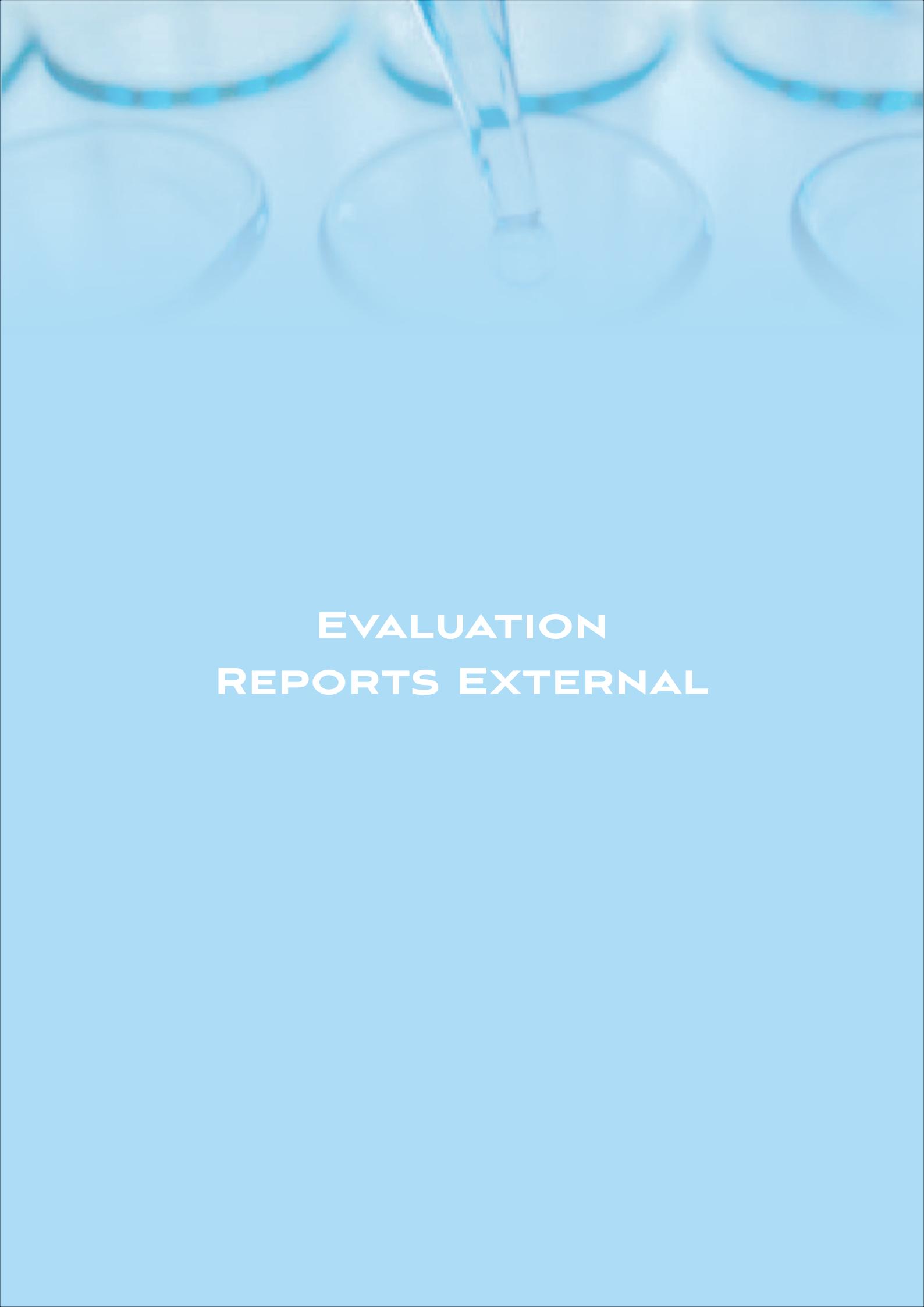
## Clinical Correlation

### Diasys Vs. BeneSphera



Diasys Vs. BeneSphera  
(Cholesterol)

Note: Data available in company records



# **EVALUATION REPORTS EXTERNAL**

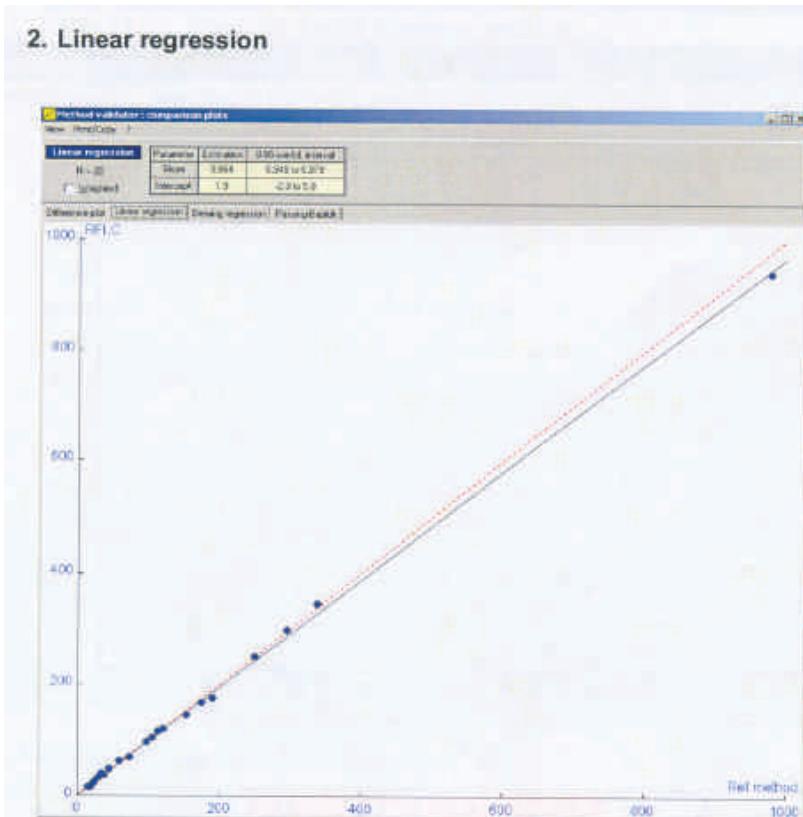


## Evaluation Report : External

### SGPT

ref meth	RFLC
15	15
19	15
24	24
30	32
34	39
38	36
45	47
60	61
74	69
98	95
106	104
115	115
122	119
154	144
175	166
191	174
250	250
295	297
338	345
980	940

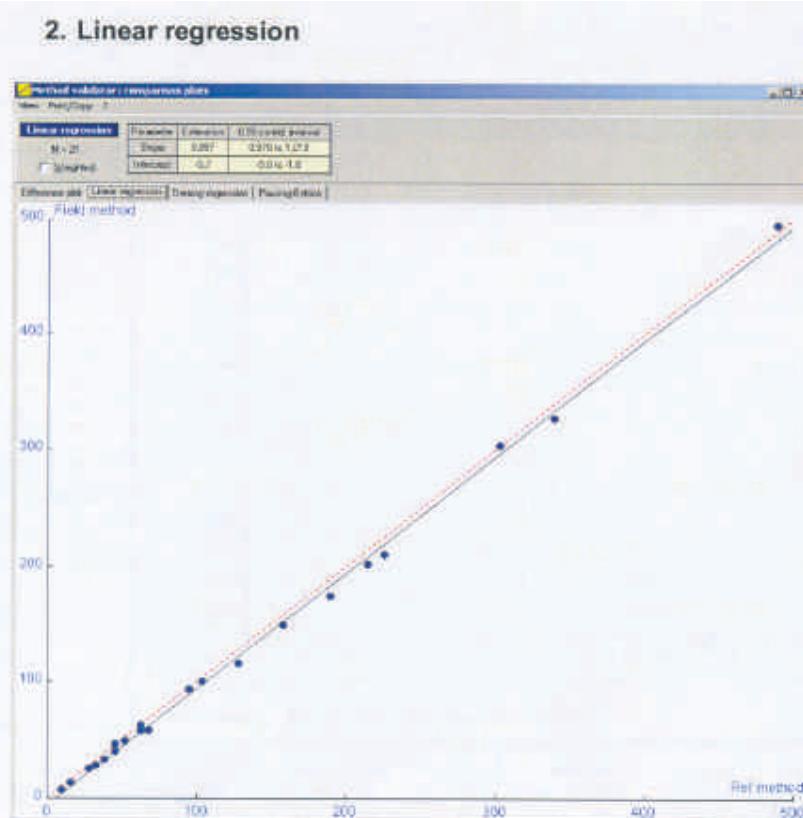
**Korrelation:** 0,9995  
**Slope:** 0,964  
**Intercept:** 1,9  
**Min:** 15 15  
**Max:** 980 940  
**Median:** 102 99,5  
**Linearity:** 170



### SGOT

ref meth	new meth
10	7
16	13
28	25
33	28
39	33
46	40
46	46
52	49
63	57
63	62
68	58
95	93
104	100
128	115
158	149
190	174
215	202
226	210
304	304
340	327
490	495

**Korrelation:** 0,9990  
**Slope:** 0,997  
**Intercept:** -5,7  
**Min:** 10 7  
**Max:** 490 495  
**Median:** 68 62  
**Linearity:** 200

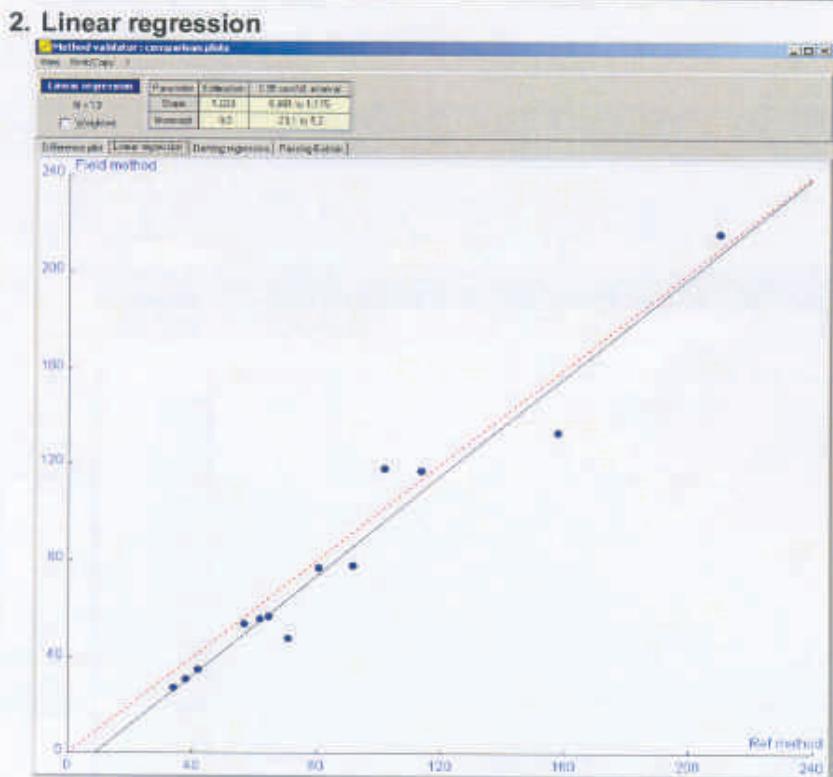


## Evaluation Report : External

### Amylase

Results	
ref meth	RFLC
34	27
38	31
42	35
57	54
62	56
65	57
71	48
81	77
92	78
102	118
114	117
158	133
210	216

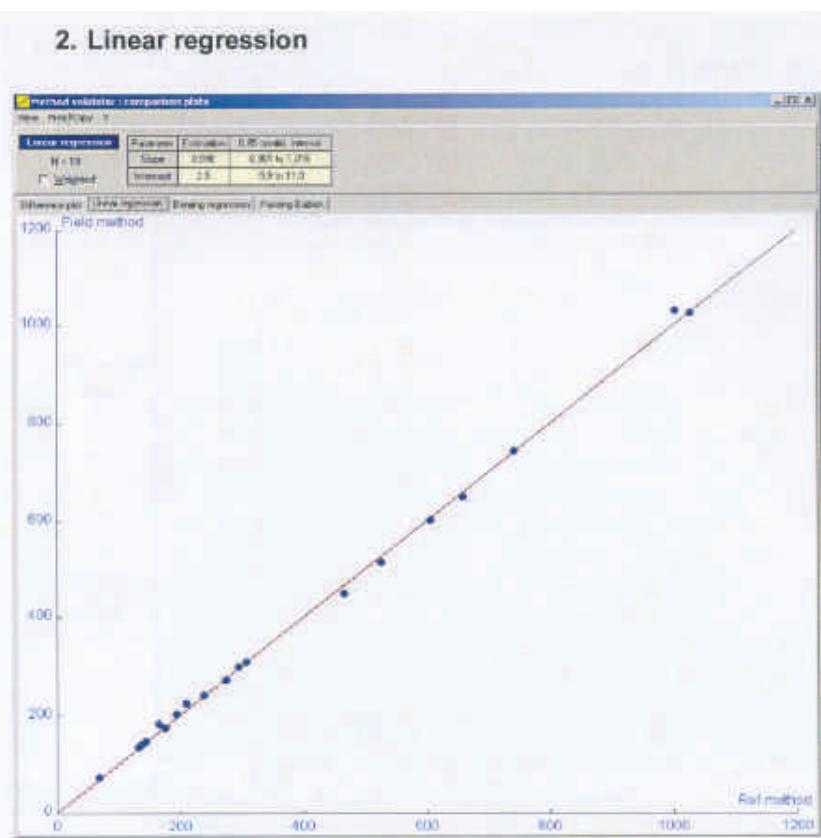
**Korrelation:** 0,9792  
**Slope:** 1,033  
**Intercept:** -9,0  
**Min:** 34      **27**  
**Max:** 210     **216**  
**Median:** 71     **57**  
**Linearity:** ~2300



### ALP

Results	
ref meth	RFLC
69	73
133	136
138	141
145	148
166	182
176	174
194	202
210	224
239	242
274	271
295	299
308	309
466	449
526	514
606	602
660	650
742	744
1004	1031
1028	1025

**Korrelation:** 0,9994  
**Slope:** 0,998  
**Intercept:** 2,5  
**Min:** 69      **73**  
**Max:** 1028    **1025**  
**Median:** 274    **271**  
**Linearity:** >1020

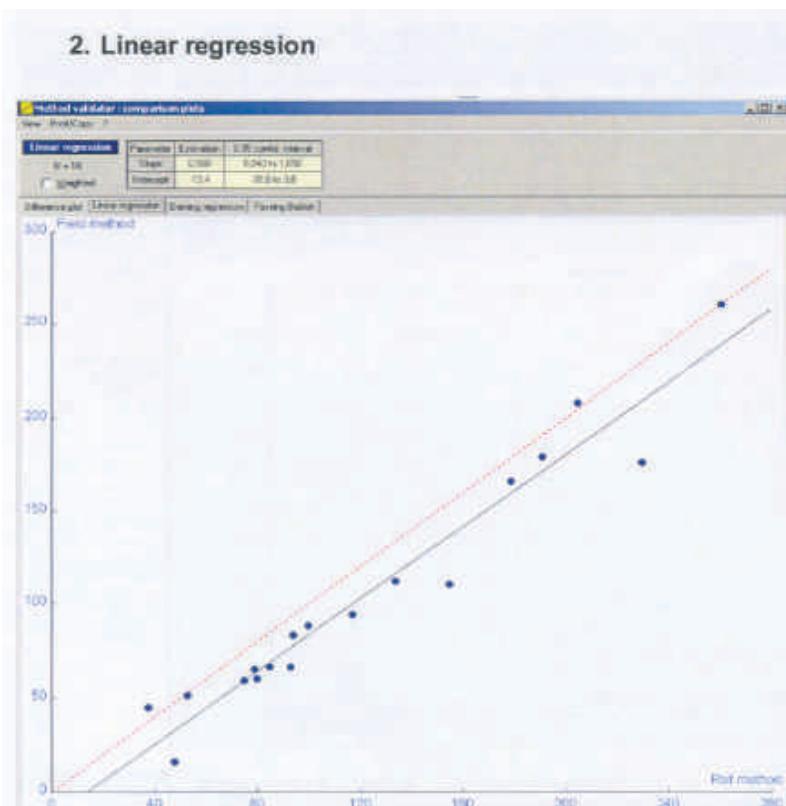


## Evaluation Report : External

### Creatine

Results	RFLC
ref meth	
38	45
48	16
53	51
75	59
79	65
80	60
85	66
93	66
94	83
100	88
117	94
134	112
155	110
179	166
191	179
205	208
230	176
261	260

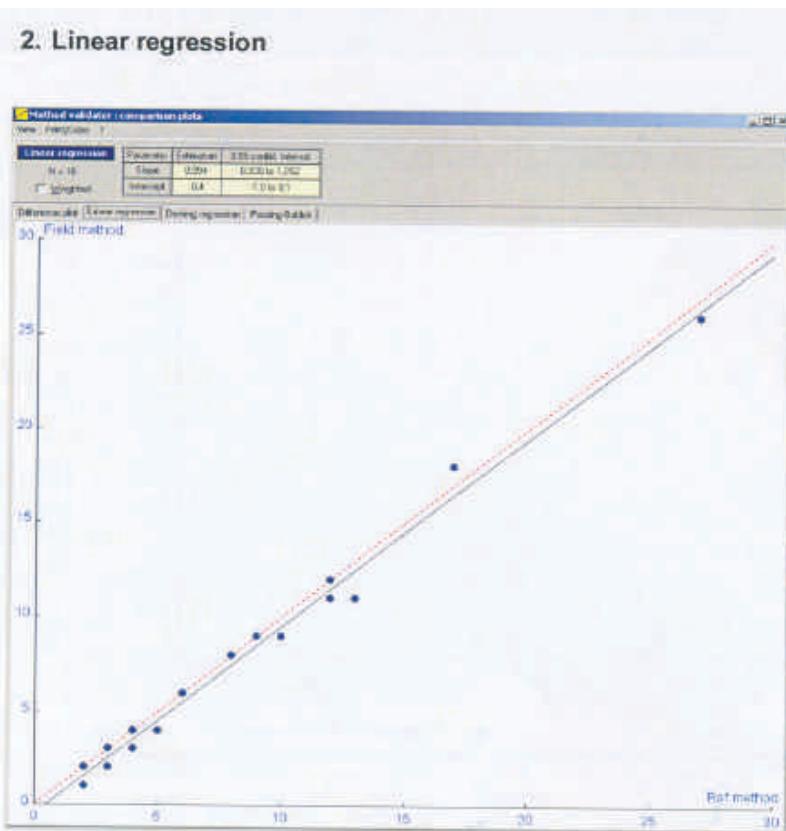
**Korrelation:** 0,9719  
**Slope:** 0,968  
**Intercept:** -13,4  
**Min:** 38      **45**  
**Max:** 261     **260**  
**Median:** 97    **85,5**  
**Linearity:** 1300



### Urea

Results	
ref meth	new meth
2	1
2	2
3	3
3	3
3	2
4	4
4	3
5	4
5	4
6	6
8	8
9	9
10	9
12	12
12	11
13	11
17	18
27	26

**Korrelation:** 0,9940  
**Slope:** 0,994  
**Intercept:** -0,4  
**Min:** 2      **1**  
**Max:** 27     **26**  
**Median:** 5,5    **5**  
**Linearity:** 46



## Evaluation Report : External

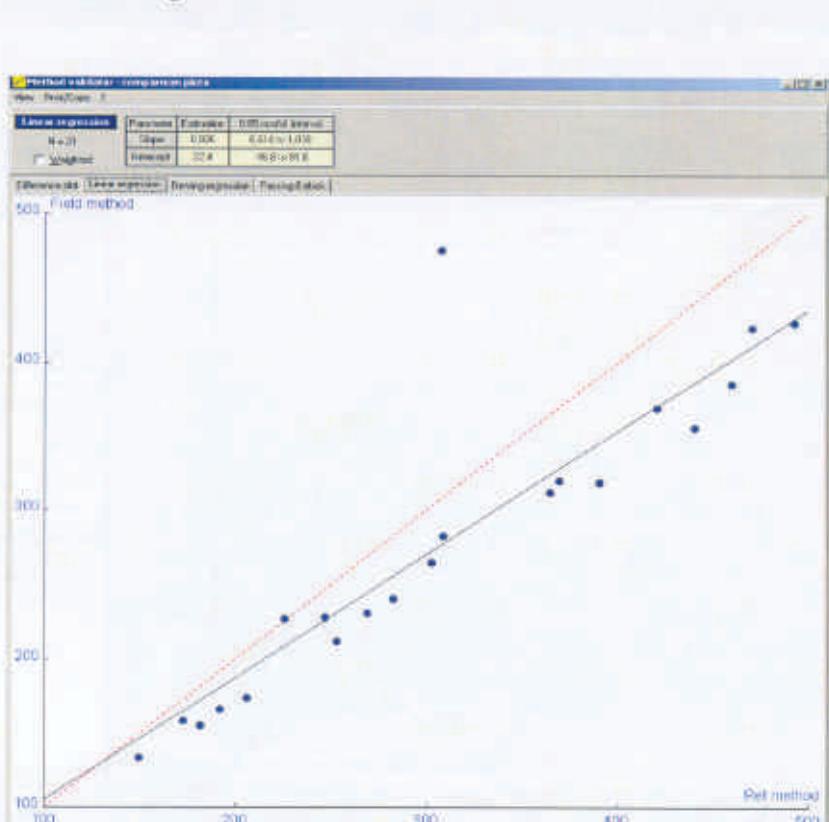
### Uric Acid

ref meth	Results	RFLC
150	133	
173	158	
182	155	
192	166	
206	174	
226	227	
247	228	
253	212	
269	231	
283	240	
303	264	
308	475	
309	282	
365	311	
370	319	
391	318	
421	368	
441	355	
460	385	
471	423	
493	426	

Korrelation:	0,8822	
Slope:	0,826	
Intercept:	22,4	
Min:	150	133
Max:	493	426
Median:	303	264
Linearity:	>400	

### 2. Linear regression



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