Manual

B·R·A·H·M·S KRYPTOR compact PLUS

Manual I Version 5

Date: 25.11.2013

Thermo SCIENTIFIC

B·R·A·H·M·S KRYPTOR compact PLUS Manual

Version 5.00

B·R·A·H·M·S KRYPTOR compact PLUS is a fully automated system for in vitro diagnostic of immunometric parameters. Immunometric parameters are detectable in various body liquids.

B·R·A·H·M·S KRYPTOR compact PLUS is routinely used for the measurement of patient samples in random access mode.

It is a closed system and can only operate utilizing special reagents offered by B·R·A·H·M·S GmbH.

The system is based on the TRACE technology (Time-Resolved Amplified Cryptate Emission). The system and the reagents are under continuous development by B·R·A·H·M·S GmbH.

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This version supersedes all earlier manuals.

Content changes versus previous version:

- Modification of layout
- **Chapter 1.1 Principle of the TRACE Technology:** Modification of TRACE Technology description
- **Chapter 2.5.3 Reaction Area:** Correction of temperature information
- **Chapter 2.7 Routine Work with B·R·A·H·M·S KRYPTOR compact PLUS:** Add possibility to run a control with a specified reagent kitbox to routine work description
- **Chapter 3.2 System Shutdown:** Add warning about closing the Kryptor program during measurement

- **Chapter 4.1.2 Add a Control to the Work List:** Add possibility to run a control with a specified reagent kitbox
- **Chapter 4.2.3 Sample Validation:** calculation of mean
- **Chapter 5.7 Maintaining Consumables:** reaction plate management when full
- **Chapter 7.3 Combined Analytes:** Modification of description for hTg recovery calculation
- **Chapter 8.2 Error Codes in the result list :** Modification of status for flag 1 and 4, add flag 29
- **Chapter 8.2.1 Description of Error Codes in the result list :** Modification of flags 12, 25 and 44 description, add description of flag 29
- **Chapter 8.5 Patient sample error messages:** Add recommendation during pipetting/reading sequences
- **Chapter 9.4 Use FIAView :** New version 2.06
- **Chapter 10.3.3 Electrical Hazard :** Modification of electromagnetic compatibility description

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The software and equipment can be used at one, non-transferable workstation.

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1. Introduction

1.1. Principle of the TRACE Technology

TRACE – the unique measuring principle of B·R·A·H·M·S KRYPTOR compact PLUS.

The measuring principle of B·R·A·H·M·S KRYPTOR compact PLUS is based on the TRACE technology
(Time-Resolved Amplified Cryptate Emission), which measures the signal that is emitted from an immunocomplex with time delay.

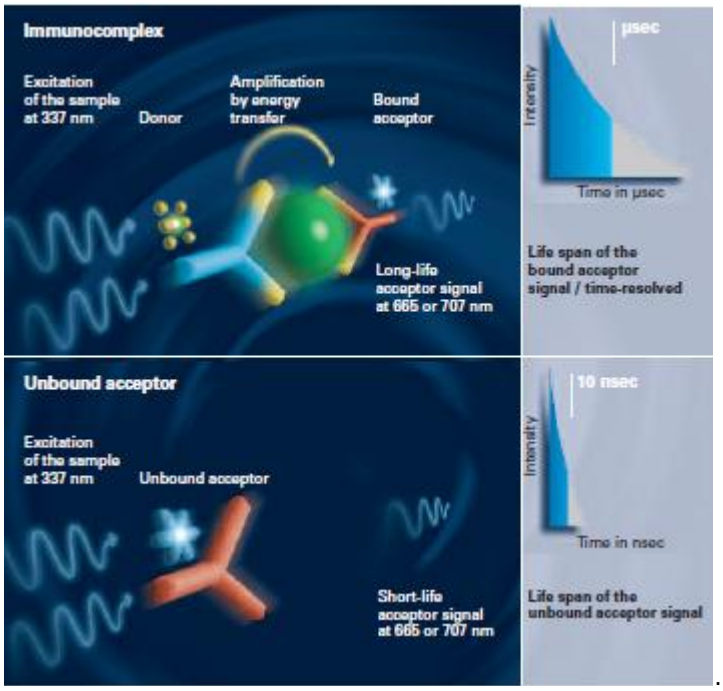
The TRACE-technology is based on a non-radiative transfer of energy between two fluorescent tracers : a donor and an acceptor.

The energy transfer is possible because of the proximity of the donor and the acceptor in a formed immunocomplex and the spectral overlap between donor emission and acceptor absorption spectra.

The formation of the immunocomplexe antigen / antibody on the one hand intensifies the fluorescent signal of the cryptate and on the other hand extends the life span of the acceptor signal, allowing for the measurement of temporally delayed fluorescence.

Precise measuring of analyte concentration

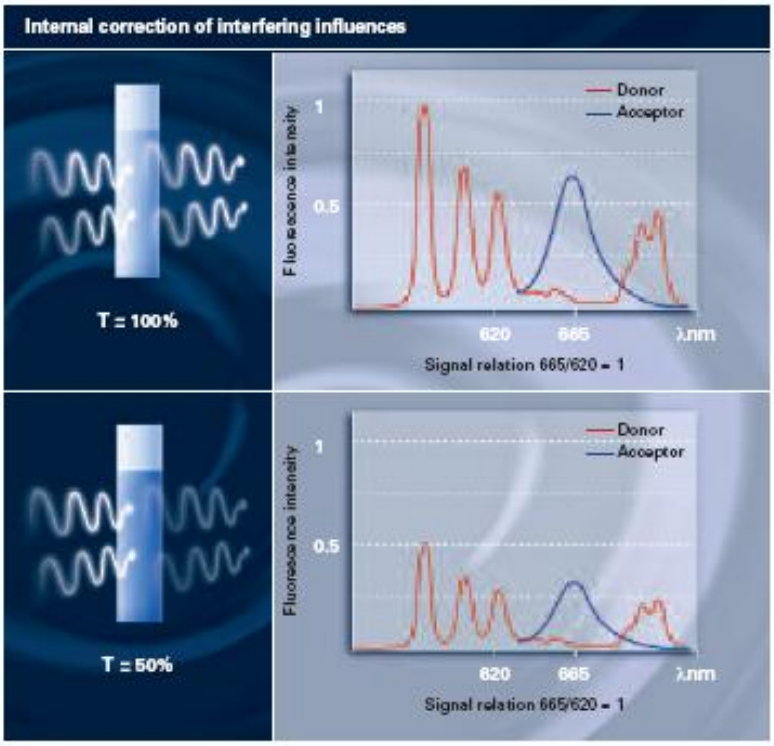
After the sample to be measured has been excited with a nitrogen laser at 337 nm, the donor emits a long-life fluorescent signal in the milli-second range at 620 nm, while the acceptor generates a short-life signal in the range of nano-seconds at 665 nm or 707nm. When both components are bound in an immunocomplex, both the signal amplification and the prolonged life span of the acceptor signal occur at 665 nm or 707nm, so that it can be measured in µ-seconds. This long-life signal is proportional to the concentration of the analyte to be measured



Safe prevention of interfering influences

Non-specific signals are eliminated by the temporal delay of the fluorescence measurement, e.g. the signals of the short-life and unbound acceptor and the medium-specific interference signals conditional upon the natural fluorescence of the sample.

The signal generated by the donor at 620 nm serves as an internal reference and is simultaneously measured with the long-life acceptor signal at 665 nm or 707nm which is the specific signal. Interfering influences, e.g. from turbid sera, are automatically corrected with the internally calculated ratio of the intensities at these wavelengths.



1.2. Working with WINDOWS

The B·R·A·H·M·S KRYPTOR compact PLUS software operates within the Microsoft WINDOWS environment and takes advantage of the numerous benefits that this environment has to offer. WINDOWS provides the interface between you and what you see on the screen.

This manual assumes that you have a working knowledge of WINDOWS. You should be familiar with the basic components of a window and WINDOWS concepts such as minimizing, maximizing, clicking, double-clicking, dragging, selecting menus, moving the cursor, etc.

Since this manual does not describe WINDOWS in detail, you should consult the Microsoft WINDOWS User Guide for further information.

The Mouse

Select: Move the pointer on the screen to the relevant item and quickly press and release the left mouse button.

Click: Quickly press and release the left mouse button.

Double-click: Click the left mouse button twice in rapid succession.

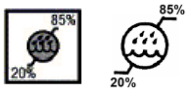
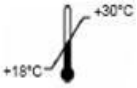
WINDOWS Command Icons

 Click to minimize the window.

 Click to maximize or restore the window.

 Click to close the software

1.3. B·R·A·H·M·S KRYPTOR compact PLUS Labelling

Symbol	Explanation	Symbol	Explanation
	**Dangerous laser**	~	Alternative current (AC)
	**Electrical hazard**		**Humidity range** minimum and maximum
	**Biohazards**		**Temperature range** minimum and maximum
	**Thermical hazard**	IVD	Medical device follows the **IVD Directive 98/79/EC**
	**Electrostatic shocks**		**Consult instructions for use**
	**User hazard**	CE	Medical device is **CE marked in conformity with the IVD Directive**
CAUTION-CLASS 3B INVISIBLE LASER RADIATION WHEN OPEN AVOID EXPOSURE TO THE BEAM	**Caution - Class 3B invisible laser radiation when open.** Avoid exposure to the beam		**Date of manufacturing**
CAUTION-CLASS 3B INVISIBLE LASER RADIATIONWHEN OPEN AND INTERLOCKS DEFEATED AVOID EXPOSURE TO THE BEAM	**Caution - Class 3B invisible laser radiation when open and interlocks defeated.** Avoid exposure to the beam		**Name and address of the Manufacturer**
LASER LIGHT DO NOT STARE INTO BEAM Maximum Output: 1.3 mW Pulse duration: 420 µs Wavelength: 650 nm CLASS 2 LASER PRODUCT IEC 60825-1:1993+A2:2001 Complies with 21 CFR 1040.10	**Laser light** Do not stare into the beam. Class 2 laser product		**Protective nominal value (Rating of electrical fuse)**
SN RD nn-0000-R	**Serial Number** of the reader module		Electric and electronic equipments have to be selectively collected under the manufacturer responsibility (B·R·A·H·M·S GmbH)
SN PT nn-0000-R	**Serial Number** of the pipetor module	**106172**	**Internal ID** number of the assembler
SN	**Identification** of the machine		

Labelling B·R·A·H·M·S KRYPTOR compact SOLUTIONS	
 Xn R 20/21/22 S 22-24  SGH 06	**Labelling BRAHMS KRYPTOR compact SOLUTION 2** Harmful. Harmful by inhalation, in contact with skin and if swallowed. Do not breathe in the aerosol. Avoid contact with skin.
 Xi R 31-36/38/ S 26  SGH 07	**Labelling BRAHMS KRYPTOR compact SOLUTION 3** Irritant. Contact with acids liberates toxic gas Irritant to eyes and skin, rinse immediately with plenty of water and seek medical advice.
 Xi R 36/38 S 26  SGH 07	**Labelling BRAHMS KRYPTOR compact SOLUTION 4** Irritant. Irritant to eyes and skin, rinse immediately with plenty of water and seek medical advice.

Precautions

The B·R·A·H·M·S KRYPTOR compact PLUS analyzer must be used only by qualified personnel.

Reading and interpretation of results must be done by a qualified user.

The B·R·A·H·M·S KRYPTOR compact PLUS instrument must only be used with materials, equipment and accessories specified in the B·R·A·H·M·S KRYPTOR compact PLUS Manual.

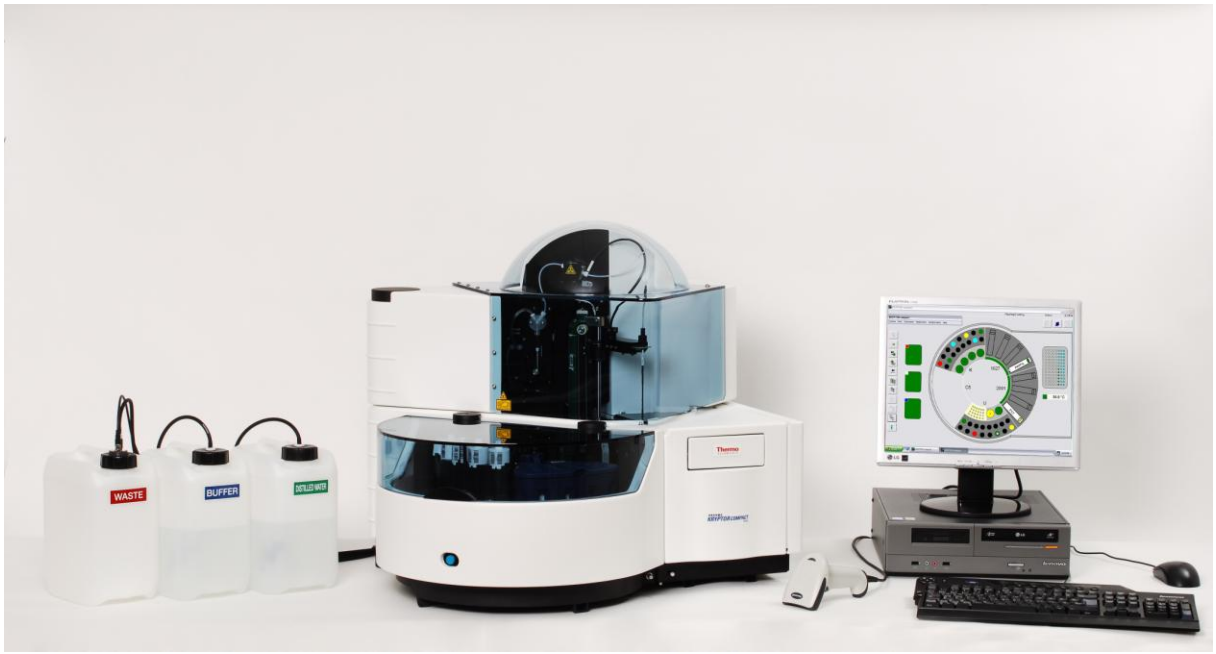
It is mandatory for users of the B·R·A·H·M·S KRYPTOR compact PLUS system to pay particular attention to SAFETY INSTRUCTIONS written in the B·R·A·H·M·S KRYPTOR compact PLUS Manual.

The non-respect of safety instructions described in the KRYPTOR compact PLUS Manual is under customer's responsibility.

Installation of the B·R·A·H·M·S KRYPTOR compact PLUS system can only be performed by a properly trained service engineer. At the time of installation all performance specifications will be verified. Any attempt to install, repair or modify the instrument by unauthorised personnel is not allowed.

2. Short Instruction

2.1. Instrument Components



B·R·A·H·M·S KRYPTOR compact PLUS is composed of two modules: pipetor and reader. The on/off button is located on the right side of the instrument. The instrument is also connected to an external computer via a dedicated USB port.

The pipetting module is composed of the pipetting unit (1), the fluidic system (2) and the carousel (3).

1. Pipetting unit

The Pipetting unit is the couple heated tip+wash station. The tip aspirates each component to do the biological analyse (sample, diluent, reagents) with capacitive liquid detection. After having aspirated the sample, the tip is heated to put the mix sample-reagent at reaction temperature before being dispensed in reaction area. At the end of dispensing, the tip is washed to avoid contamination between samples.

Caution: any fluidic hood opening stops tip motions.

2. Fluidic system

The fluidic system includes 3 bottles of 5 liters:

One for the wash liquid (label: BUFFER) used to wash the tubing system after pipetting process. The buffer is stable for 15 days after reconstitution (one pack for 5L distilled water)
order code: B·R·A·H·M·S KRYPTOR BUFFER

The second bottle will be filled with distilled water (label: DISTILLED WATER). The user can also use demineralized, or type II water.

Caution: never use tap water. The water will be used as liquid system by priming before pipetting process and keep the tubing line in water during instrument stand-by or switch-off.

Third bottle (label: WASTE) is used to collect liquid waste. Only this bottle contains a floating sensor (inside the cap) to manage the liquid level and a mechanical sensor for bottle presence.

Liquid level of buffer and water bottle is managed by a floatting sensor in the buffer and water intermediate tanks. When the bottle turns to red on the user interface, it is possible to refill it during pipetting or reconstitution steps. No sensors on the water and buffer bottles.

3. Carousel

Carousel is divided into 5 positions. Sections 1,2,3 are hybrid locations where reagent and sample trays (cassettes) can be loaded. Positions 4 and 5 are only dedicated to sample trays. When the hood is open, it is possible to move the carousel to make the access to sample and reagent trays easier.

Reagent Tray

4 reagent units can be loaded at the maximum.
The cooling system (2...8 °C) is activated only when the tray is in the carousel area and instrument on.
An infra-red system is used to detect reagent tray during carousel rotating movement and to communicate temperature.
Reagent units will be automatically identified by barcode label, placed on the edge of the box. The kit must be placed in the right position, barcode behind the plexi window, to allow the reading of the label. Information of each kit, contained in the barcode, and temperature will be managed on the user interface by color code.

Sample / dilution plate / SOLUTIONS 1,2,3,4 tray

This tray contains in the lower part 16 positions for tube:
primary, secondary tube, height: 60mm-110mm,
diameter: (11mm-17mm);
calibrator vials; control vials and microcup holder for pediatric sample
(specific metallic adaptator).

On the upper part, different consumables can be loaded:
dilution plate (24 wells), SOLUTIONS 1,2,3,4.
Each part (tube, dilution plate, SOLUTIONS, sample tray) will be identified with barcode labels.

B·R·A·H·M·S KRYPTOR compact SOLUTIONS (Order code: B·R·A·H·M·S KRYPTOR compact SOLUTION 1-4)

The SOLUTIONS 1 and 2 are used for freeze-dried reagent reconstitution. SOLUTIONS 3 and 4 are dedicated to different washing steps between samples pipetting. Their use depends on the analyte. They can be used during 4 weeks after opening. Do not mix various bottles. These SOLUTIONS will be identified by barcode label, volume and expiration date will be managed by software, and color-code on the user interface. Their presence is mandatory to launch reconstitution (1 and 2), or pipetting and washing sequences (3 and 4).

DILUTION PLATE (Order code: B·R·A·H·M·S KRYPTOR compact DILCUP)

The KRYPTOR compact PLUS system is able to perform the “intelligent” dilution to reduce the concentration of high concentrated sample. This dilution will take place in the tip or in a dilution well. This dilution plate is also used for recovery test (TG determination). Recovery SOLUTION (TG) and diluent are provided inside the kitbox of each reagent unit.
Dilution plate is identified by barcode label, expiration date and number of used wells will be managed by color-code in the user interface.
Stick are provided with dilution plate to cover it before throwing it in the biological waste bin.

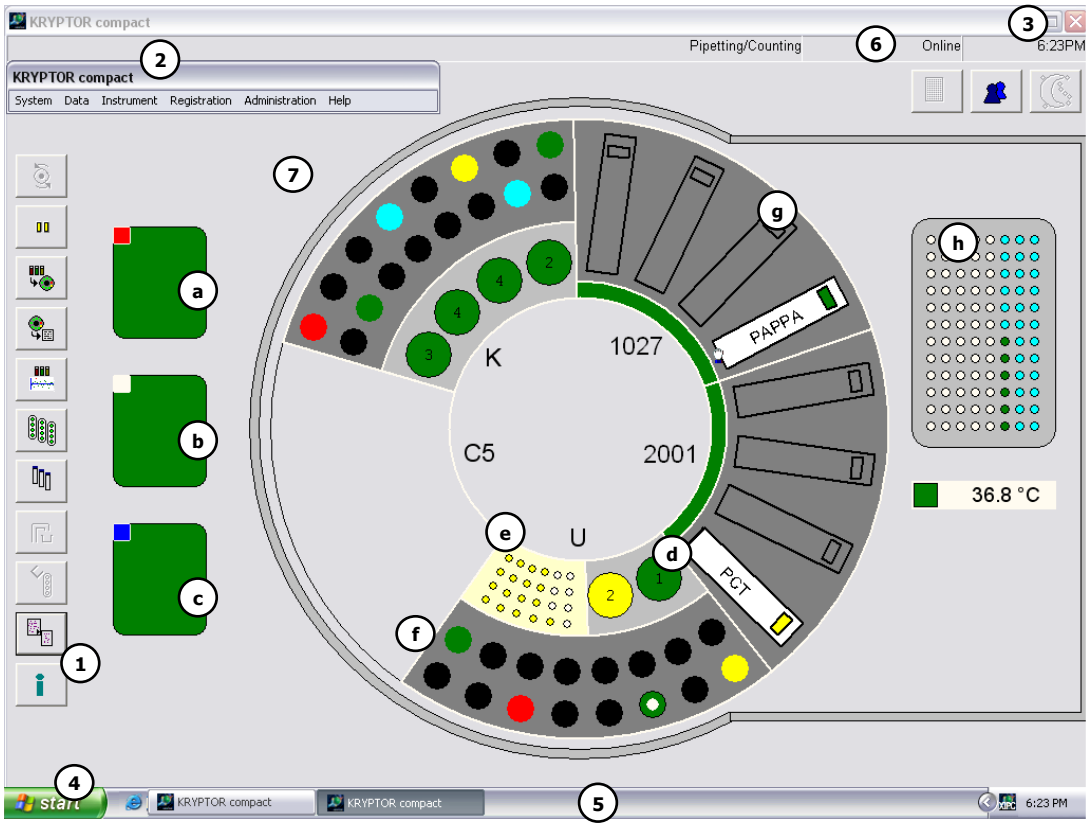
4. Reaction Module

This module is composed of the reaction area and the optical system to measure the signal emitted by the immuno-complex.
The 96 wells reaction plate (Order code: B·R·A·H·M·S KRYPTOR compact REACT) is loaded in the reaction area, identified by a barcode label. To load the reaction plate, scan the barcode with the hand-held scanner. The reaction area is heated at 37°C +/- 0.5°C, and can be used for 7 days at maximum. Before disposing of the plate, cover it with the “biological hazard” sticker.

5. Barcode Reader

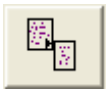
The barcode reader is used to scan into the system all data related to reagents, calibrators and controls, and also barcode label of the reaction plate to load it into the system.

2.2. System Status Window



1.) Acces to the **main menus**	a.) Waste
2.) KRYPTOR compact PLUS **tool bar**	b.) Liquid System (distilled water)
3.) WINDOWS **command bar**	c.) Wash Liquid (Buffer PBS)
4.) WINDOWS **Start button**	d.) KRYPTOR compact SOLUTIONS 1-4
5.) WINDOWS TASK BAR	e.) Dilution plate
6.) **Status bar**	f.) Sample tray
7.) KRYPTOR compact PLUS **work surface**	g.) Reagent tray
	h.) Reaction plate

2.3. Main Menu

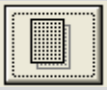
These menus are available by clicking on the following icon: 

The main menus bar appears 

System	Data	Instrument	Registration	Administration	Help
Logon	Worklist	Rescan Carousel	Calibrator/Standard	Panels	User Manual
Shutdown	Results	Start Processing	Control	Analytes	About
Maintenance	QC Functions	Pause Processing	Reagent Lot	Combined Analytes	
Maintenance Log	Work Analysis	Query All		Reflex Testing	
Session Log		Prime		User Accounts	
Service Diagnostics		Reconstitute Kits		Instrument Parameters	
Printer Setup		Reaction Plate		LIS Interface	
Close		Sample Carousel		Preferences	
		Reagents			

To close it, click again on the toolbar icon 

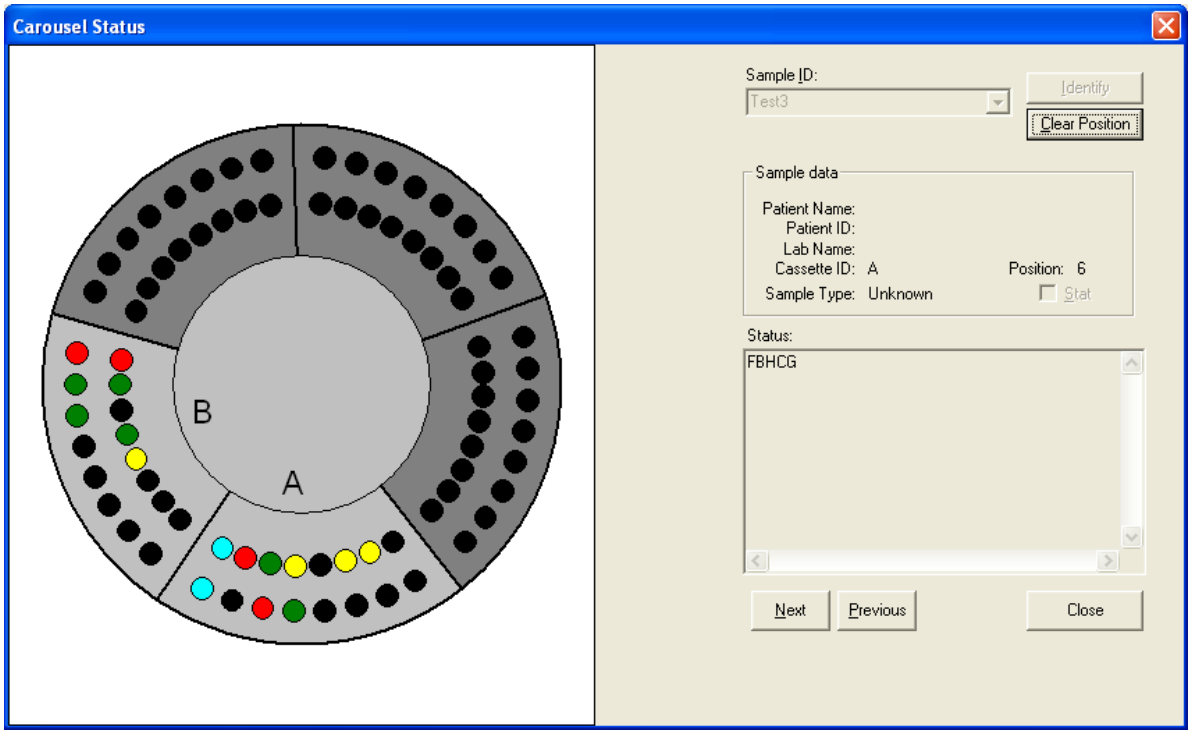
2.4. Tool Palette

ICON	COMMAND	FUNCTION	MENU OPTION	DESCRIPTION
	**Scan Carousel**	F1	Instrument Rescan Carousel	Identification of samples without starting a run
	**Start Processing**	F2	Instrument Start Processing	
	**Pause Processing**	F3	Instrument Pause Processing	This icon is available after a start process. If you use this icon to pause the system, you need to push to blue button on the instrument to open the hood. If you press only the blue button on the instrument, hood opens automatically.
	**Manage the current Worklist**	F5	Data Worklist	
	**View/Validate Results**	F6	Data Results	
	**View Instrument QC Data**	F7	Data QC Functions	
	**Manage Reagent Lot**	F8	Registration Reagent Lot	
	**Register/View Calibrator Lot**		Registration Calibrator Lot	
	**Prime liquid handling system**	F9	Instrument Prime	
	**Reconstitute Reagents kits**	F10	Instrument Reconstitute Kits	
	**Advanced Menu**		Advance Menu toolbar	To close the Menu Toolbar, click on it again
	**Load/Unload Reaction Plate**		Instrument Reaction Plate	
	**System Logon procedure**		System Logon	
	**System Shutdown procedure**		System shutdown	
	**Help Menu**		Help User Manual	Access to user manual

2.5. Work Surface Color Codes

2.5.1. Sample Carousel

Double clicking on a sample position in the carousel opens the **Carousel Status** window.



Color	Explanation
●	**Black:** no sample present
●	**Dark green:** the sample is ready to be tested
○	**Dark green with a white point:** sample during pipetting process
●	**Dark green with a red circle:** STAT sample
●	**Blue:** sample to be removed (all the tests of this sample have been processed successfully including the out of range detection)
●	**Yellow:** sample with barcode without test in worklist or presence on carousel of same ID on different sample tube
●	**Red:** Test will not be run because a problem was identified by the system prior to processing. Example: reagent kit not reconstituted or kit not on-board.
○	**Red with a white point:** System problem identified after sample pick-up. Example: clot detection.

If the system is connected to LIS, there are different colors for the sample status (see **5.3 Query All**).

2.5.2. Reagent Area

Each reagent cassette has its own identification. During the carousel scan, the kit barcode label is read by the system and different information appear on the screen. An information area appears by clicking (left button of the mouse) on reagent tray drawing, giving ID and temperature in °C of the kit.

A colour code on the circle portion exists as a quick visual check of the right temperature in the reagent area or a reagent cassette's fan default

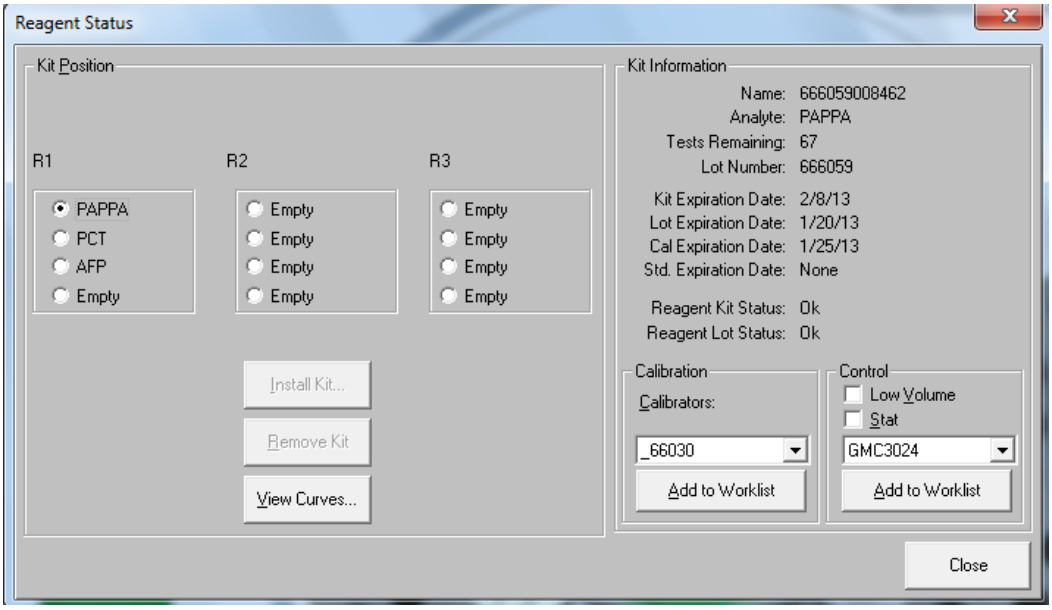
Temperature bar on the reagent area

Color	Explanation
	Green: 2,0 - 8,0 °C
	Blue: < 2,0 °C
	Red: > 8,0 °C or communication failed
	Yellow: One or more reagent cassettes's fan is out of order

Reagent kits on-board are managed by a color coded scheme.
The background color indicates the kit availability and the color of the rectangle indicates the number of remaining tests.

Color	Explanation
	White background: Kit OK (calibration and reconstitution OK) **Red rectangle:** Number of tests remaining ≤ 5
	White background: Kit OK (calibration and reconstitution OK) **Yellow rectangle:** 5 < number of tests ≤ 10
	White background: Kit OK (calibration and reconstitution OK) **Green rectangle:** Number of tests remaining > 10
	Yellow background: Kit or calibration expires tomorrow **Green rectangle:** Number of tests remaining > 10
	Red background: Problems: kit to reconstitute, to calibrate or expired kit or no test remaining

Double clicking anywhere in the reagent tray opens the **Reagent Status** window. This window enables you to display information about individual reagent kits and to **request calibration** for the different analytes.



2.5.3. Reaction Area

Reaction plate is barcode labeled to allow the loading of the plate. The reaction plate has to be loaded to activate its preheating and allow the dispensing of samples.

Click on the plate to view the exact number of tests dispensed and completed.

When the reaction plate is full, you must unload it by clicking on reaction plate.

A reaction plate not used but unloaded could be loaded again during 24 hours after its first loading.

There is no automatic shutdown (machine remains in ready stage).

As long as the reaction plate is on board, it is ready to be used, until 7 days are passed or plate is full.

After 7 days, the plate is automatically unloaded at the next end of day (first ready or initialized stage after midnight).

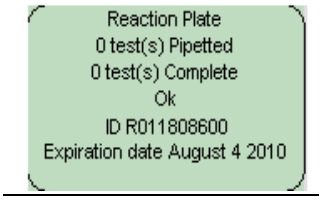
Time validity status of reaction plate is available when clicking with the left mouse button on the reaction plate on the screen.

If there is an “XY position error”, the plate is automatically unloaded, and cannot be used any more.

Each used well has a color code:

Color	Explanation
	**Green**: Proportion of tests running and not completed
	**Blue**: Proportion of tests completed

Quick information concerning reaction plate (ID, wells used, expiration date) is available by a left-click of the mouse.



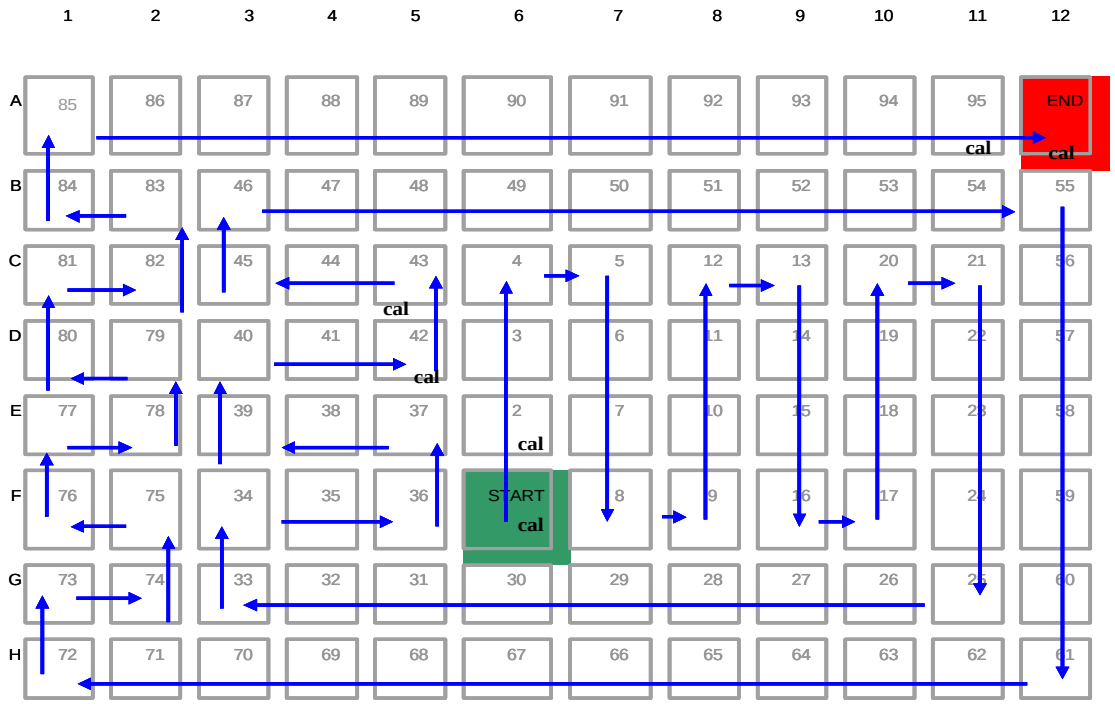
Temperature of reaction area

	Green: 36,2…38,2 °C
	Blue: < 36,2 °C
	Red: > 38,2 °C

Pipetting sequence does not start if the reaction area temperature is below 35,7°C or above 38,7°C.

After loading the reaction plate, a preheat countdown starts and takes between 10' to 35' to warm up the reaction area to the right temperature.

Dispensing order in reaction plate

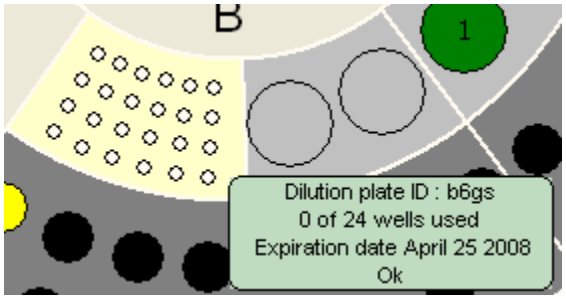


Note : the dispensing order is different from the one shown on the user interface.

2.5.4. Dilution Tray

Color	Explanation
○	**White well** = available well / Colored well = used well
●	**Green:** more than 10 wells available (< 24 wells used)
●	**Yellow:** from 5 to 10 wells available
●	**Red:** less than 5 wells available, or plate expired (more than 365 days)

Quick information concerning dilution plate (ID, wells used, expiration date) is available by a left-click of the mouse.



2.5.5. B·R·A·H·M·S KRYPTOR compact SOLUTION 1 to 4

Color	Explanation
●	**Green:** OK
●	**Yellow:** Warning volume. User needs to replace it soon, or bottle expires the day after.
●	**Red:** SOLUTION needs replacement or are expired, system will not start.

Each bottle has its own barcode label. Each cap of each bottle must be identified manually by the user by writing the number of the SOLUTION on the top of the cap. Cap can be placed in dedicated position on the sample tray.

When color of SOLUTION 1 and 2 turn to red during reconstitution process, there is enough dead volume to finish kit reconstitution.

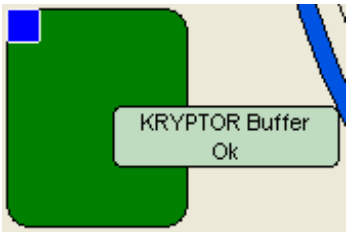
Dead volume of SOLUTION 1 is about 12ml, SOLUTION 2 is about 8ml, SOLUTIONS 3 and 4, dead volume is about 4ml.

Quick information concerning SOLUTIONS (SOLUTION ID, volume, expiration date) is available by a left-click of the mouse.

2.5.6. Fluidic System

Color	Explanation
	Green: ➢ OK
	Red: ➢ Buffer bottle empty ➢ Water bottle empty ➢ Waste bottle full ➢ Cap of the waste bottle non screwed correctly ➢ Intermediate tank from the waste line (non visible by user) full: in this case please contact the hotline

Quick information available on the user interface by a left-click of the mouse on the bottle.



2.6. Preparing the Work Surface

This section discusses how to prepare the work surface of the instrument for processing.

When preparing the work surface it is recommended that you

- ✓ Check the level of fluid in the system fluidic bottles (wash liquid and system liquid), and empty the waste bottle.
- ✓ Check the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles and caps absence.
- ✓ Load a reaction plate.
- ✓ Place dilution plates on the work surface.
- ✓ Load necessary reagent kits into the reagent tray.

Check fluid level

Before starting routine work you must check the status of the system's liquid sources:

- ✓ the waste bottle,
- ✓ the wash liquid bottle (B·R·A·H·M·S KRYPTOR-BUFFER)
- ✓ the system fluidic bottle with distilled water
- ✓ the B·R·A·H·M·S KRYPTOR compact SOLUTIONS

Bottles ready for use appear in green.

Load reaction plate

The reaction plate must be loaded before beginning the process.

When the system is initialized, you can place the reaction plate in the reaction area.

The reaction plate can be loaded automatically after scanning the barcode label on the front side.

Be careful that plexiglass window is closed.

You can also load the reaction plate with the following Icon  in case the hand-held scanner is defective. Click on the icon, write the barcode number and click on ok to load the plate.

Place dilution plates on the work surface

Dilution plates should be placed on the work surface before starting a run.
You can pause the system if you need to place or replace a dilution plate during a run. They will be identified by the barcode label.

Install reagent kits

Place the kitbox in the reagent tray. Barcode sticked on the kitbox will be read during a carousel scan.

If the barcode cannot be read, you are able to enter the identification manually.

Select a kit location in the reagent tray using the right mouse button. The manual entry of barcode information window is displayed.
Enter the identification number located under kit barcode in the **Kit Barcode Data** field.
Select **Install.**

Caution: for manual entry, it is under the user's responsibility to check that the kitbox is in the good position in the reagent tray, compared to the position he has chosen on the screen.

Caution: Manual identification of consumables or sample tubes is under user responsibility. Entering incorrect data may lead to wrong result.

This option is to be used only in case of barcode reading fault while waiting for repair of problem cause.

When you hold the mouse cursor over an icon, the description is shown on the status bar.

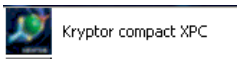
2.7. Routine Work with B·R·A·H·M·S KRYPTOR compact PLUS

Start-up

Fill the fluidic system bottles with distilled or demineralised water and wash liquid system with PBS buffer, empty the waste bottle.

Check that caps of BRAHMS KRYPTOR compact SOLUTIONS 1-4 are removed from the bottles. If B·R·A·H·M·S KRYPTOR compact SOLUTIONS 1-4 are closed, open the caps. Put caps into specifics locations and inscribe the caps with number of SOLUTION.

After a power off

- ✓ Check if carousel hood is closed.
- ✓ Switch on the instrument by O/I button located in the right side of the instrument.
- ✓ Wait until the two LEDs in front of the instrument are switched on.
- ✓ Switch on the XPC, monitor and printer.
- ✓ If a network password box appears, press **Enter**.
- ✓ Click on Windows Start button and choose 

icon to launch the B·R·A·H·M·S KRYPTOR compact PLUS software

Then, two programs start automatically :

- ✓ XIPC program, check XIPC icon appears in the clockbar 

- ✓ XPC program that corresponds to the Kryptor user interface.

After a Shutdown start here.

- ✓ Check that carousel hood is closed.
- ✓ Click on  or System / LogOn
- ✓ At the system log on screen, select USER NAME, PASSWORD (e.g. user Admin, password Admin)

Attention: Initialization of the system starts. An automatic carousel scan is launched just after initialization and also every 2 minutes if carousel hood is closed in order to check reagent trays temperature.

- ✓ Do **Maintenance** as requested.
- ✓ Place a new reaction plate, close the plexiglass window and load it by scanning the barcode.
- ✓ Push the pause (blue) button in front of the instrument to open carousel hood.
- ✓ Put new dilution plate on the instrument.
- ✓ Load the reagent kits in the reagent tray.
- ✓ Check the placements of B·R·A·H·M·S KRYPTOR compact SOLUTION 1- 4. (Reminder: SOLUTIONS 1 and 2 are used only for reconstitution step)
- ✓ After closing the lid of the reagent tray, check it is closed correctly in order not to disturb carousel motion and pipetting sequences.

After an automatic change of day

The automatic change of day procedure is launched every day, on the first ready or intialized stage after midnight.

This will perform automatically all the initializations (init pipetor + init reader).

You are informed that you have to logon with the message “KRYPTOR compact - Change of day made – Maintenance needed” in the title of the window.

- ✓ Check that carousel hood is closed.
- ✓ Click on  or System / LogOn
- ✓ At the system log on screen, select USER NAME, PASSWORD (e.g. user Admin, password Admin)
- ✓ Do **Maintenance** as requested.
- ✓ Replace consumables and reagents if necessary

You can go on using the analyser, without logon, in case of use by night team, who wants that maintenance is performed by “morning team”.

Maintenance

Items on the maintenance screens only need to be performed if they are marked ***Expired***.

[1)] These procedures are automatically performed during the system initialization.

Daily maintenance

- **Initialize Pipetor**[1)] To be done only if problems occur during run on pipetor module.
- **Initialize Reader**[1)] To be done only if problems occurs during run on reader module.
- **Prime Liquid Handling System.**[1)] Check visually the absence of leaks and bubbles during the priming procedure.
- **Check and Clean Reader Head Window** use a cotton-swab first with water and then with alcohol.
- **Check and clean condensation in reagent cassette** Remove kits from the reagent cassette, and wipe off the condensation with an absorbent paper. Replace the kits in the reagent cassette after the maintenance.
- **Lis end of day**
  This action enables to purge LIS files and avoid the occurrence of data transmission problems.
- **Check dilution plate cleanness**
  Look at dilution plate already in board if there is no dirty particles on dilution well.

Weekly maintenance

- **Check for liquid leaks.** Open the fluidic hood. Check the tubing system (tubing, connectors, intermediate tanks, syringe, tip). Do not close the hood before the next maintenance.
- **Tip path decontamination**. Clean serum splashes with paper slightly wet with water, then alcohol or decontamination solution. Close the fluidic hood, automatic initialization of pipetor module.
- **Backup Data Bases.** Backup of all databases older than 3 days.
- **Backup Log Files.** Backup of the log files (session, maintenance...).
- **Remove messages from BoxOffice**. This action enables to purge the box office and avoid the occurrence of data transmission problems.
- **Cleaning of water bottle**. Empty the water bottle and refill it with some new distilled or demineralised water.
- **Clean Carousel Pan** with a paper slightly wet with water, and then repeat the operation with alcohol or specific decontamination solution.

Monthly maintenance

- **Bottles Decontamination**. For waste bottle: Pour 500 ml of bleach containing 3.6 % of chlorine for 5 liters of waste or 700 ml of bleach containing 2.6 % of chlorine for 5 liters of waste or 3 tablets (each containing 73 % sodium di-chloro isocyanate) for a 5 liter waste bottle.
  Empty the three bottles and pour in 1 liter of 5 % sodium hypochlorite SOLUTION. Fit a bottle cap and swirl the liquid inside the bottle so that it comes into contact with all the internal surfaces. Allow to stand for 15 minutes, then empty and rinse the bottle with water.
- **Secure Tip Cleaning**. Tip parking over night or if instrument is not in use for a long time. B·R·A·H·M·S KRYPTOR compact SOLUTION 3 and 4 must be available in an adequate amount. The process "Secure tip cleaning" will automatically be done after shutdown from the system.
- **Automatic check dot**
  Tip coming on dot point. If adjustment is correct, tip coming back to wash cup. In case of adjustment problem, you should open the fluidic hood and check if tip can be slightly bended to enter the hole.

Registration of reagents

For the following working steps installation of valid version of K-DISK ANA is needed once.

Necessary when using new lots only:

Reagent

- ✓ Click on Reagent Lot Manager: 
- ✓ Click on Register.
- ✓ Scan the barcode sheet.
- ✓ Click on OK and confirm the registration with Yes.

Calibrator

- ✓ Click on Calibrator/Standard Manager: 
- ✓ Click on Register.
- ✓ Scan the barcode sheet.
- ✓ Click on OK and confirm the registration with Yes.

Control

- ✓ Click on: 
- ✓ Click on: 
- ✓ Click on Register new Controls.
- ✓ Scan the barcode sheet.
- ✓ Click on OK.

Perform a Calibration

Calibrator

- ✓ Double click on the kit you want to calibrate.
- ✓ Select a calibrator lot from the drop-down arrow list.
- ✓ Click on **Add to worklist, OK, Close**.
- ✓ Open the carousel hood with the pause button on the instrument
- ✓ Place the calibrator tube on the sample carousel making sure the barcode fills the slot.
- ✓ Close the hood.
- ✓ Start the instrument: 

Results

- ✓ Select the results window: 
- ✓ Select the calibrator result and click on **Validate curve**.
- ✓ The instrument indicates if the new calibration curve is acceptable or not:

  if **Yes** 

  if **No** 

Run Controls

Control

Adding a control through worklist

- ✓ Select Add control in the **Data, Worklist**: 
- ✓ Select a control from the list, press **Add to worklist, Close, Close**.
- ✓ Open the carousel hood with the pause button on the instrument
- ✓ Place the control tube on the sample carousel making sure the barcode label.
- ✓ Close the hood.
- ✓ Start the instrument: 

Adding a control to be tested on a specific reagent kit

- ✓ Double click on the kit which should be used to measure the controls.
- ✓ Select a **control lot** from the drop-down arrow list.
- ✓ Select **Low volume** and/or **Stat status** for this control
- ✓ Click on **Add to worklist, OK, Close**.
- ✓ Open the carousel hood with the pause button on the instrument
- ✓ Place the control tube on the sample carousel making sure the barcode fills the slot.

✓ Close the hood.

Start the instrument: 

Results

✓ Select the results window: 

✓ Accept the results if they need resolution.

✓ Select the B·R·A·H·M·S KRYPTOR compact PLUS Quality Control Program: 

Accepting the control automatically sends the result to the QC program if it is open.

Run Patient Samples

Manual sample entry

✓ Select **Add sample** from **Data**, **Worklist**: 

✓ Enter the **Sample ID**. **Cassette Number** and **Sample Tube Position** are added only if the tube has no barcode label.

✓ Select tests and dilutions from the displayed list by clicking on **Add**.

✓ **Save sample** and continue with required samples, **Close**.

✓ Place the sample tubes on the sample carousel.

✓ Close the hood.

✓ Start the instrument: 

Click on the **Stat** box for an urgent sample to be processed next in line.
Click on the **Low Volume** box if using a low volume sample cup.

Working with LIS

✓ Make sure the KRYPTOR compact PLUS LIS program (KIM) is open.

✓ Place the sample tubes on the sample carousel.

✓ Close the hood.

✓ Start the instrument: 

Results

✓ Select the results window: 

✓ Select a test.

✓ Tests pending, detecting or counting can be cancelled, if necessary (only if the instrument's status is "Ready" and the pipetting procedures are stopped).

✓ Results needing resolution can be: **Accepted**, **Re-run** or **Rejected**.

✓ Select the results and then **Print Report** to print your results.

End of Day

Shutdown (stand by modus)

- ✓ Check inventory of reagents on board for tomorrow's workload.
- ✓ Check the waste, buffer and water bottles.
- ✓ Shutdown procedure needs BRAHMS KRYPTOR compact SOLUTION 3 on board.
- ✓ Select **Shutdown** from the System menu or with following icon: 
- ✓ Answer Yes to confirm the shutdown procedure
- ✓ Follow the procedure to unload the reaction plate from the reaction area. Do not forget to close the plexiglass window. System will now perform the cleaning procedures.

To power OFF the instrument

- ✓ Remove the reaction plate, the dilution plate, the samples and the reagents, close the hood.
- ✓ Select **Shutdown** from the System menu or with following icon: 
- ✓ Answer Yes to confirm the shutdown procedure
- ✓ Unload the reaction plate and confirm the popup window with OK.
- ✓ Close the transparent damper and confirm the popup window with OK
- ✓ Instrument is washing, wait the completion of steps (SOLUTION 3 and water washing) in case of instrument power off
- ✓ Close the B·R·A·H·M·S KRYPTOR compact PLUS software 
- ✓ Close Windows by clicking on Start and Shutdown or Turn off
- ✓ Switch off the XPC, then switch off the B·R·A·H·M·S KRYPTOR compact PLUS with the O/I button on the right side of the instrument.

2.8. Analytes with Pre-incubation

Principle

The measurement requires 2 phases

Phase I: the system aspirates one of the 2 conjugates and the Antigene (sample). The system dispenses the mixture into the reaction well and the pre-incubation starts.

Example: For TRAK assay, the time required for the phase I is 15 min.

Phase II: the system aspirates the second conjugate and dispenses it into the reaction well. At this moment the Out of Range detection starts.

Example: For TRAK assay, the time required for the incubation time is 29 min.

In the following procedure is described:

- How to deal with the phase I and II.
- Precautions of use parameters with a pre-incubation.

Recommendations before starting

✓ Check if buffer and water bottles are completely filled in with 5 L.

✓ Empty the waste bottle (red labelled bottle).

✓ Check the presence and validity of B·R·A·H·M·S KRYPTOR compact SOLUTION 1, 2 and 3.

✓ Check the presence of 2 bottles of B·R·A·H·M·S KRYPTOR compact SOLUTION 4.

✓ Check the presence of the dilution plate.

✓ Check that the carousel hood is closed.

Phase I – Pre-incubation phase

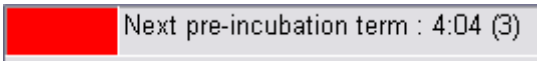
The system aspirates the first conjugate (XL) and the Antigen (Sample) before dispensing into the reaction well.

Once the dispensing has been made, there is a padlock on the reagent unit as indicated in the following picture:

Note: pipetting of Cryptate (phase II) has to be done from the same reagent unit.

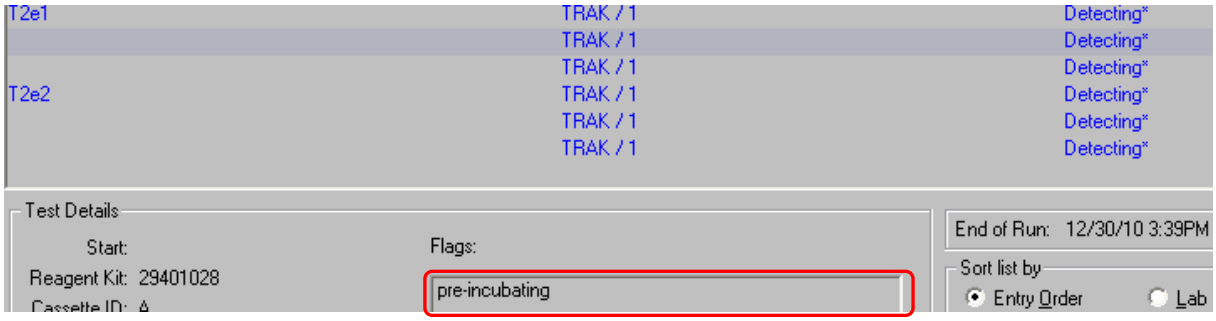
Caution: As long as the padlock is present on the reagent, the reagent kit must not be removed, even if the reagent is empty or colored in red.

A red square is blinking on the left top corner of the user interface if a measurement is in phase I (pre-incubation). There you will find a countdown which shows you the time when the next pipetting step of phase II will start. In brackets you will find the number of measurements which are currently in the pre-incubation phase I (refer to the picture below).



During the pre-incubation, in the result list, tests are in blue and flagged “pre-incubating”

Note: this flag is for information only.



Phase II: Pipetting and incubation phase

When the pre-incubation phase is over, the system aspirates the second conjugate (Cryptate) and dispenses it into the same well of the reaction plate

Once the pipetting process is finished and if no more tests are in pre-incubation, the pad lock on the reagent unit and the red square on the left top corner disappear.

In phase II, the test in the result list turns to black and is no longer flagged in “pre-incubating”.

The “Start” time for the test is indicated in the result list

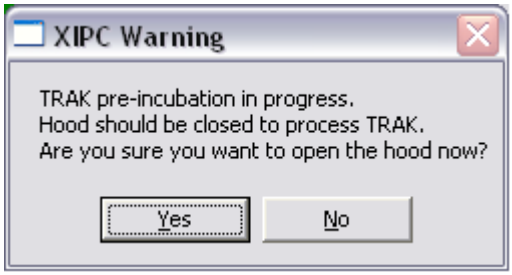
Note: this time does not take into account the pre-incubation.

Troubleshooting and precaution of use

During the pre-incubation (phase I), e strongly recommend you to follow the advice given hereafter to secure proper use of parameters with a pre-incubation:

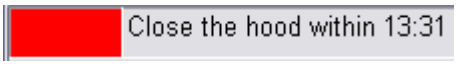
Carousel hood management during the pre-incubation:

When you want to open the carousel hood while parameters with a pre-incubation are in progress, the following pop up window is displayed:



If you select **YES** :

The carousel hood opens at the end of the current task. Then the message “next pre-incubation term” turns to “close the hood within … “. The time indicated takes into account the time of scan carousel and the time of phase II pipetting.



An alarm sound warns you that the carousel hood is opened and that you should close it within the time indicated.

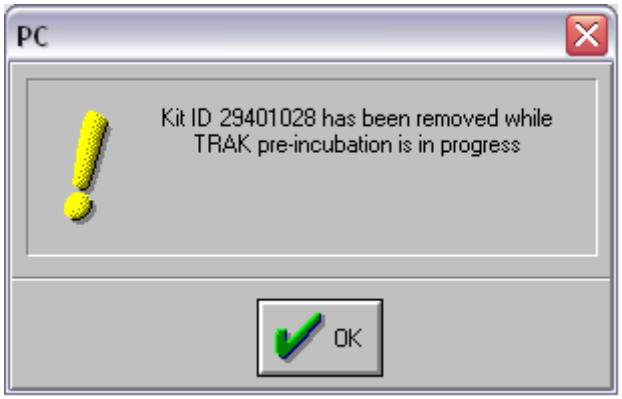
Note: that the countdown stops at 0:00 (no negative value).

If the user asks the carousel hood opening 1 or 2 minutes before the next phase II, the hood will open once the next phase II is finished.

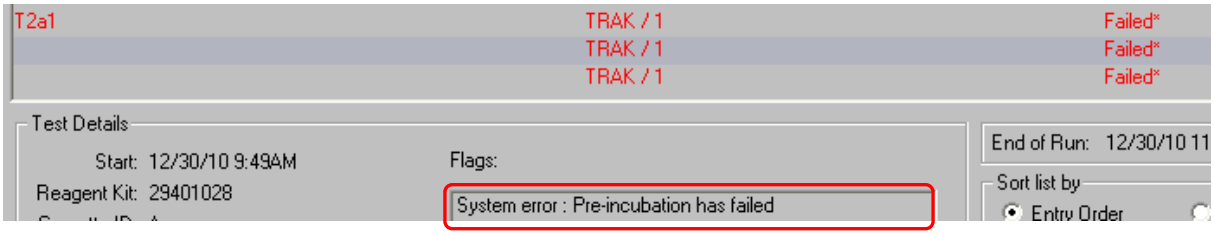
We recommend that you leave the carousel hood closed during phase I to avoid test failure.

Reagent unit management during the pre-incubation:

After the Carousel hood is closed, a scan is performed. If a reagent unit used for phase I with tests still in pre-incubation is not on board the following pop up is displayed to warn the user:



If the kit is not re-loaded on board before the phase II: tests are in red in the result list and flagged: System error: “Pre-incubation has failed”



Do not remove the Kit if the padlock is activated even if the Kit turns in red (Both incubation phases “phase I” and “phase II” have to be pipetted from the same kit for one sample).

Fluidics and washing solutions management during the pre-incubation:

B·R·A·H·M·S KRYPTOR compact SOLUTION 3 and 4 should be available to start the phase II.
If they are not, the hood is automatically opened and the alarm sound will warn the user.
If one of the 2 bottles is not available in time, the test is failed and flagged “System error: Pre-incubation has failed”

For the same reason, the waste bottle should be empty and the water and the buffer bottles should be filled.

Recommendations and remarks:

When a sample is detected as Out Of Range, the system will perform the re-dilution at the end of the batch of the phase II – pipetting.

To allow the results list refresh, please do not leave it displayed.

To ensure the worklist refresh, please click on the “start” button after you close the carousel hood.

Error messages:

Flag 69: “Pre-incubating”
Pre-incubation test, awaiting Phase II incubation
Possible causes: • No action necessary, information about pre-incubation only

Flag 70: System error: Pre-incubation has failed
The pre-incubation has failed and the Phase II cannot be proceed
Possible causes: • Pipetting problem during the Phase II. • No reagent unit on board at the end of the pre-incubation • The carousel hood is still open at the end of the pre-incubation • Kit discrepancy because the diluent is empty (Insufficient reagent volume) • B·R·A·H·M·S KRYPTOR compact SOLUTION 3 and 4 are empty • Water or Buffer bottles are empty • The waste bottle is full.

2.9. Manual entry of consumables and reagents

Caution: Manual identification of consumables or sample tubes is under user responsibility. Entering incorrect data may lead to wrong result.

This option is to be used only in case of barcode reading fault while waiting for repair of problem cause.

In case the consumables (reagent, dilution plate, BRAHMS KRYPTOR compact SOLUTIONS) are not read automatically by the system, it is possible to load them manually by entering the barcode with the keyboard of the external computer.
User must be careful to match the consumable position in the carousel with the position he has chosen on the user interface screen when entering identification manually.

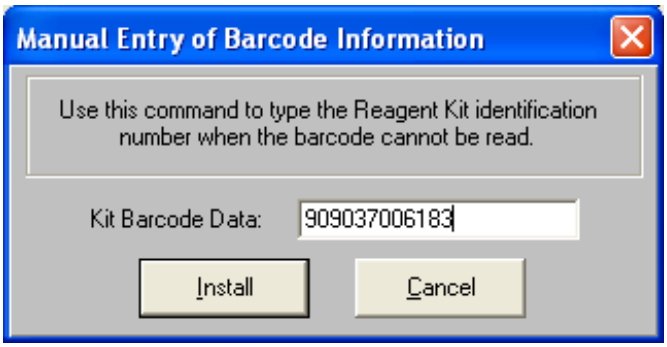
Each manual entry is indicated on screen by a small symbol (small white hand)  except reaction plate. Each manual registration will be logged in the session.log file.

If during the next carousel scan, a barcode is automatically read by the system whereas the consumable had been registered manually, the ID detected by the system takes priority over the manual ID. The automatic unload of the "manual entry" consumable is logged in the session log file.

Reagent manual entry

Open the carousel hood by pressing the pause (blue) button in front of the instrument to place the kit inside the reagent tray. Be careful to put the kit in the good position, by placing the notch towards the plexiglass window (see picture below)

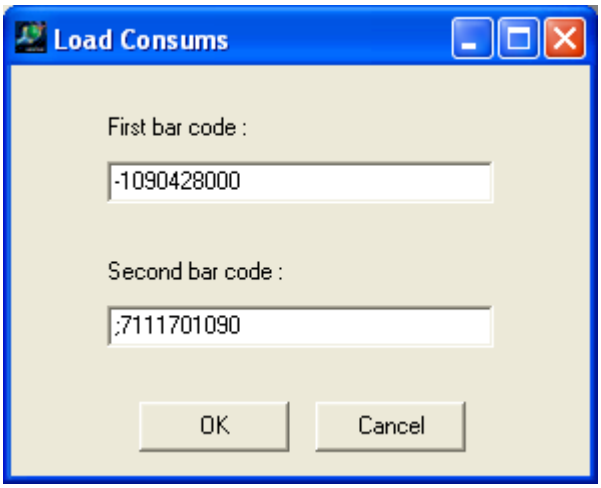
Select the position of the kit on the screen, then do a right-click of the mouse:
Following window appears:



Enter manually the ID of the kit written on the biggest part of the kitbox.
Click on **Install**, kit appears on the screen, close the carousel hood.

B·R·A·H·M·S KRYPTOR compact SOLUTIONS 1-4 manual entry:

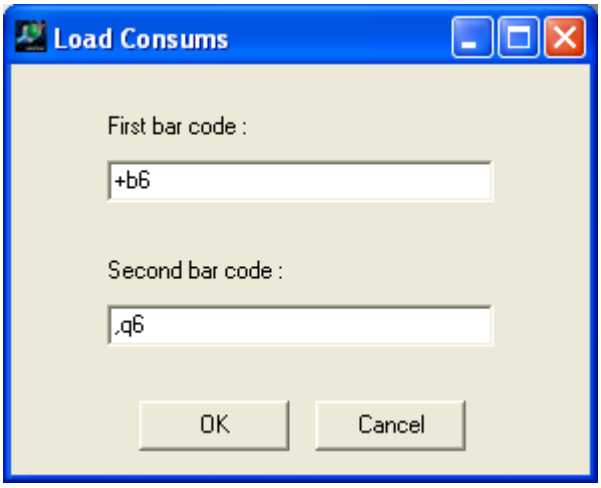
Open the carousel hood by pressing the pause (blue) button in front of the instrument.
Select on the screen the position where you will put the SOLUTION, right-click with the mouse:
Following window appears:



Enter the ID of the first barcode number (**-**xxxxxx), then enter the second barcode number(**;**xxxxxx).
Click on **OK**, SOLUTION appears on the screen.

Dilution Plate manual entry :

Open the carousel hood by pressing the pause (blue) button in front of the instrument.
Select on the screen the position where you will put the dilution plate, right-click with the mouse:
Following window appears:



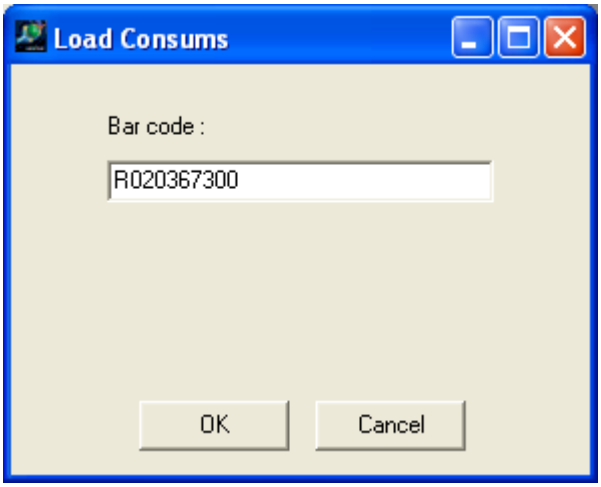
Enter the ID of the first barcode label (**+**xx), then enter the second barcode (**,**xx).
Click on **OK**, dilution plate appears on the screen.

Reaction Plate manual entry:

Place the reaction plate in the open reaction area. Be careful to close the plexiglas window.

Click on the following icon: 

Following window appears:



Enter the ID of the barcode label, always begin with an "**R**"
Click on **OK**, reaction plate will be loaded automatically.

3. System Menu

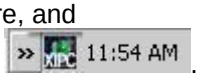
3.1. Starting up

Before turning on the instrument :

- ✓ Refill the fluidic system with distilled or demineralised water (green labelled bottle).
- ✓ Refill the wash liquid system with B·R·A·H·M·S KRYPTOR BUFFER (blue labelled bottle).
- ✓ Empty the waste bottle (red labelled bottle).
- ✓ Check B·R·A·H·M·S KRYPTOR compact SOLUTION 1 to 4 (open caps).
- ✓ Close the carousel hood.

After a power off/after a power cut

- ✓ Switch on the instrument by pressing the power switch on the right side of the reader module to the ON position.
- ✓ Switch on the external PC, the monitor and the printer.
- ✓ Click on the icon 

.
- ✓ Two programs are activated by this operation:
  the B·R·A·H·M·S KRYPTOR compact PLUS software, and
  the XIPC program that can be seen in the clock bar 

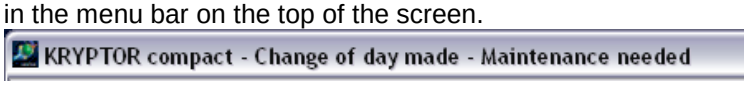
.

After a shutdown, start here

- ✓ At the system log on screen, select the user name and enter the password.
- ✓ Wait until the initialization is complete. An automatic carousel scan is released after the initialisation, and every two minutes if the carousel hood is closed to check the temperature in the reagent trays.
- ✓ When the instrument is ready for operation, the message Online is displayed in the status bar.
- ✓ Do maintenance as requested (see maintenance checklist **3.3 Maintenance Checklists**).
- ✓ Place a new reaction plate, close the plexiglass window and load the plate by scanning the barcode through the plexiglass window with the hand-held scanner.
- ✓ Open the carousel hood by clicking on the blue button in front of the pipetor module.
- ✓ Load one or more reagent trays on specific positions. Load kits when the temperature status is green.
- ✓ Check the status of dilution plate and SOLUTIONS on the interface. Load new consumables if necessary.

After an automatic change of day

✓ You will see the information “KRYPTOR compact - Change of day made – Maintenance needed” in the menu bar on the top of the screen.



✓ Click on **System/Logon** or  and select the user name and enter the password.
You can go on using the analyser, without logon, in case of use by night team, who wants that maintenance is performed by “morning team”.

✓ Due to the automatic change of day procedure the daily maintenance steps “Initialize pipettor”, “Initialize reader” and Prime liquid handling system” were performed automatically every day, on the first ready or intialized stage after midnight.

✓ Do remaining maintenance steps as requested (see maintenance checklist **3.3 Maintenance Checklists**).

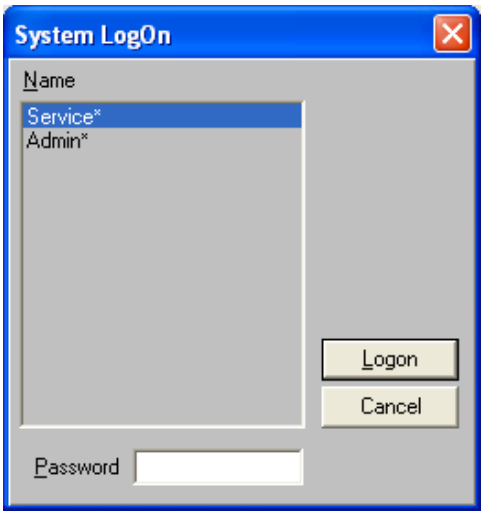
✓ If no reaction plate is loaded, place a new reaction plate, close the plexiglass window and load the plate by scanning the barcode through the plexiglass window with the hand-held scanner.
If a reaction plate was loaded before this can still be used.

✓ Check the status of dilution plates, KRYPTOR compact SOLUTIONS and reagentkits on the interface. Load new consumables and reagentkits if necessary.

Logging on

When you first enter the B·R·A·H·M·S KRYPTOR compact PLUS software after booting up, the **System LogOn** window is displayed.

Click on the icon  or select **Logon** from the **System** menu to display the same window. This window enables you to access the B·R·A·H·M·S KRYPTOR compact PLUS software at various user levels. Predefined levels are Service and Admin (Lab manager).



Select your account name from the list box. Password protected accounts are marked with an asterisk.
Enter your password and click on the **Logon** button.

You can log on even if the instrument is being initialized. However, you cannot process samples until the **Online** and **Ready** messages are displayed in the status bar of the **System Status** window.

For detailed information about creating different user accounts, refer to the chapter **Administration Menu**, function **User Account**.

3.2. System Shutdown

The shutting down of the instrument results in the following:

- All internal motors are turned off.
- The temperature control is turned off, except for reagent cooling. The temperature in the reagent cassette is maintained for storing reagent kits overnight.

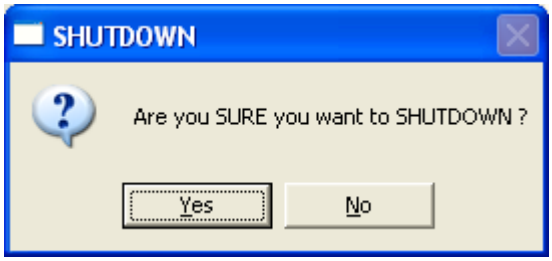
B·R·A·H·M·S KRYPTOR compact SOLUTION 3 must be kept on-board during system shutdown for the tip cleaning.

The B·R·A·H·M·S KRYPTOR compact PLUS is designed to run 24 hours a day and can be used as a STAT analyzer.

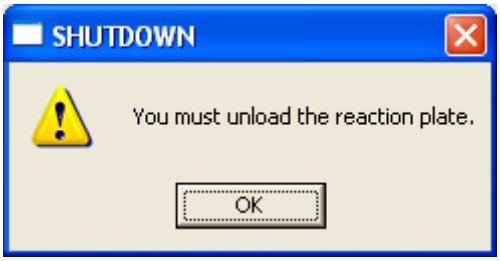
Manual Shutdown (Stand by modus)

✓ Check inventory of reagents on board for tomorrow's workload.
Check the buffer, distilled or demineralised water and waste bottles.

Click on the icon in the up right hand corner  to perform the shutdown. The instrument shutdown is also accessible in the menu **System / Shutdown.**



✓ Answer **YES** to confirm the shutdown procedure.



✓ Click on **OK** to unload the reaction plate. Remove it and **close the plexiglass window**.

✓ Click on **OK** to confirm the unloading of the plate.
Wait for the end of the tip cleaning procedure.

The instrument shutdown is also accessible in the menu **System / Shutdown.**

Switch off the Instrument

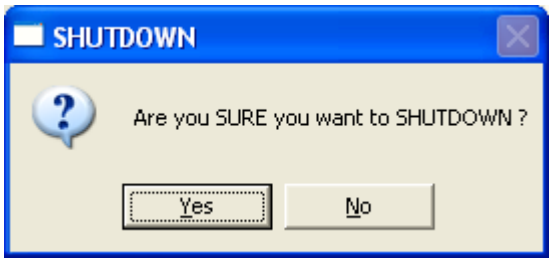
✓ Open the carousel hood (press the blue pause button) on the pipetor module.
Remove samples from the sample trays and dilution plate.

B·R·A·H·M·S KRYPTOR compact SOLUTIONS can be kept on board for 29 days after opening.

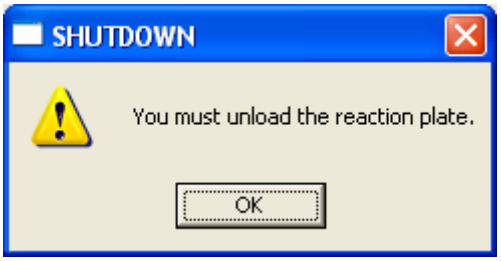
✓ Remove kits from the reagent trays, and keep them in a fridge.

✓ Close the carousel hood.

✓ Click on the icon in the up right hand corner  to perform the shutdown.



✓ Answer **YES** to confirm the shutdown procedure.



✓ Click on **OK** to unload the reaction plate. Remove it, and **close the plexiglass window**.

✓ Click on **OK** to confirm the unloading of the plate.
Wait for the end of the tip cleaning procedure.

✓ Exit the B·R·A·H·M·S KRYPTOR compact PLUS software and all other programs by clicking on  .

✓ Close WINDOWS by clicking on **Start**, **Shutdown** or **Turn off** and **Yes**.

✓ Switch off the external PC, the monitor and the printer.

✓ Finally switch the B·R·A·H·M·S KRYPTOR compact PLUS off by pressing the **O/I** button on the right side of the instrument.

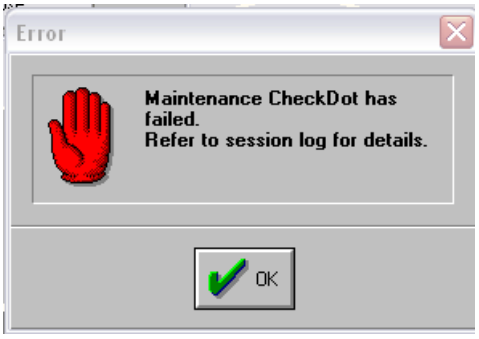
Caution: Do not close the Kryptor program by choosing the icon in the Windows taskbar you may lose tests that are in measurement. The system will not warn you not to close the Kryptor program while measurement.

3.3. Maintenance Checklists

After selecting **Logon** in the system **LogOn** window or **Maintenance** in the **System** menu, the maintenance checklists are successively displayed. Each checklist displays the tasks you need to perform every day, every week or every month. A message will be displayed adjacent to each task. The number of days indicates the time remaining before you have to perform the required maintenance. The word **Expired** indicates that the remaining time has elapsed.

To perform maintenance or to indicate that maintenance has been carried out, click on **Maintain**. A check mark (X) will appear on the left of the item to indicate task completion. Select **Close** at each window to display the next checklist.

A popup window will appear when a maintenance step failed (see example below). In this case check session log for more informations (see **chapter 3.5 Session Log**).



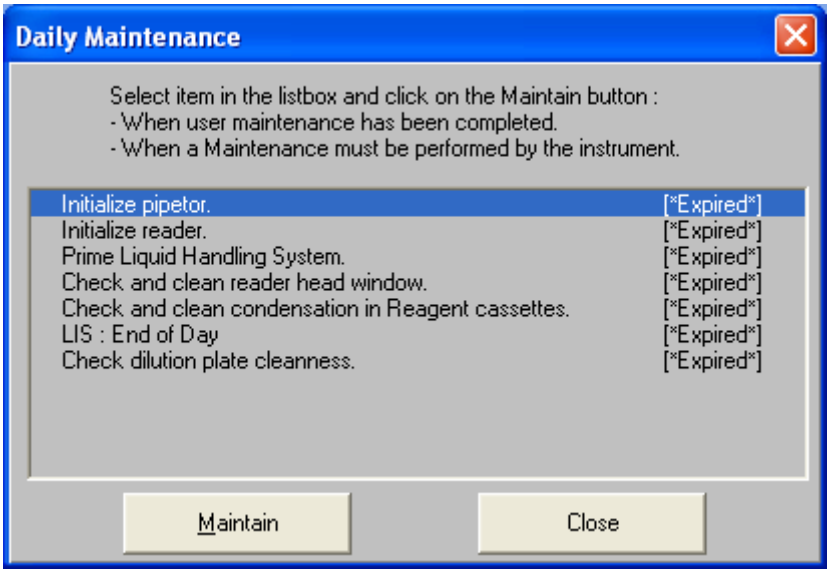
The **Daily Maintenance** checklist is displayed first followed by the **Weekly Maintenance** and the **Monthly Maintenance** checklists.

Maintenance checklist menus are always available directly in the **System** menu, but some maintenance actions are available only when the instrument is in **Ready** status.

A maintenance window is not displayed automatically if all the items are in a **Not expired** status in the checklist. We recommend that maintenance should be carried out in order to prevent any failure of a software or mechanical nature.

Maintenance actions are indexed and available in the **Maintenance Log** file in the **System** menu or under *C:\KRYPTOR\Maintain\maintain.log.*

3.3.1. Daily Maintenance



Initialize pipetor

This maintenance procedure is used to re-home motors of the pipetor module.

It is automatically done during initialization. There is no need to routinely carry out this procedure. This function has to be used after encountering any mechanical problems during the daily run. All mechanical problems have to be taken into account. If the problem persists, call the Service Line.

After initialization you should check the session.log file in the **System** menu, **Session log** to ensure that there are no mechanical errors that could affect results.

Initialize reader

This maintenance procedure is used to re-home motors of the reader module.

It is automatically done during initialization. There is no need to routinely carry out this procedure. This function has to be used after encountering any mechanical problems during the daily run. All mechanical problems have to be taken into account. If the problem persists, call your local Hotline.

After initialization you should check the session.log file in the **System** menu, **Session log** to ensure that there are no mechanical errors that could affect results.

Prime Liquid Handling System

This maintenance is used to prime the fluidic system with buffer and water, in order to eliminate bubbles and to check for the absence of leaks.

During priming, the user has to stay in front of the B·R·A·H·M·S KRYPTOR compact PLUS device to detect any bubbles or leaks from the syringe or the sample tip.

Micro-bubbles could occur if B·R·A·H·M·S KRYPTOR compact PLUS is stopped for a long time, e.g., because of week-end or shutdown. Double priming normally solves this problem. If this is not the case, the presence of micro-bubbles indicates a problem of tightness leading to high CVs in the results.
If the problem of micro-bubbles persists, please call the service line.

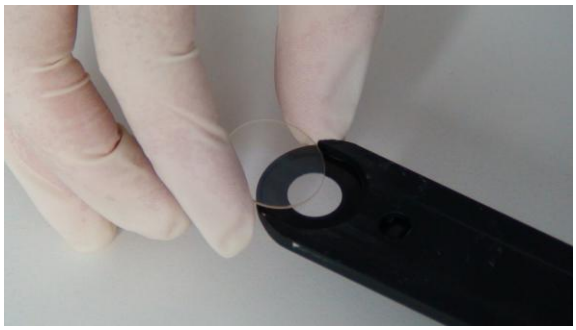
Check and clean reader head window

To remove the window on the right side of the reader module:

- ✓ Handle the drawer close to the silica window
- ✓ With your pointer, push **gently** on the silica window, keep on pushing and extract the Silica window at the same time.
- ✓ Clean up the silica window using a lint-free paper saturated with distilled water to remove serum splashes.
- ✓ Rinse the blade with the 90% or 95% alcohol wash bottle for the drying process. Avoid using a kitchen towel, it may leave some lint.

Notes: It is strongly advised not to use paper or optic paper handkerchief and modified alcohol, since these products may contain fluorescent substances that have not been tested.

CAUTION: Always use water before using alcohol in order not to fix the proteins on the window



To put the silica window back in the drawer:

- ✓ Put the silica window back using a lint-free paper.

Caution: The silica window can fall down when turning the drawer upside down.

Check and clean condensation in reagent cassette

When the B·R·A·H·M·S KRYPTOR compact PLUS is in sleeping mode, all internal controls on the instrument are turned off, except the reagent cassettes. The temperature in the reagent cassette is maintained for storing reagent kits overnight. This is the reason why you can have some condensation in reagent cassette.

Remove kits from the reagent cassette, and wipe off the condensation with an absorbent paper. Replace the kits in the reagent cassette after the maintenance.

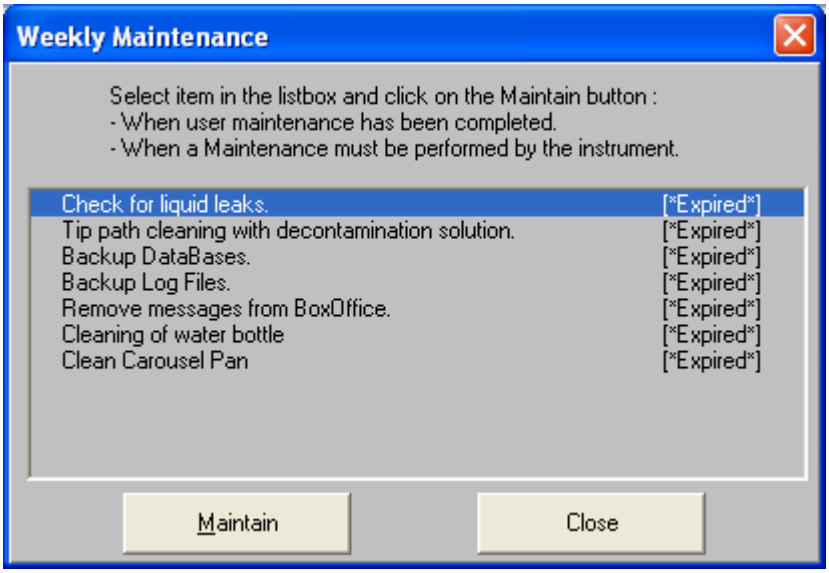
LIS end of day

This action enables to purge LIS files and avoid the occurrence of data transmission problems.
This maintenance step deletes archive folders in the sending and receiving folders.
Please note, that if maintenance is not performed, communication will get frozen when reaching 1000 files in an archive folder.

Check dilution plate cleanness

Check that you will not have particles in the wells of dilution plates placed on board of the KRYPTOR compact PLUS. If necessary replace the dilution plates.

3.3.2. Weekly Maintenance



Check for Liquid Leaks

Open the fluidic hood to check the tubing system such as tubing connectors, syringes and joints in order to confirm the absence of PBS or water smudges which are seen as white splashes.
The presence of white splashes indicates liquid leaks and can lead to incorrect pipetting. In this case the connectors should be fixed manually (not using a tool).
If the liquid leaks persist, call the service line.

When the fluidic hood is open, all pipetor's motors are disabled. When you close it, the pipetor initialization is done automatically.

Tip path cleaning with decontamination solution

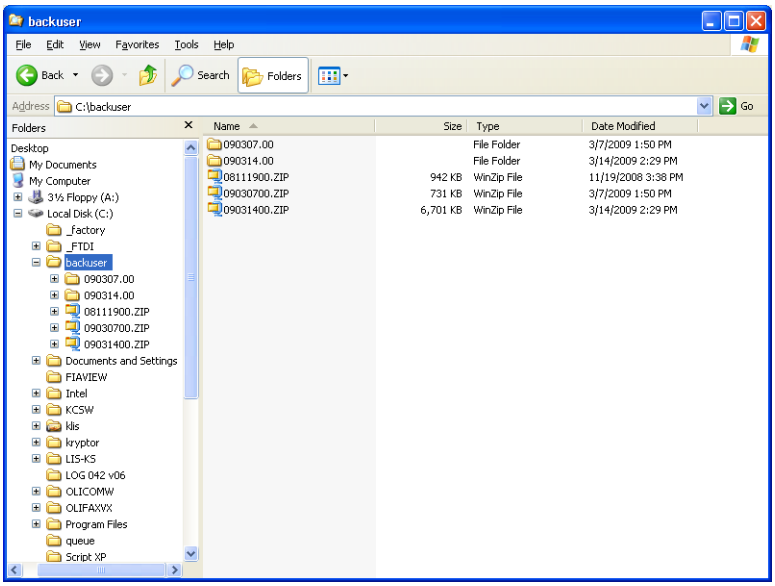
This maintenance is done to clean serum splashes on the tip path. Clean the tip path with a paper slightly wet with water, and then repeat the operation with alcohol or specific decontamination solution.

Backup Data Bases

This maintenance procedure leads to the automatic backup of all databases older than 3 days.

Data are automatically saved in a subdirectory. A folder and a new zip file are automatically created in the C:\ BACKUSER directory.

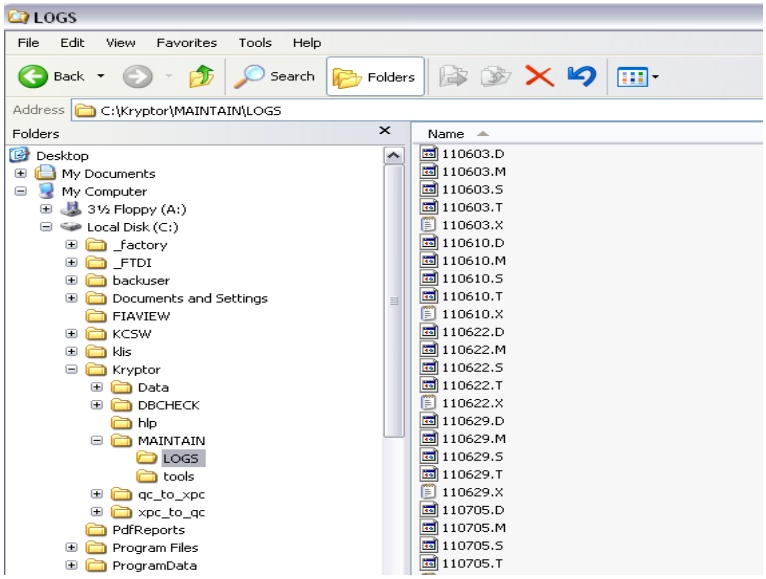
The name file consists of the date plus two digits corresponding to the number of backusers created on the same day, e.g.YYMMDD.xx.



For each backup the previous unzipped backup older than two months is deleted.

Backup Log Files

This maintenance routine leads to an automatic backup of the log files session.log detail.log and maintain.log in the C:\Kryptor\Maintain\Logs directory.



The file name consists of the date “YYMMDD” and a letter corresponding to the log files in question (D = detail.log, M = maintain.log, S = session.log).

Remove messages from Box-Office

This action enables to purge the box office and avoid the occurrence of data transmission.
This maintenance deletes:
All MAPI messages present in the Inbox (Sent Items messages are backed up).

Cleaning of water bottle

Empty the water bottle and refill it with some new distilled or demineralised water.
On the B·R·A·H·M·S KRYPTOR compact PLUS, you can use:

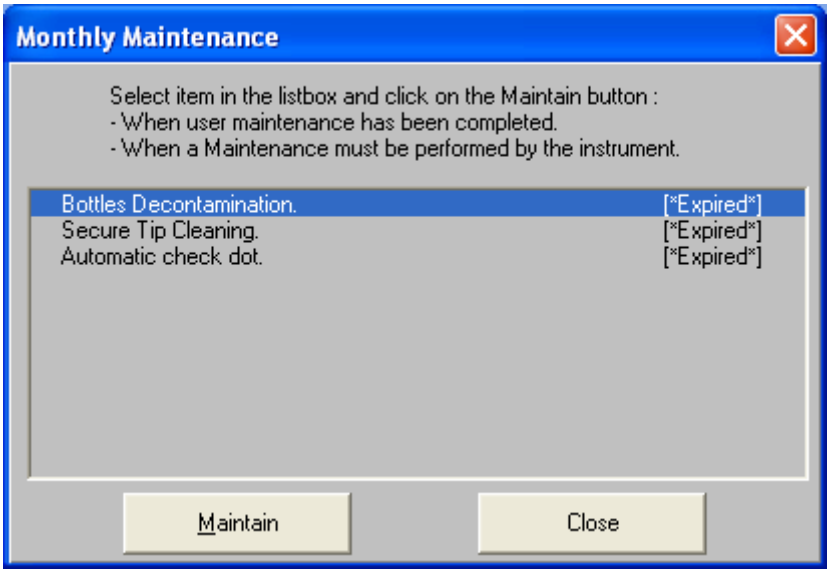
- distilled water
- demineralised water
- water type II.

Clean Carousel Pan

This maintenance is done to clean serum splashes and condensation from the reagent cassette in the carousel pan.

Clean the carousel pan with a paper slightly wet with water, and then repeat the operation with alcohol or specific decontamination solution.

3.3.3. Monthly Maintenance



Bottles Decontamination

This is a three steps maintenance procedure:

1. Waste effluent decontamination

The following steps must be carried out for this maintenance procedure:
Wear an overall, gloves and goggles.

- ✓ Put the B·R·A·H·M·S KRYPTOR compact PLUS waste into a container.
- ✓ Pour bleach into the waste container:
  500 ml of bleach containing 3.6 % of chlorine for 5 liters of waste
  or 700 ml of bleach containing 2.6 % of chlorine for 5 liters of waste
  or 3 tablets (each containing 73 % sodium di-chloro isocyanate) for a 5 liter waste bottle.
- ✓ Homogenize by magnetic or mechanical agitation.
- ✓ Leave in contact for 12 hours before eliminating waste. Waste disposal must be carried out in accordance with local legislation (3.6 % of chlorine is equivalent to 12° chlorine).

2. Empty the water and buffer bottles

3. Clean the three bottles for buffer, water and waste

Pour 1 liter of 5 % of sodium hypochlorite SOLUTION in each bottle. Apply the cap to the bottle, and swirl the liquid inside the bottle so that it comes into contact with all the internal surfaces. Allow to stand for 15 minutes, then empty and rinse the bottle with water. Waste must be disposed of in accordance with local legislation.

Secure Tip Cleaning

Place B·R·A·H·M·S KRYPTOR compact SOLUTION 3 and 4 in their compartments and click on the task to initiate the automatic decontamination sequence.

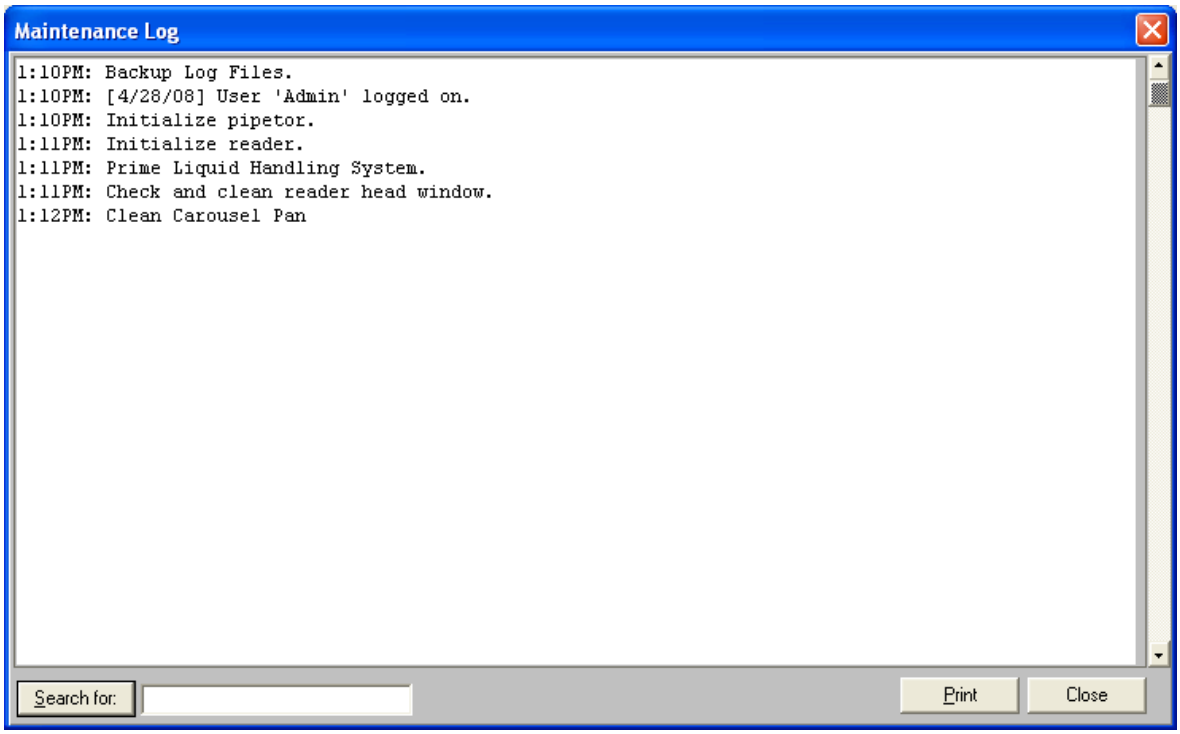
It must be carried out prior to probe intervention in order to prevent any biohazard contamination.

Automatic check dot

This maintenance step is done to check that the tip position is correct.
During the maintenance step the Tip moves to dot hole. If adjustment is correct, tip moves back to wash cup and starts a pipettor initialization. In case of adjustment problem, you should open the fluidic hood and check if tip can be slightly bended to enter the dot hole.

3.4. Maintenance Log

Selecting **Maintenance Log** from the **System** menu displays the **Maintenance Log** window. An up-to-date chronological list of maintenance performed on the instrument is displayed. The most recent maintenance actions are listed last.



- **Date:** The date on which the maintenance task was performed.
- **Time:** The time of day on which the maintenance task was performed.
- **User:** The logon designation of the user reporting completion of the maintenance task.
- **Maintenance task:** The completed maintenance task.

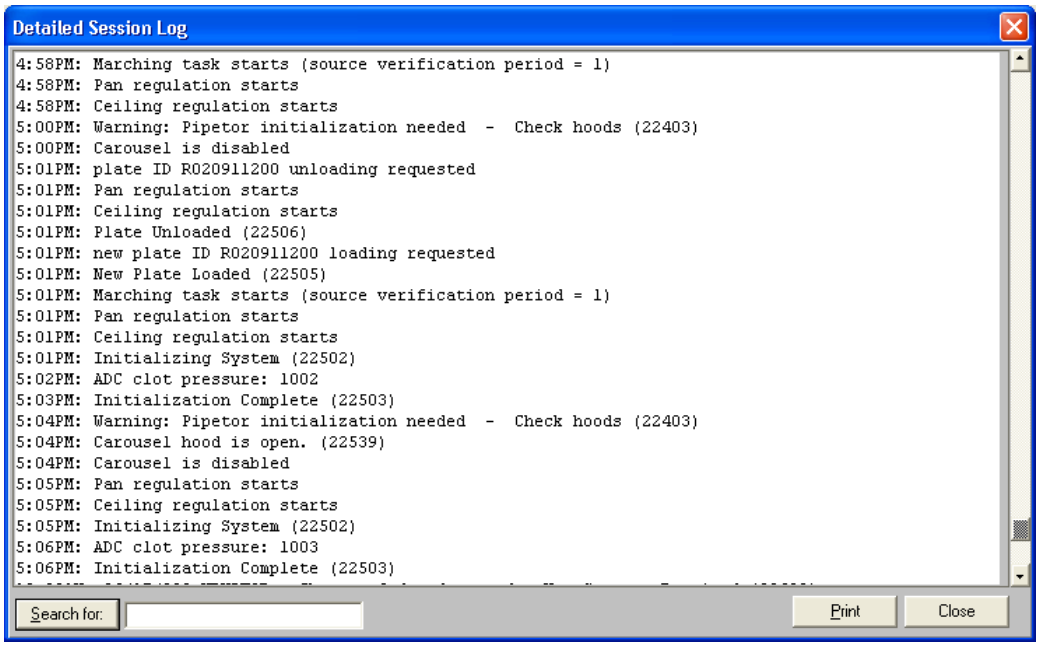
You can report a maintenance task as completed at one of the appropriate maintenance checklists. The date of completion as well as the user logon designation is written to the maintenance log.

You can print the entire maintenance log file by selecting **Print**.

You can use a keyword to search the maintenance log by selecting **Search for**.
The keyword is highlighted in the list. Keep selecting **Search for** if the keyword appears several times. This feature is useful when the log file consists of many pages and you want to find a maintenance task quickly.

3.5. Session Log

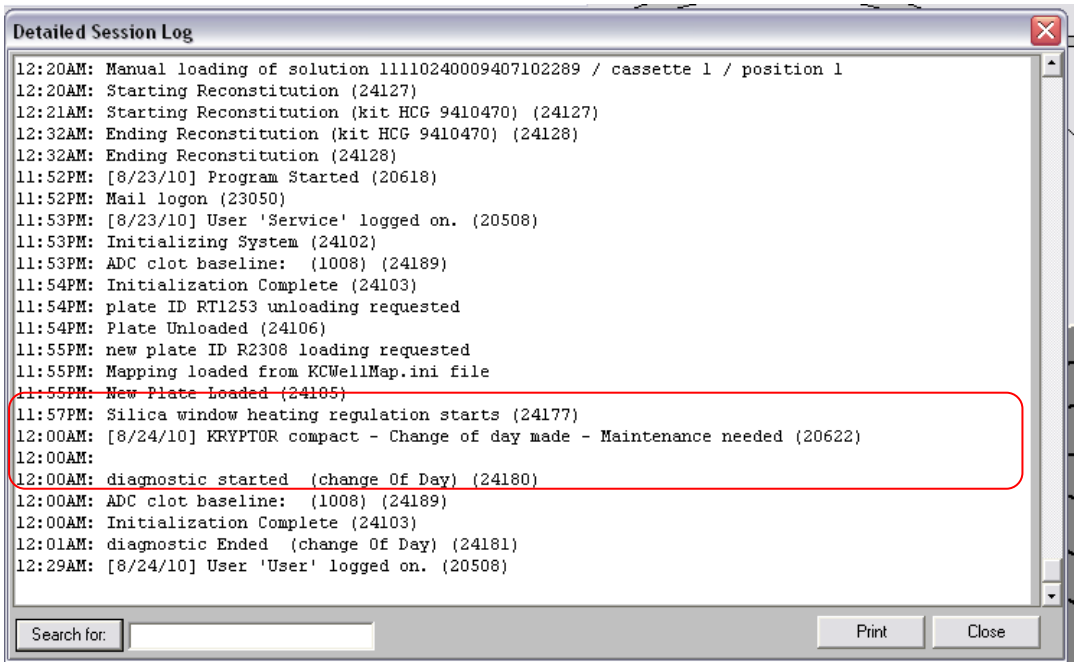
Selecting **Session Log** from the **System** menu will open the **Detailed Session Log** window. This window displays all B·R·A·H·M·S KRYPTOR compact PLUS actions and error messages or warning messages, which have occurred in the system since it was switched on. The list is sorted by date, with the most recent message listed last.



You can print the entire session log file by selecting **Print**.

By entering a keyword and selecting **Search for** you can search the session log for single error messages.

An empty line is inserted after each change of day in order to ensure a quicker analysis of the problems faced every day.

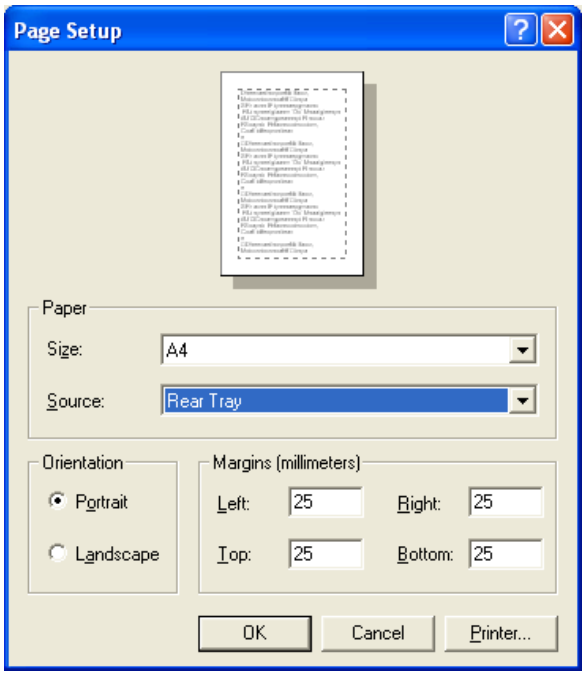


3.6. Service Diagnostics

This function is only accessible when you are logged on as **Service**.

It is used for the B·R·A·H·M·S KRYPTOR compact PLUS diagnosis by the service technicians.

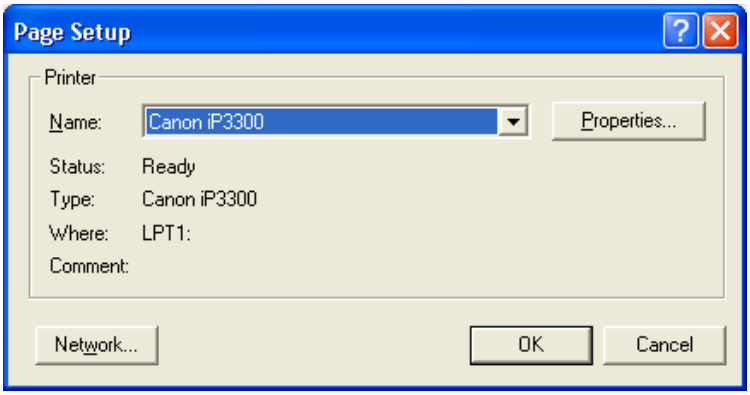
3.7. Printer Setup



This window enables you to choose the printer via the select button: 

.

See the following example:



Select **OK** to validate the choice.

When the printer is selected, it is possible to modify:

- The paper size
- The page format (Portrait or Landscape)
- The document margins

To print, click on **OK** once the printer configuration is completed.

4. Data Menu

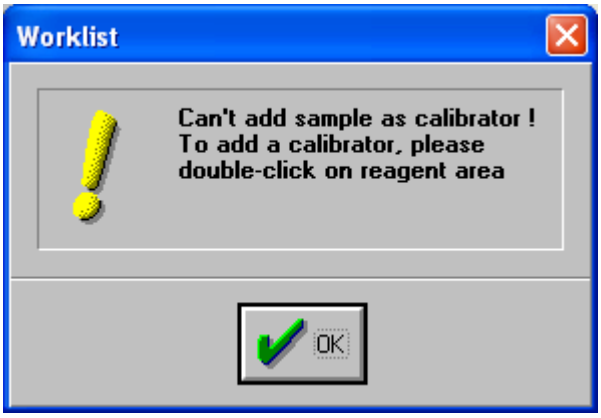
4.1. Managing the Worklist

The worklist enables you to register patient samples and controls you want to perform.
It is possible to register a sample with or without barcode identification.
In the first case, you only need to indicate the sample ID, because the system automatically recognizes the sample in the sample tray.
In the second case, you have to register the cassette ID and the tube cassette position.

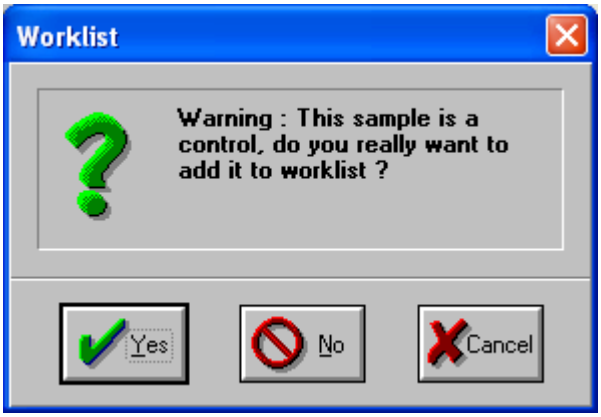
Restrictions:

1. It is forbidden to use the "_" sign (which is specific to the calibrator) while adding a sample. The purpose is to prevent sampling errors due to differences in tip position, depending on the type of pipetted tube: sample or calibrator.

   A notification message indicates that the calibrators will only be included into the work list when you double-click on the reagent area. For further information on the registration of a calibrator into the work list, please refer to the following chapter:
   4.1.1. Add a Calibrator to the Work List



2. A notification message is displayed on screen if the sample ID corresponds to a control ID. This message requires the user to confirm such a registration. For further information on the registration of a control into the work list, please refer to the following chapter:
   4.1.2. Add a Control to the Work List

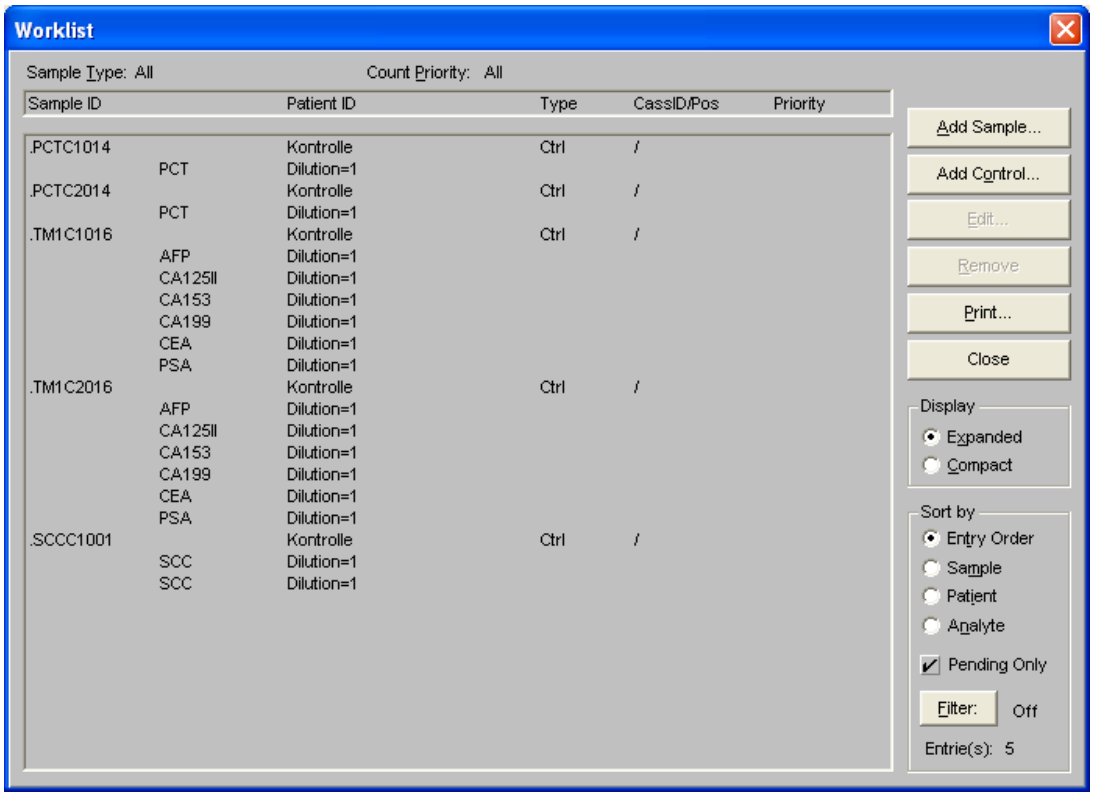


3. It is forbidden to use the "R" sign (which is specific to the reaction plate) while adding a sample.

   Cause the system recognizes a sample starting with "R" as a reaction plate. The following notification message appears:

Selecting **Worklist** from the **Data** menu displays the **Worklist** window.

This command is also available from the icon  or with **F5**.



The following features are available on the **Worklist** window:

- Add a sample or add a control.
- Edit a sample.
- Print a work list: The work list is printed in the same order as it is displayed.
- Remove samples, controls or calibrators from a work list: Select a line in the work list and remove a sample, a calibrator or a control (Only possible in compact view).
- Display the work list in expanded or compact format.
- Display the work list sorted by various options like Entry Order, Sample ID (ascending order), Patient Name (control or calibrator), Analyte or showing still pending samples.
- Filter options: Select a filter from the list of sample type and count priority.

4.1.1. Add a Calibrator to the Work List

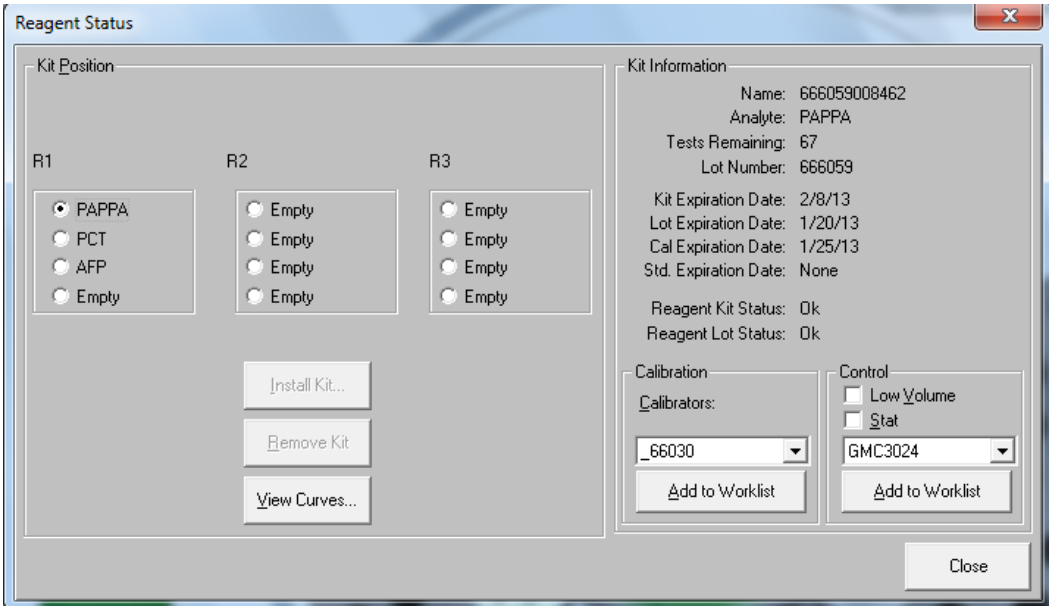
A calibration curve is used to convert the B·R·A·H·M·S KRYPTOR compact PLUS response to an antigen concentration.

A factory curve is associated with a particular lot of reagent; factory curves differ from various reagent lots of the same analyte due to the slight manufacturing variation between the different lots. Parameters defining the factory curve are downloaded to the B·R·A·H·M·S KRYPTOR compact PLUS software when registering a new lot of reagent.

Each reagent lot must be calibrated before first use and every 7 or 15 days thereafter depending on the parameter.

When double-clicking on the reagent area or selecting **Reagents** in the **Instrument** menu, the **Reagent Status** window is displayed.

Select the kit to be calibrated.

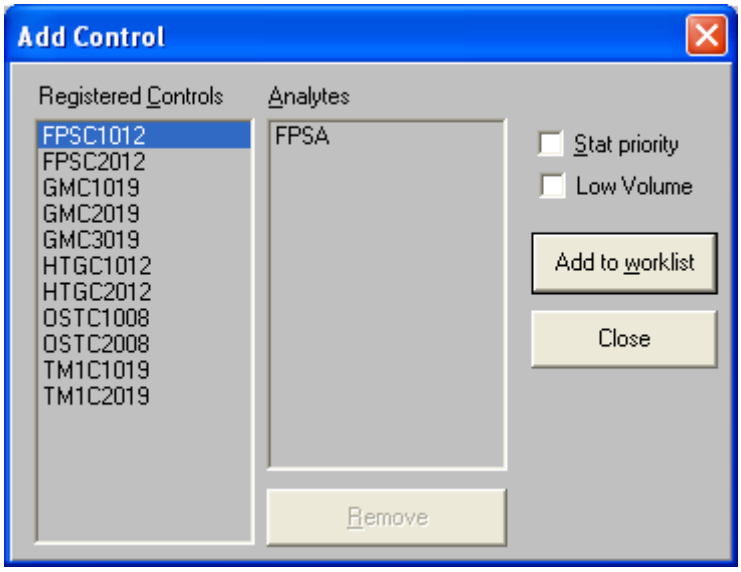


To choose a calibrator lot :

- ✓ Select the drop-down arrow in the **Calibrator** window
- ✓ Choose a calibrator lot from the list
- ✓ Select **Add to Worklist** and confirm with **OK** and **Close**
- ✓ Place the calibrator vial on a sample cassette in the sample carousel
- ✓ Close the hood and start the instrument

4.1.2. Add a Control to the Work List

To add a control to your work list, select **Add Control** in the **Worklist** window; the **Add Control** window is displayed.



Select a registered control from the left list. All parameters which can be measured in this control are shown on the right analyte list.

To launch an control as an urgent sample, use the **Stat priority** button. The control runs as a priority. If you have a control in a low-volume tube, mark the **Low Volume** check box.

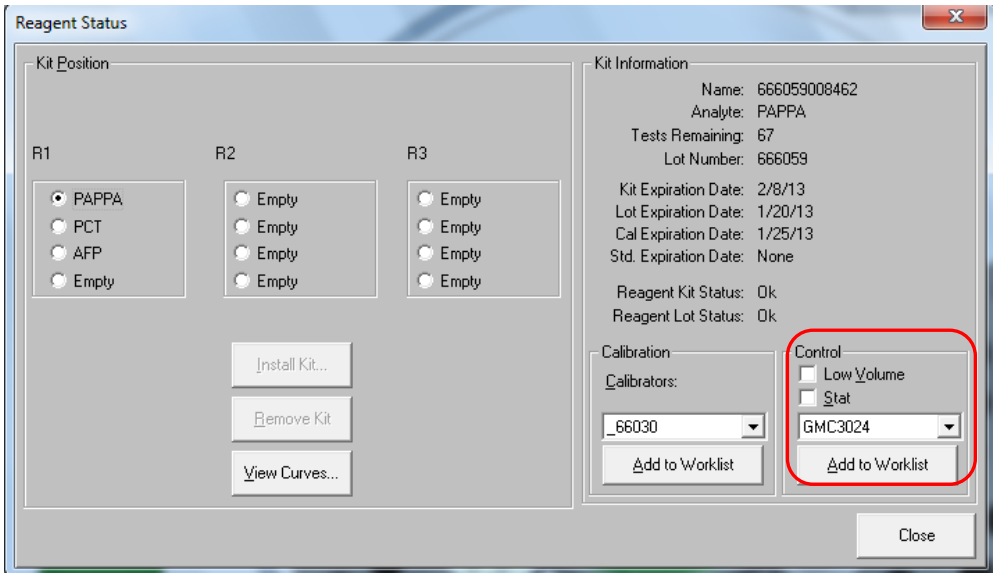
Then select **Add to Worklist** and **Close**.

If you do not want to measure all the relevant parameters, you can remove one or more from the list. To remove an analyte, select one or more analytes from the list with the keyboard **Ctrl** button. Select **Remove** and then select **Add to Worklist** and **Close**.

Add a control to be tested on specific reagent kit

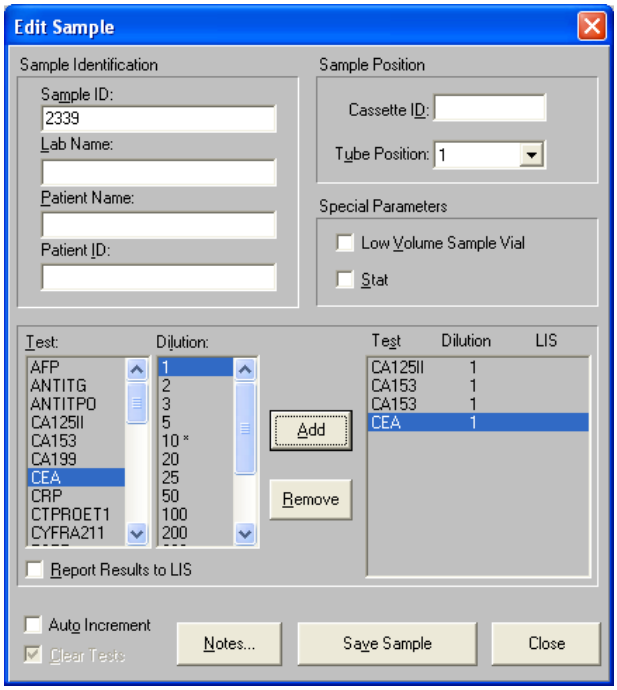
- ✓ Double click on the kit which should be used to measure the controls
- ✓ Select **control lot** from the drop-down arrow list
- ✓ Select **Low volume** and/or **Stat** for this control
- ✓ Click on **Add to worklist**, **OK**, **Close**.

In case of multi-parameters controls, only the control associated to the selected kit will be run.



4.1.3. Add a Sample to the Work List

To add a sample to your work list, select **Add Sample** in the **Worklist** window. The **Edit Sample** window is displayed.



To launch an urgent sample, use the **Stat** button. The sample runs as a priority.
If you have a sample in a low-volume tube or vial as in the case of pediatric samples, mark the **Low Volume Sample Vial** check box.

When you select **Auto Increment**, the system automatically increments the sample ID by one digit when you select **Save Sample**.

You can enter sample notes by selecting **Notes**.

To transfer a relevant result to HOST, select **Report Results to LIS** before adding the parameter to the test list.

Barcoded sample tubes

You need to enter the following information for each sample to create a work list.

- ✓ Enter the sample ID number which corresponds to the barcode label of the tube.
- ✓ Select a test from the left displayed list.
- ✓ Select a dilution factor for the test and **Add** (1 is the default dilution factor). If you want to run replicates, just press **Add** the appropriate number of times.
- ✓ If you want to remove a test, select it from the right list and then click on **Remove**. When you have finished registering the sample, select **Save Sample**.
- ✓ When all the samples have been defined, select **Close**.

Non-bar-coded sample tubes

- ✓ Enter in addition to the above mentioned information the sample cassette ID (A, B, …) and the sample tube position in the cassette (1-16) on the **Edit Sample** window.

  Make sure that you place the samples in the correct position on the sample cassette as defined in the work list.
- ✓ Place the cassette in the sample carousel.
- ✓ Close the hood and start the instrument.

Modify a sample request

- ✓ First press the **Pause** button.
- ✓ Select **Worklist** in the **Data** menu, remove  from the **pending only** field and select the sample.
- ✓ Click on **Edit**. The **Edit Sample** window is displayed.
- ✓ Add the parameter to the test list.
- ✓ Select **Report Results to LIS** if you want to transfer the result to HOST after processing.
- ✓ Select **Save** and **Quit** after any modifications.
- ✓ The sample ID cannot be modified.
- ✓ Neither is it possible to edit a sample during the pipetting process.

4.2. Result Validation

Once the calibrator, control and/or samples have been processed in the current run, you can validate the result on the **Results** window.

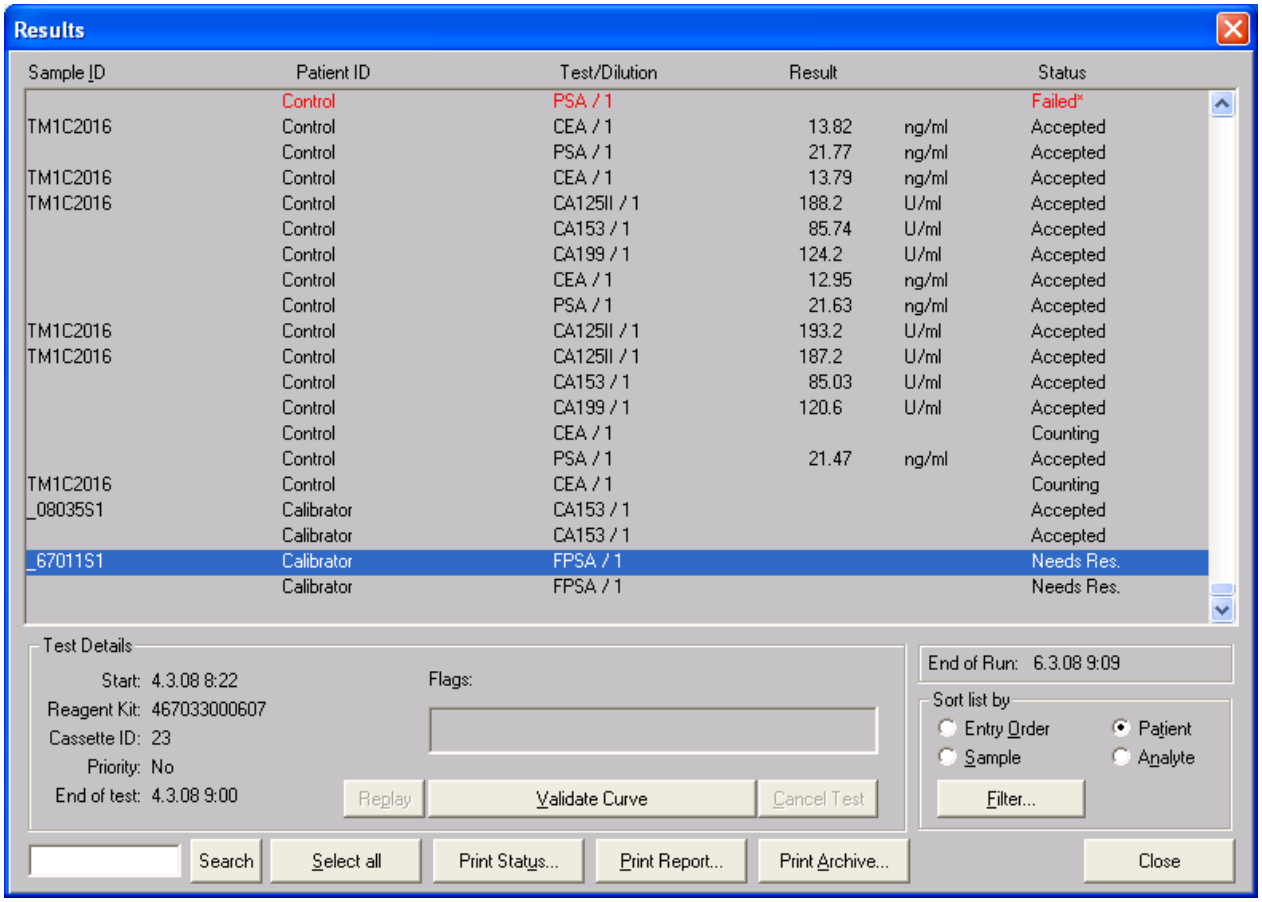
To display the results window, select **Results** from the **Data** menu.

This command is also available from the icon  or **F6**.

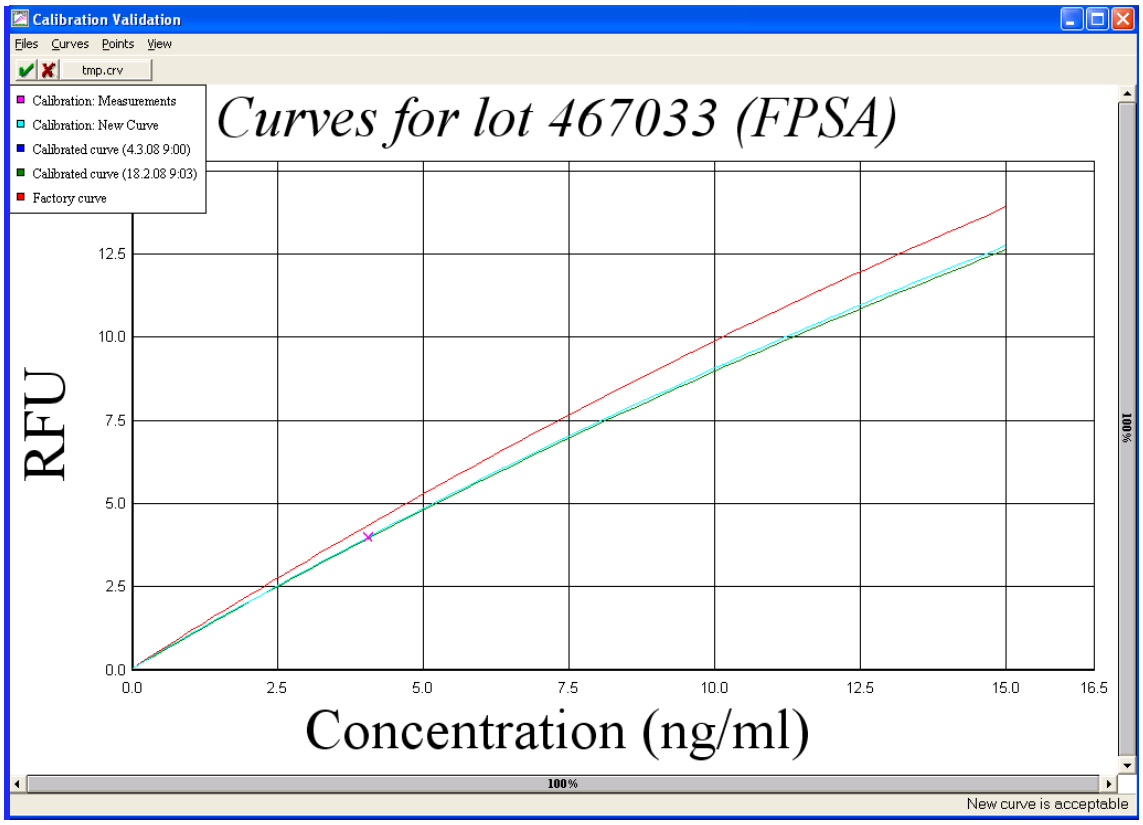
All the results of previously finished tests are shown here.
The **Results** window allows you to look at the results, to validate them and to obtain information about the status of processed samples.

4.2.1. Calibration Validation

To accept the calibration, select the calibration result and click on **Validate Curve**.



The **Calibration Validation** window is displayed together with the factory curve and the 3 previous calibrations.



The calibration curves displayed in the curve utility always have the same colors, based on the order of calibration:

Factory curve	Red
First calibration curve	Green
Second calibration curve	Dark blue
Third calibration curve	Light blue
Calibration points	Magenta

When more than 3 calibrations are performed on the same reagent lot, the colors are assigned as the same.

Validate the curve

When the **New curve is acceptable** message is displayed on the right bottom in the status bar, you need to accept the calibrated curve by clicking on the  icon.
The status bar message explains this icon.

A newly accepted calibration curve replaces any previous calibration curve for the same reagent lot. When a new curve is accepted, the user can no longer go back to the previous curve for the sample concentration calculation.

A curve can be rejected even if it was accepted by B·R·A·H·M·S KRYPTOR compact PLUS on the user's responsibility.

Reject the curve

If the message bar indicates that the curve is rejected, the icon  is not accessible. This can occur if

- the measured calibration deviates too much from the factory curve,
- one of the replicates is missing,
- the ratio of the t0 measurement in both channels is out of range,
- the corresponding CV is too high,
- the CV of duplicates is too high or
- the CV is out of range.

The criteria for automatically accepting or rejecting are software defined.

✓ Click on the  icon.

✓ Rinse the instrument by pressing **Instrument**, **Prime**.

✓ Clean the reader head window (see **3.3.1 Daily Maintenance**)

✓ Repeat the calibration.

Print the curve

✓ To print the current curve, click on **F8** or **Reagent Lot Manager** and select the corresponding curve.

✓ Click on **View curve**.

✓ Select **File** menu and **Print**.

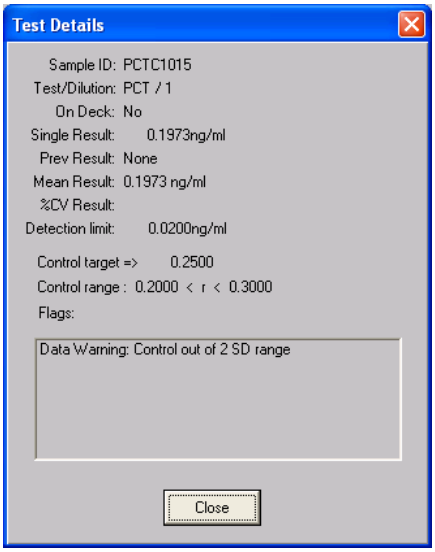
Once the new curve is accepted, it replaces the last calibration curve. It means that you can't come back to the previous curve for the sample result calculation.

4.2.2. Control Validation

Results for controls are automatically accepted, when they are within the defined control range and automatic validation is activated in menu **Administration/Preferences**. For further details on this function, please refer to the **Chapter 7.9 Preferences**.

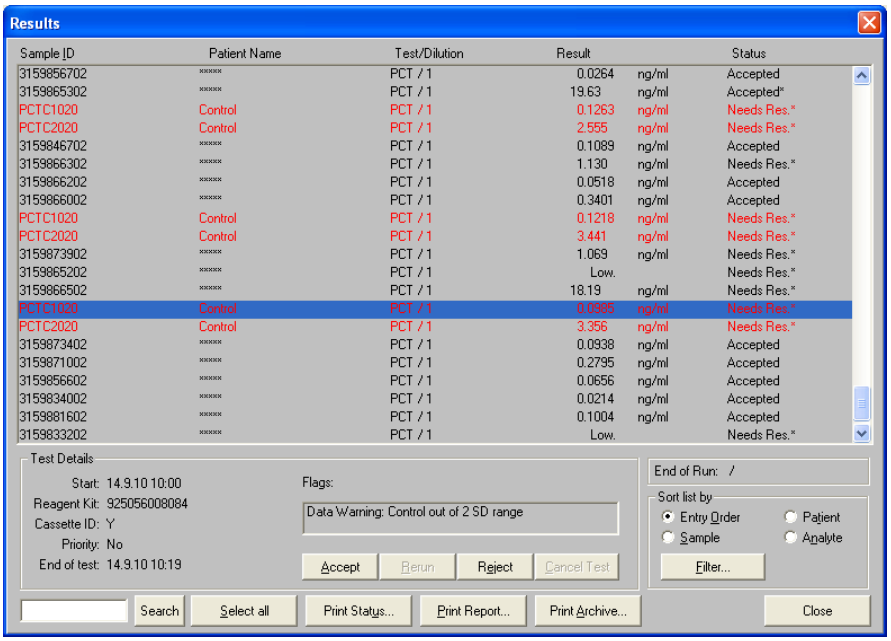
If an error occurs a flag is shown on the **Flags** area. Check the associated flag and accept, cancel and / or rerun your QC.

In the results list, double-clicking on a control result will open a detail window containing information defined in the QC program (Target value, control range, control result etc.)..



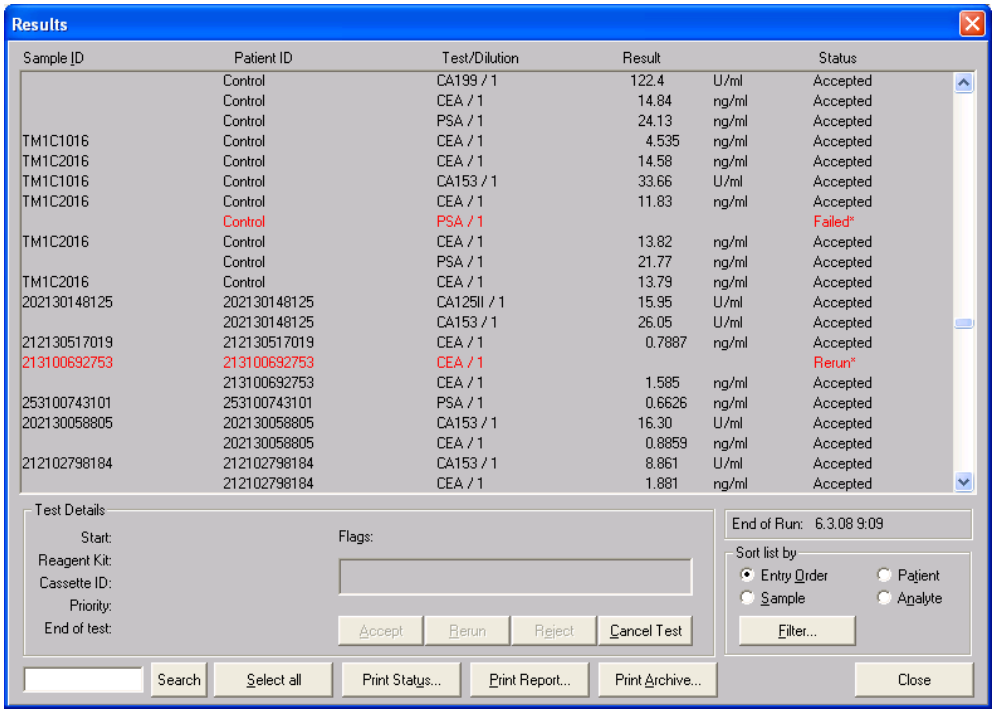
The controls are flagged above or below normal (+/-2 SD), according to the defined control range. In this case, the "Data Warning: Control out of 2 SD range" message is displayed.

The result is highlighted in red on screen.



Your acceptance of the control result which **Needs Resolution** will send the result automatically to the **KRYPTOR compact PLUS QC Utility**.

4.2.3. Sample Validation



When samples are processed, most of the results are listed as accepted in the status column of the **Results** window if automatic validation is activated in menu **Administration/Preferences**. For further details on this function, please refer to the **Chapter 7.9 Preferences**.

If an error occurs and a flag is shown on the **Flags** area, it is up to the user to accept or reject the result.

Following flags are marked in red color in the result list.

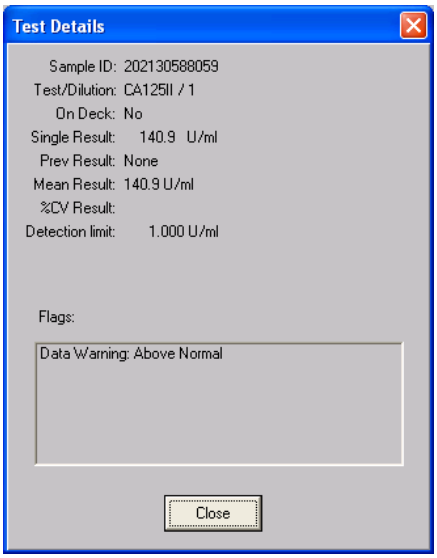
T1	System Error: Reaction plate position	**T18**	System Error: Pipetting in Reaction Area
T3	System Warning: Incubator Out Of Range	**T19**	System warning: Heated tip out of range
T4	System Error: Missed Reading	**T33**	Data Warning: Abnormal
T6	System Error: Insufficient Sample Volume	**T42**	Concentration not consistent with dilution used
T13	System Error: Clot Detected	**T43**	Sample pipetting problem - check sample
T14	System Error: Pipetting in Sample Area	**T44**	Data warning: abnormal kinetics
T15	System Error: Pipetting in Dilution Area	**T48**	Data Warning: out of 2 SD range
T16	System Error: Pipetting in Reagent Area	**T51**	Inconsistent incubation time

If a result needs to be validated by the user, select a line in the result list with **Needs Resolution** status and select **Accept** according to the flag.

Regarding Mean result: the mean value is not calculated if one of the result is flagged “below detection limit” or “Above Max Range”. Besides this observation only the “accepted” and “Needs. Resol” tests are used for mean calculation.

For out of range or unreliable results, re-run or redilution is automatically triggered by B·R·A·H·M·S KRYPTOR compact PLUS.

To obtain further information on a result, double-click on the corresponding line in the result list. A pop-up window shows all the information about the sample and the corresponding flags.



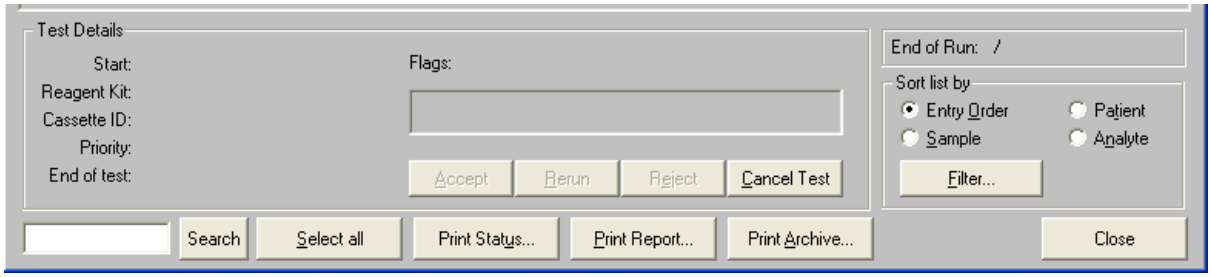
Reject a result by selecting a line in the result list and selecting **Reject**.

To cancel a test, select the blue **Pause** button on the front of the system, then select the line and click on **Cancel Test**.
This option is possible only for pending or running tests.

From the results list, you can print the
4.2.5.1 Sample Status Report or the
4.2.5.2 Sample Results Report respectively.

4.2.4. Result window features

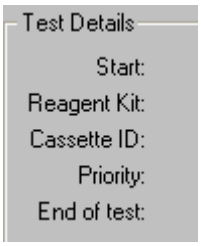
In the result list you will find several information about your tests and you have the possibility to search for results and sort results in the way you want to the view.



If you want to select all the tests in the result list, choose **Select all**.

Information about End of test:

An **End of Test** prediction is possible in the result list. This indication is updated each time the **Results** window is opened during the run.

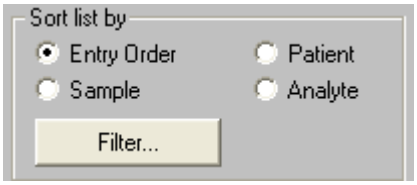


The **End of Run** prediction shows the end of the completed run. This indication is updated each time the **Results** window is opened during the run.

Search function:

By adding a search term in the window on the left hand side on the bottom of the result window and click on Search button, you can search for a defined sample.

Sort and filter function:

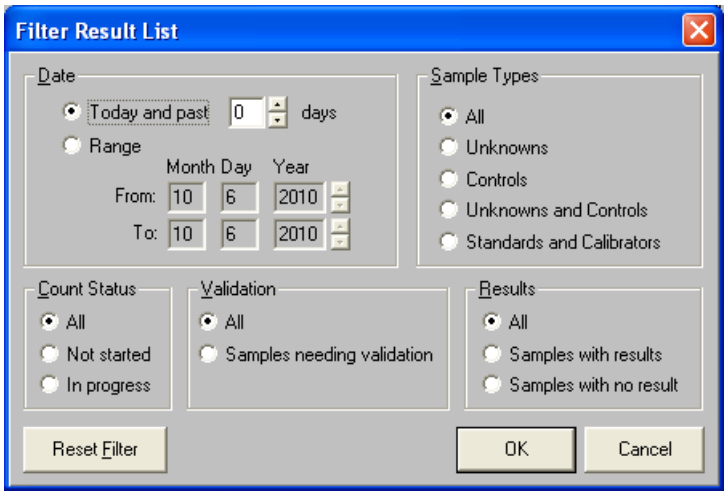


You can choose the order of sorting the results as followed:

- **Entry order:** Results are sorted in the order as added to the Worklist (first entry on the top of the list, last entry on the bottom of the list).
- **Sample:** Result list is sorted by the column Sample ID
- **Patient:** Result list is sorted by the column Patient ID
- **Analyte:** Result list is sorted by the column Test/Dilution in alphabetical order

The filter function enables you to choose the time period of results shown in the result list and to choose a selection what kind of results you want to see in these list.

Default settings of the **Filter Result list** are as followed:



In the section **Date/Today and past** you can choose a time period of results you want to see in the result list .

- **0** = only today
- **1** = today and yesterday

…

In the section **Range** you can choose a defined day or time period by date range

In section **Sample Types** you can choose which type of sample you want to see in the result list

- **All** = All results are shown
- **Unknowns** = Only patient results are shown
- **Controls** = Only control results are shown
- **Unknown and Controls** = Only patient and control results are shown
- **Standards and Calibrators** = Only calibrator results are shown

In section **Count Status** you can choose the measuring status of sample you want to see in the result list

- **All** = All results are shown
- **Not started**= Only pending orders are shown
- **In progress**= Only samples in counting or detection status are shown

In section **Validation** you can choose the validation status of sample you want to see in the result list

- **All** = All results are shown
- **Samples needing validation=** Only samples with status “needs resolution” are shown

In section **Results** you can choose if you want to see samples with or without result in the result list

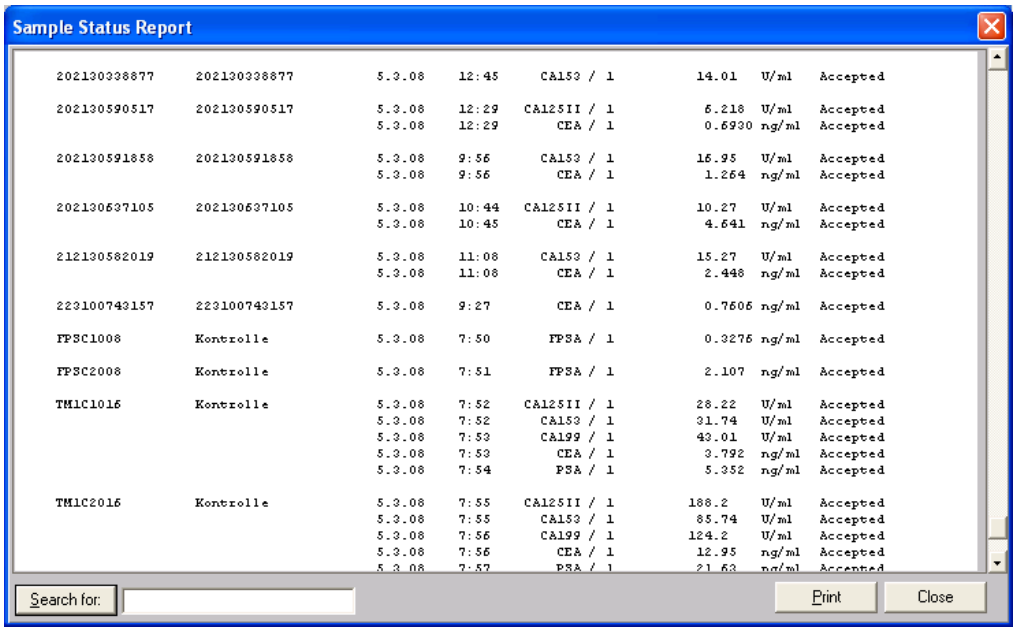
- **All** = All results are shown
- **Samples with result** = only samples with result are shown
- **Samples with no result** = only samples without result are shown

4.2.5. Print Reports

4.2.5.1. Sample Status Report

In the **Sample Status Report**, the selected tests are printed without associated flags.

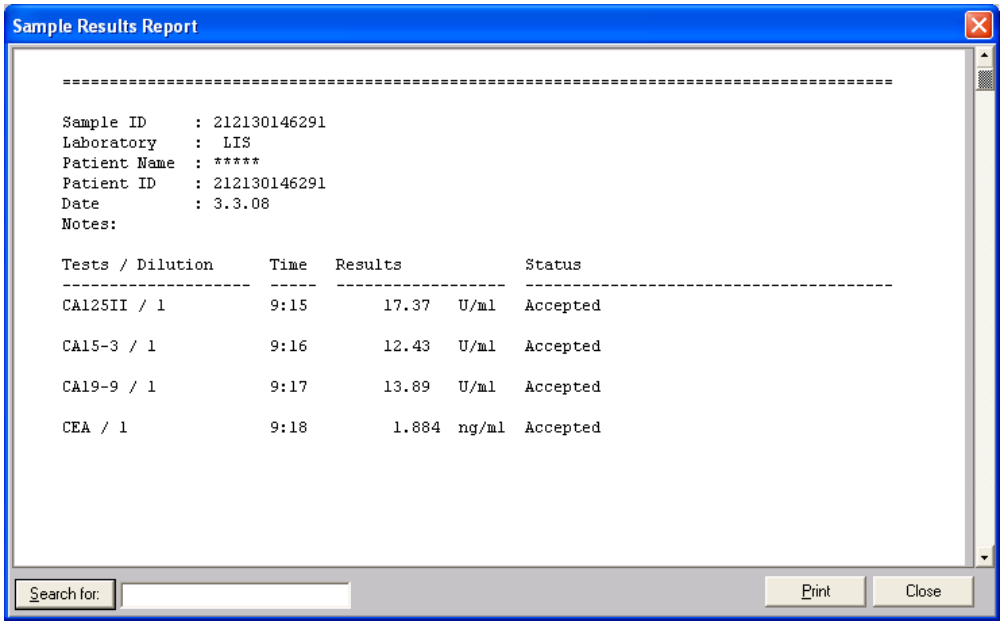
Select **Print Status** and then **Print** for a hardcopy or **Disk File**, choose the path and define a name for the file to save data in text file format (.txt).



4.2.5.2. Sample Results Report

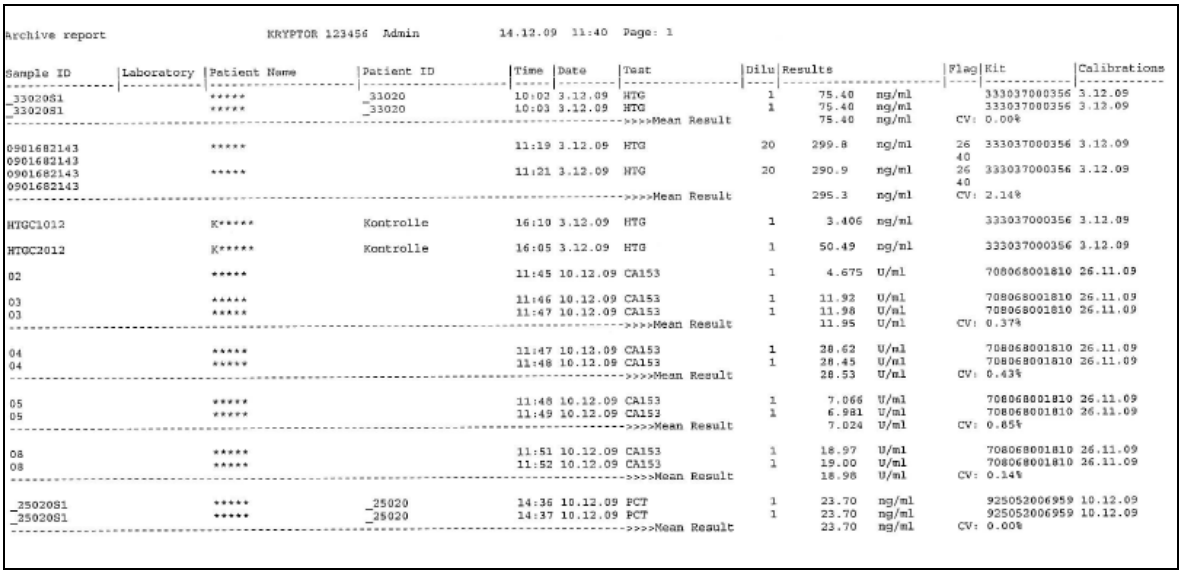
The **Sample Results Report** will provide a print-out of chosen sample IDs with the associated flags. The **Results List** must therefore be sorted by **Entry Order**.

Select **Print Report** and then **Print** for a hardcopy or **Disk File**, choose the path and define a name for the file to save data in text file format (.txt).



4.2.5.3. Archives

Select **Print Archive** and then **Print** for a hardcopy or **Disk File**, choose the path and define a name for the file to save data in text file format (.txt).



Archive report KRYPTOR 123456 Admin 14.12.09 11:40 Page: 1

Sample ID	Laboratory	Patient Name	Patient ID	Time	Date	Test	Dilu	Results		Flag	Kit	Calibrations
_33020S1		*****	_31020	10:02	3.12.09	HTG	1	75.40	ng/ml		333037000356	3.12.09
_33020S1		*****	_33020	10:03	3.12.09	HTG	1	75.40	ng/ml		333037000356	3.12.09
						>>>>Mean Result		75.40	ng/ml	CV:	0.00%	
0901682143		*****		11:19	3.12.09	HTG	20	299.8	ng/ml	26 40	333037000356	3.12.09
0901682143 0901682143 0901682143		*****		11:21	3.12.09	HTG	20	290.9	ng/ml	26 40	333037000356	3.12.09
						>>>>Mean Result		295.3	ng/ml	CV:	2.14%	
HTGC1012		K*****	Kontrolle	16:10	3.12.09	HTG	1	3.406	ng/ml		333037000356	3.12.09
HTGC2012		K*****	Kontrolle	16:05	3.12.09	HTG	1	50.49	ng/ml		333037000356	3.12.09
02		*****		11:45	10.12.09	CA153	1	4.675	U/ml		708068001810	26.11.09
03		*****		11:46	10.12.09	CA153	1	11.92	U/ml		708068001810	26.11.09
03		*****		11:47	10.12.09	CA153	1	11.98	U/ml		708068001810	26.11.09
						>>>>Mean Result		11.95	U/ml	CV:	0.37%	
04		*****		11:47	10.12.09	CA153	1	28.62	U/ml		708068001810	26.11.09
04		*****		11:48	10.12.09	CA153	1	28.45	U/ml		708068001810	26.11.09
						>>>>Mean Result		28.53	U/ml	CV:	0.43%	
05		*****		11:48	10.12.09	CA153	1	7.066	U/ml		708068001810	26.11.09
05		*****		11:49	10.12.09	CA153	1	6.981	U/ml		708068001810	26.11.09
						>>>>Mean Result		7.024	U/ml	CV:	0.85%	
08		*****		11:51	10.12.09	CA153	1	18.97	U/ml		708068001810	26.11.09
08		*****		11:52	10.12.09	CA153	1	19.00	U/ml		708068001810	26.11.09
						>>>>Mean Result		18.98	U/ml	CV:	0.14%	
_25020S1		*****	_25020	14:36	10.12.09	PCT	1	23.70	ng/ml		925052006959	10.12.09
_25020S1		*****	_25020	14:37	10.12.09	PCT	1	23.70	ng/ml		925052006959	10.12.09
						>>>>Mean Result		23.70	ng/ml	CV:	0.00%	

4.3. QC Function

This enables you to register new controls and to monitor you QC results process.

To open the QC program, select **Data** / **QC Functions**, the icon  or **F7**.

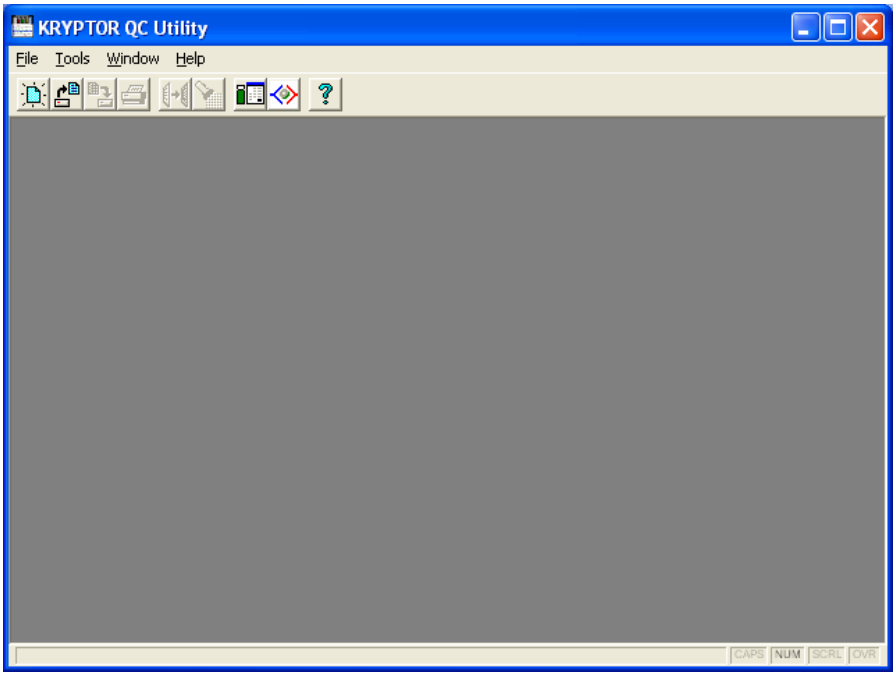
You can work with the QC program and the B·R·A·H·M·S KRYPTOR compact PLUS software at the same time.

This icon  or **Tools / Switch to KRYPTOR**, enables you to switch back to B·R·A·H·M·S KRYPTOR compact PLUS program.

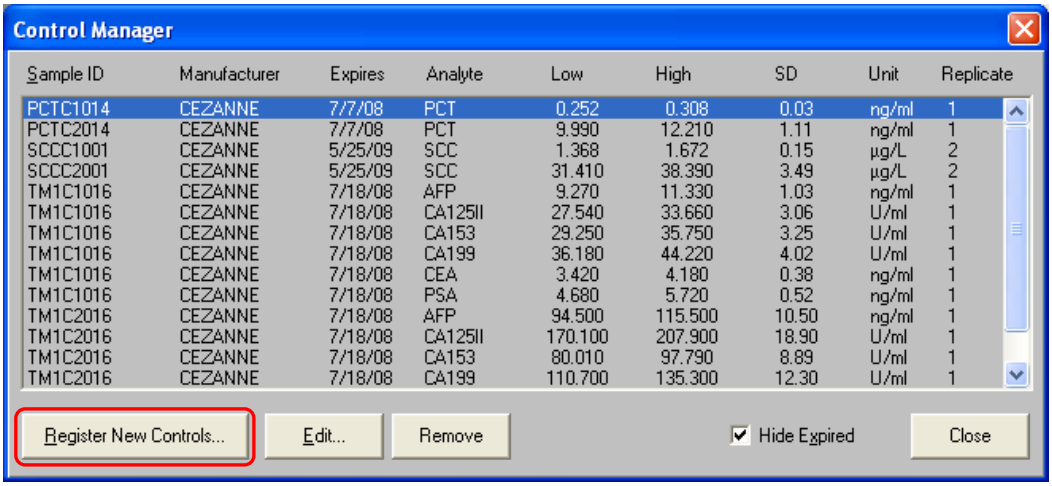
Accepted control results are sent automatically to the QC program, every time the QC program is opened.

4.3.1. Registration of Controls when using default concentration units

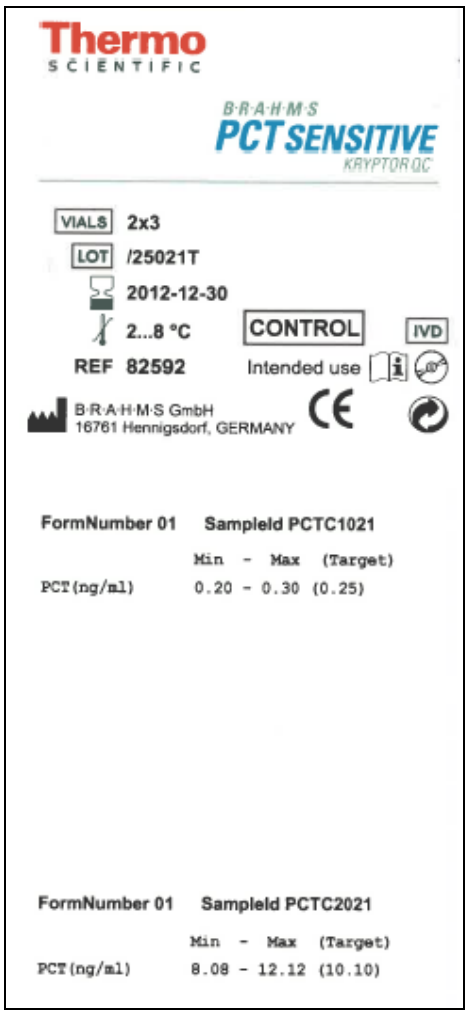
✓ To register new controls, click on the icon  in the KRYPTOR QC Utility window.



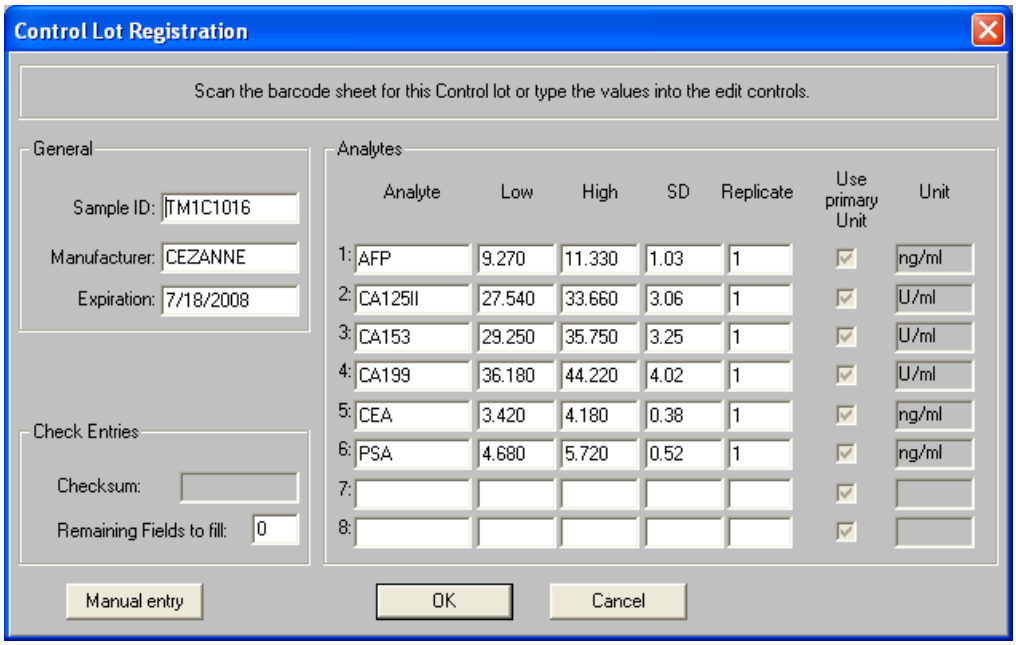
✓ The **Control Manager** is opened and you can click on **Register New Controls**.



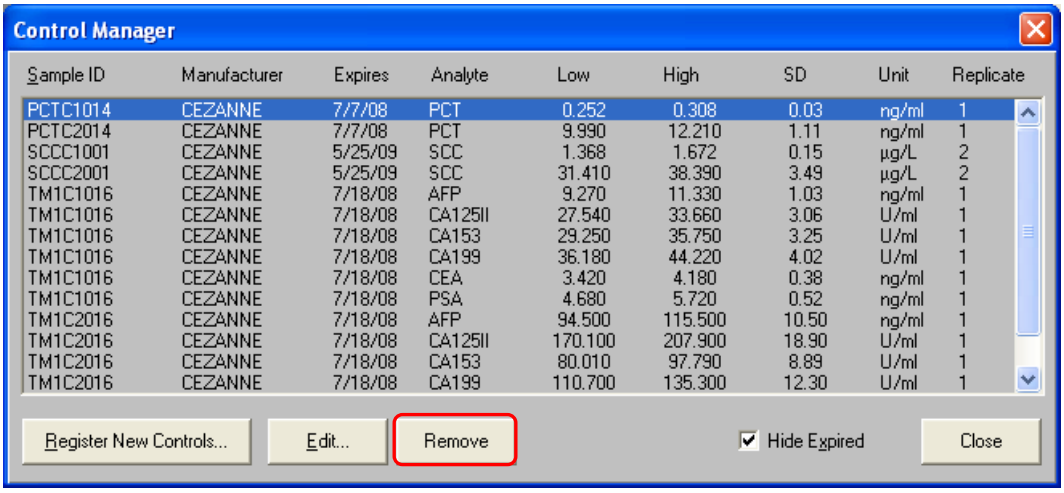
✓ The **Control Lot Registration** window is displayed . Scan one of the barcode labels on the sheet or enter the information manually.



✓ When you have entered or scanned in all of the required information, select **OK** on the **Control Lot Registration** window.



✓ If you do not use an analyte on the instrument you can have to remove it. In the Control manager window select the analyte and then click on **Remove**.

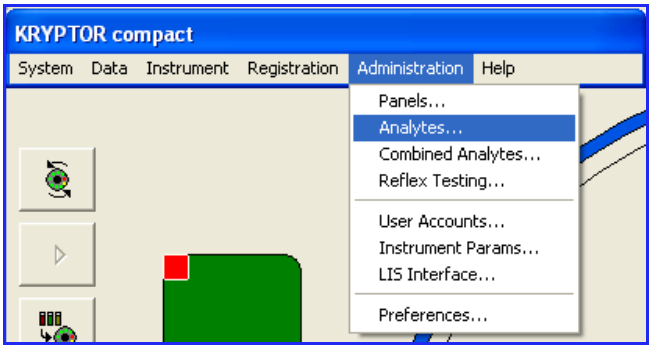


✓ Confirm that you want to remove the analyte for this control with Yes.

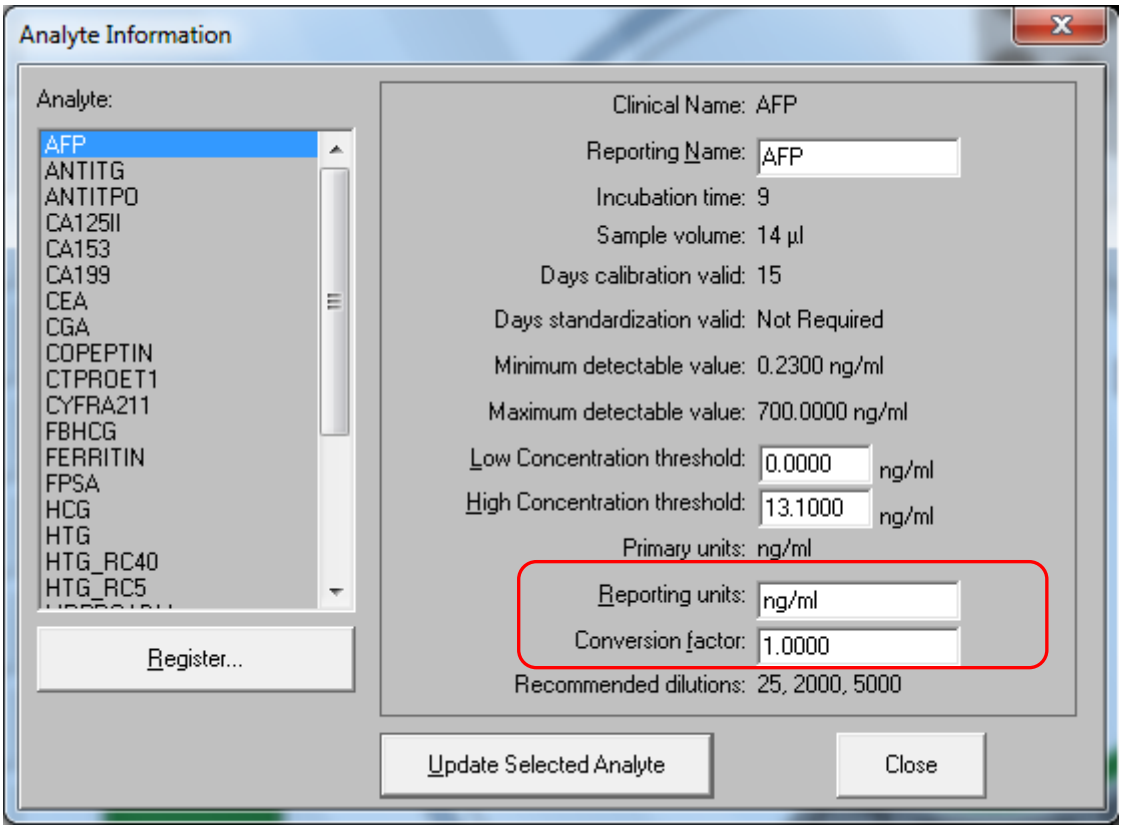
4.3.2. Registration of Controls when using laboratory specific concentration units

✓ Logon in KRYPTOR compact PLUS program under **System / Logon** with **Admin** is necessary

✓ Click in main menu on **Administration** and select **Analytes**



✓ Change the **reporting units** or/and the **conversion factor**



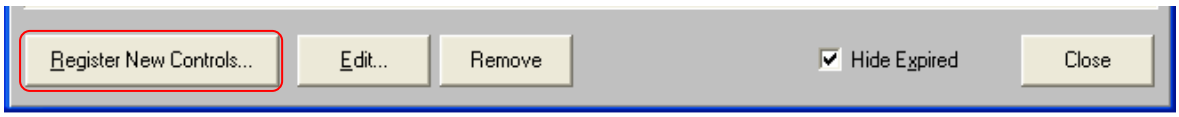
✓ Click on **Update Selected Analyte** and **close** the submenu

Now you have two possibilities to register your quality control

1) Register your new control by using your **Barcode sheet**

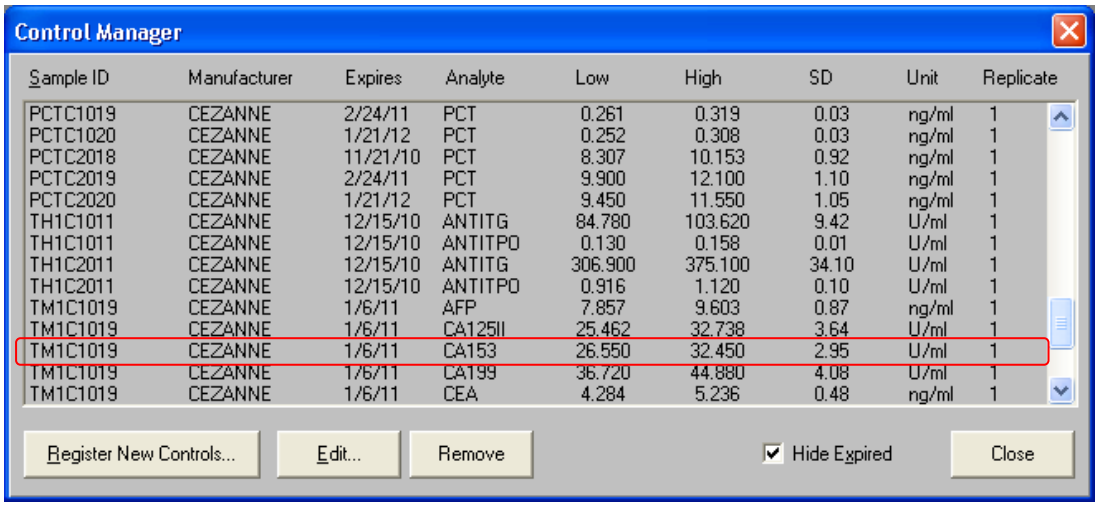
✓ Open the QC program by selecting **Data** / **QC Functions**, the icon  or **F7**.

✓ Click on the icon  in the **KRYPTOR QC Utility** window and select **Register new Controls**



✓ Scan your Barcode sheet and confirm the QC data with **OK**.

The values and units will be automatically recalculated with your appropriate conversion factor

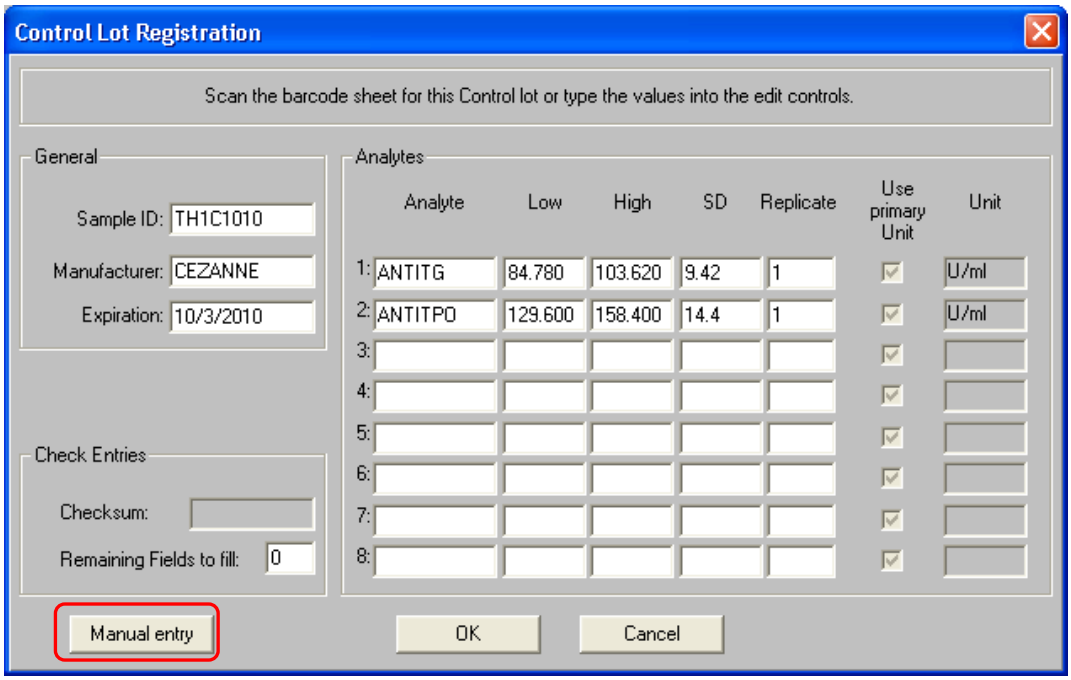


2) Register your new control manually by using **Manual entry**

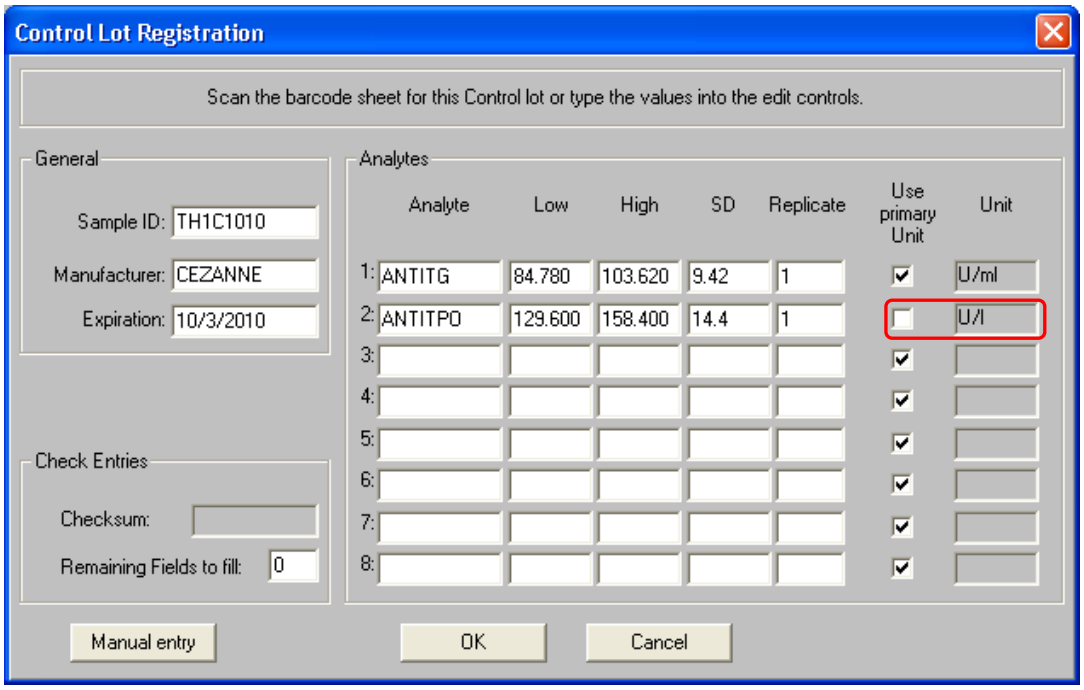
✓ Open the QC program by selecting **Data** / **QC Functions**, the icon  or **F7**.

✓ Click on the icon  in the **KRYPTOR QC Utility** window and select **Register new Controls**

✓ Scan your Barcode sheet and click on **Manual entry**



✓ deactivate the checkbox from your Analyte with your modified Units in **Use primary Unit**

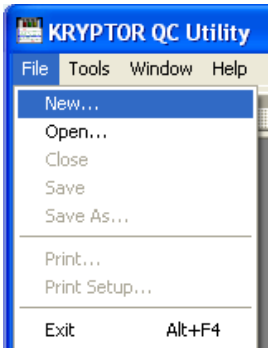


The values will be automatically converted.

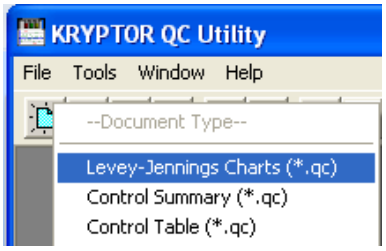
4.3.3. Monitoring of Quality Control Results

Monitoring of your QC results process is available as following when opening the presentation the first time:

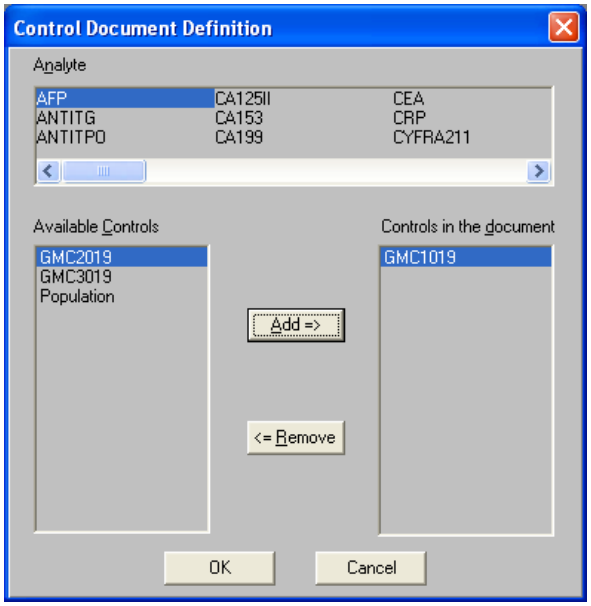
✓ Click on File and New



✓ choose the type of presentation you want to look at (for example, the Levey-Jennings chart).



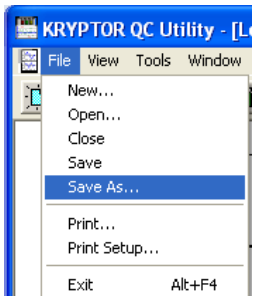
✓ The **Control Document Definition** window is displayed. Select an analyte from the above list, then a control from the left list (**Available Controls**),then **Add**.



✓ Repeat this process for each control you want to add. You can add up to three controls for each analyte.

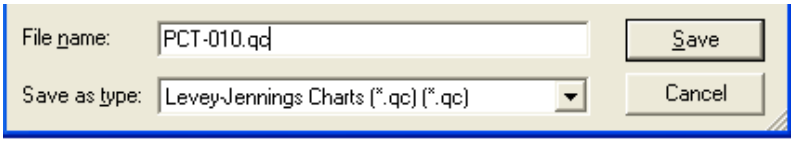
✓ Select **OK**. The selected document is shown

✓ To save the presentation click on **File** and **Save as**.



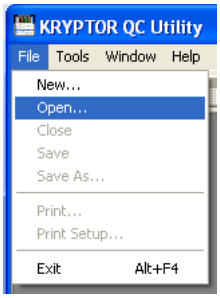
✓ Choose under **Save in** the folder **DataQC**

✓ Enter a name for the file in the **File name** (e.g. PCT-010.qc) entry box, and quit via **Save** to save the document.

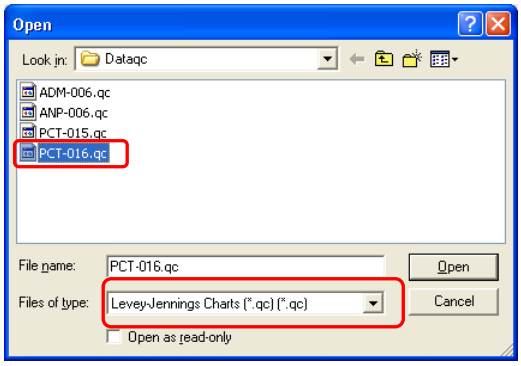


Different formats for the viewing of QC results are available

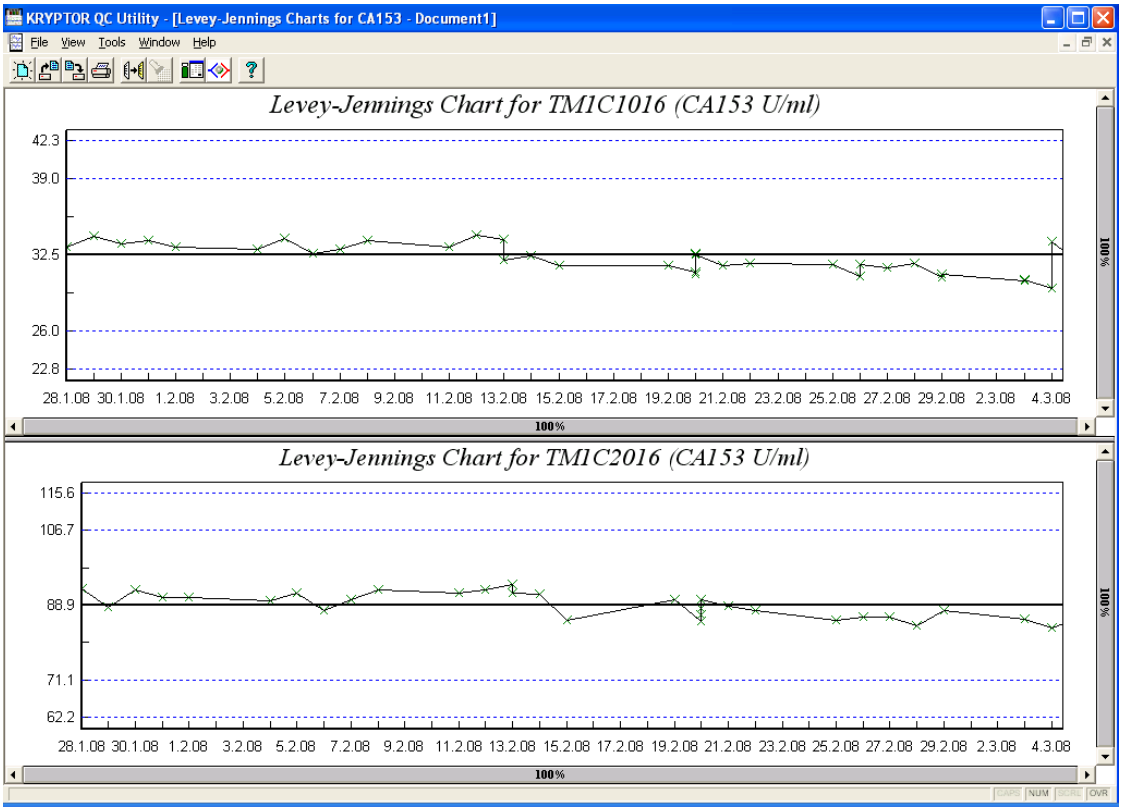
✓ Next time when you want to open the saved presentation again select **File** and **Open** from the QC program menu bar.



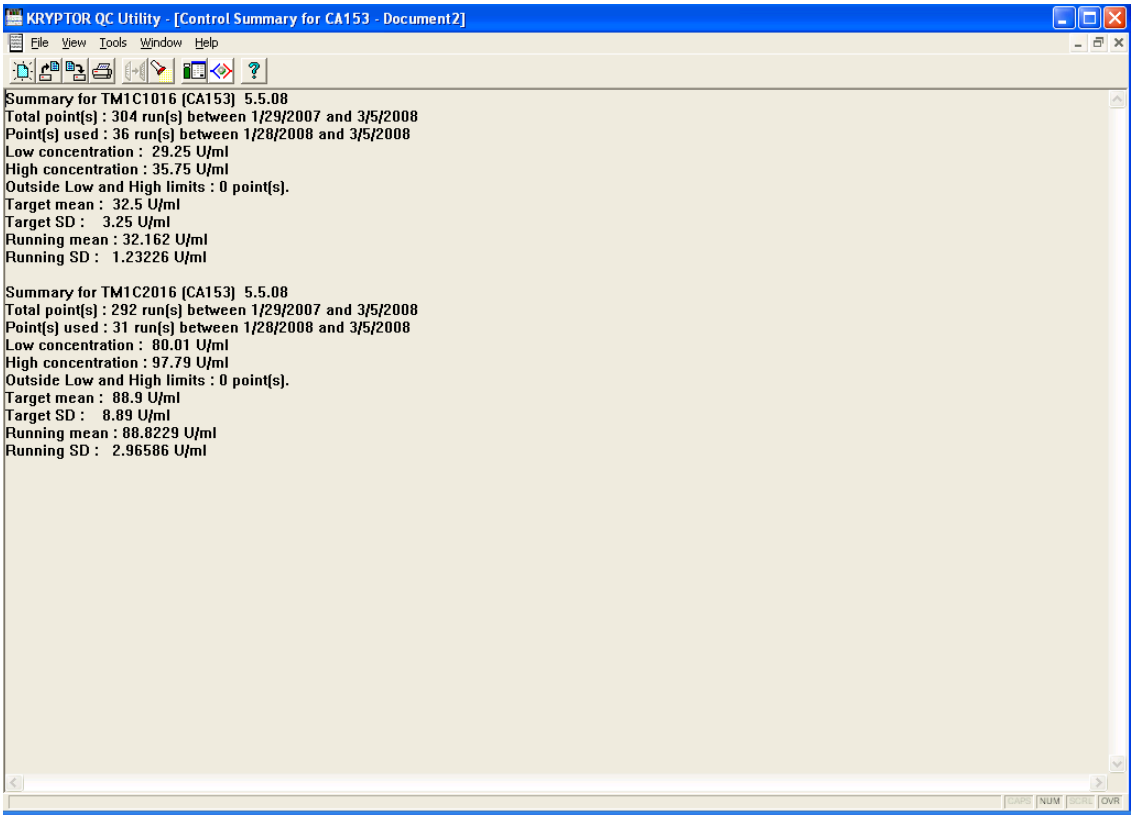
✓ Select the name of the presentation and the type of view you want to see (see examples on next page). Klick on **Open** to show the presentation.



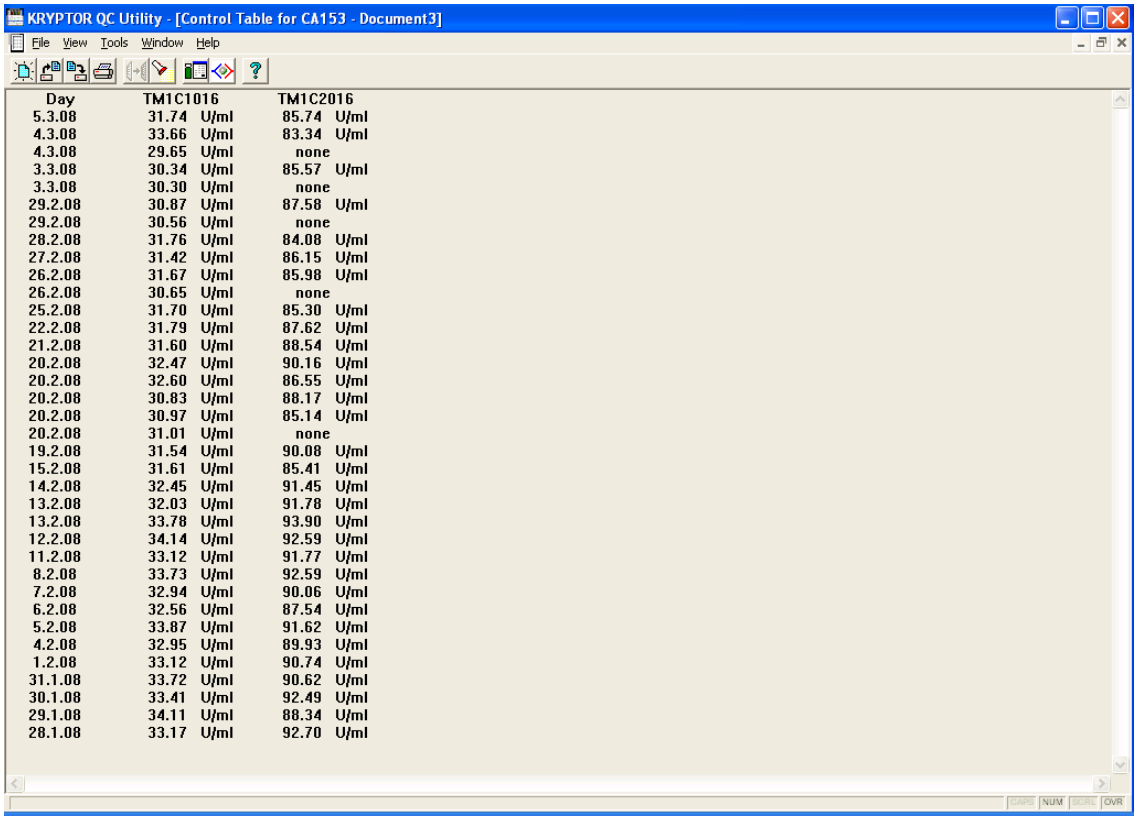
Example of a Levey Jennings chart



Example of Control Summary



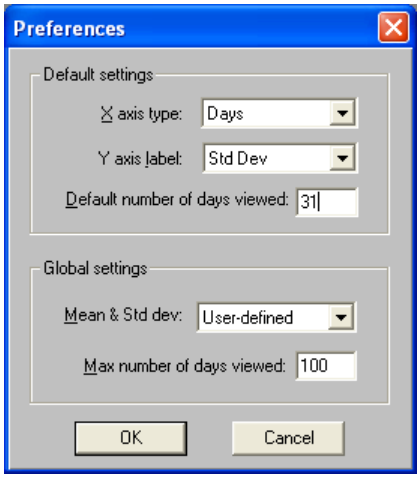
Example of Control Table



Day	TM1C1016	TM1C2016
5.3.08	31.74 U/ml	85.74 U/ml
4.3.08	33.66 U/ml	83.34 U/ml
4.3.08	29.65 U/ml	none
3.3.08	30.34 U/ml	85.57 U/ml
3.3.08	30.30 U/ml	none
29.2.08	30.87 U/ml	87.58 U/ml
29.2.08	30.56 U/ml	none
28.2.08	31.76 U/ml	84.08 U/ml
27.2.08	31.42 U/ml	86.15 U/ml
26.2.08	31.67 U/ml	85.98 U/ml
26.2.08	30.65 U/ml	none
25.2.08	31.70 U/ml	85.30 U/ml
22.2.08	31.79 U/ml	87.62 U/ml
21.2.08	31.60 U/ml	88.54 U/ml
20.2.08	32.47 U/ml	90.16 U/ml
20.2.08	32.60 U/ml	86.55 U/ml
20.2.08	30.83 U/ml	88.17 U/ml
20.2.08	30.97 U/ml	85.14 U/ml
20.2.08	31.01 U/ml	none
19.2.08	31.54 U/ml	90.08 U/ml
15.2.08	31.61 U/ml	85.41 U/ml
14.2.08	32.45 U/ml	91.45 U/ml
13.2.08	32.03 U/ml	91.78 U/ml
13.2.08	33.78 U/ml	93.90 U/ml
12.2.08	34.14 U/ml	92.59 U/ml
11.2.08	33.12 U/ml	91.77 U/ml
8.2.08	33.73 U/ml	92.59 U/ml
7.2.08	32.94 U/ml	90.06 U/ml
6.2.08	32.56 U/ml	87.54 U/ml
5.2.08	33.87 U/ml	91.62 U/ml
4.2.08	32.95 U/ml	89.93 U/ml
1.2.08	33.12 U/ml	90.74 U/ml
31.1.08	33.72 U/ml	90.62 U/ml
30.1.08	33.41 U/ml	92.49 U/ml
29.1.08	34.11 U/ml	88.34 U/ml
28.1.08	33.17 U/ml	92.70 U/ml

4.3.4. QC Preferences

The default QC settings can be modified by selecting **KRYPTOR QC Utility**, **Tools** and **Preferences**.



Possible modifications are:

- **X axis type** for Levey Jennings (days or months)
- **Y axis label** for Levey Jennings (standard deviation or absolute values)
- **Default number of considered days** for Levey Jennings
- **Mean & standard deviation** (User-defined or running values)
- **Maximum number of considered days**

4.4. Using the Work Analysis Window

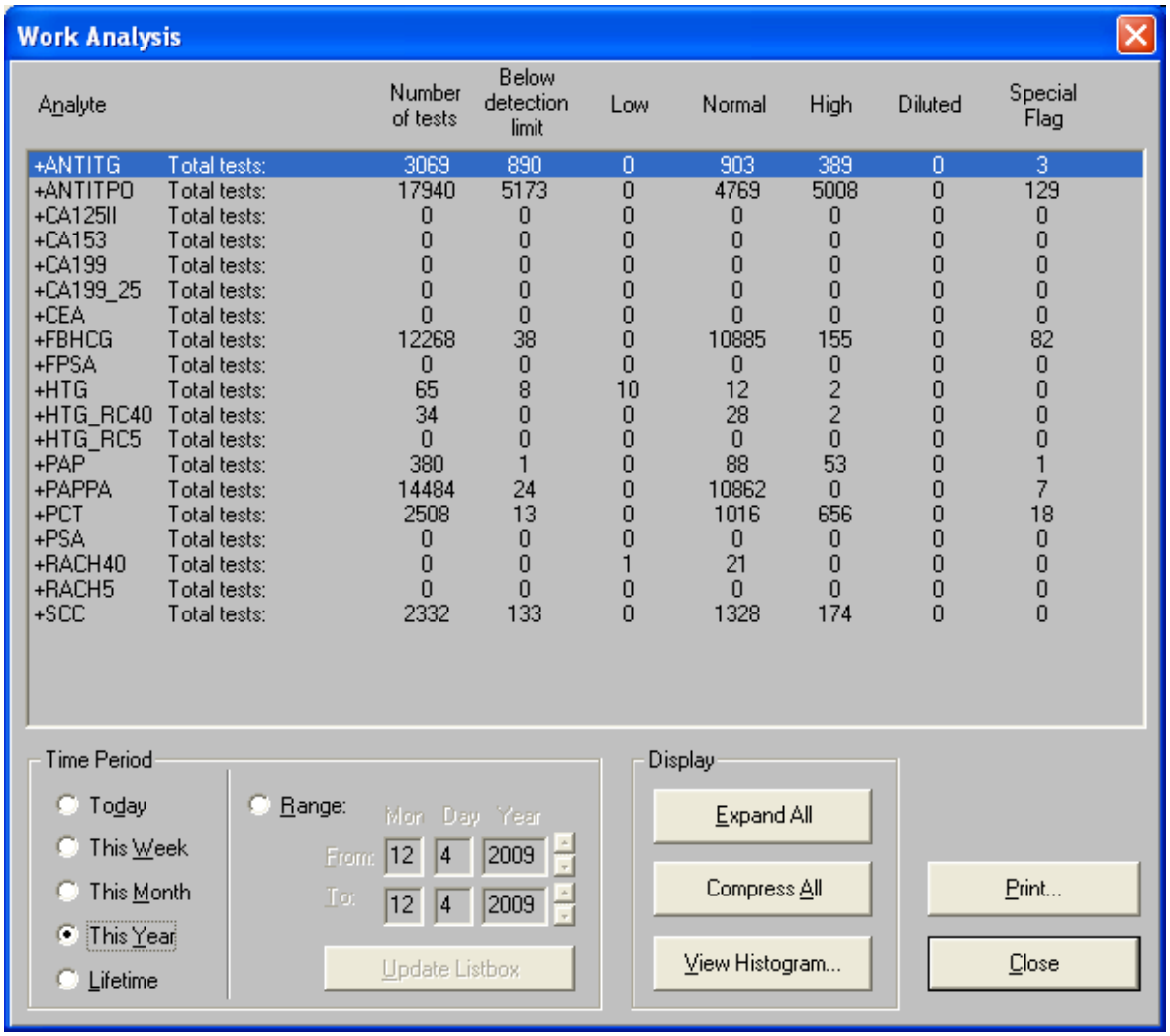
The **Work Analysis** window enables you to display information for each analyte you can currently use. The information represents analyte activity over a user-specified period of time.

The **Work Analysis** window can be displayed by selecting **Work Analysis** from the **Data** menu. You can perform the following tasks:

- Display the list in expanded or compressed format
- Specific time period of activity
- Histogram of a selected analyte
- Print analyte information

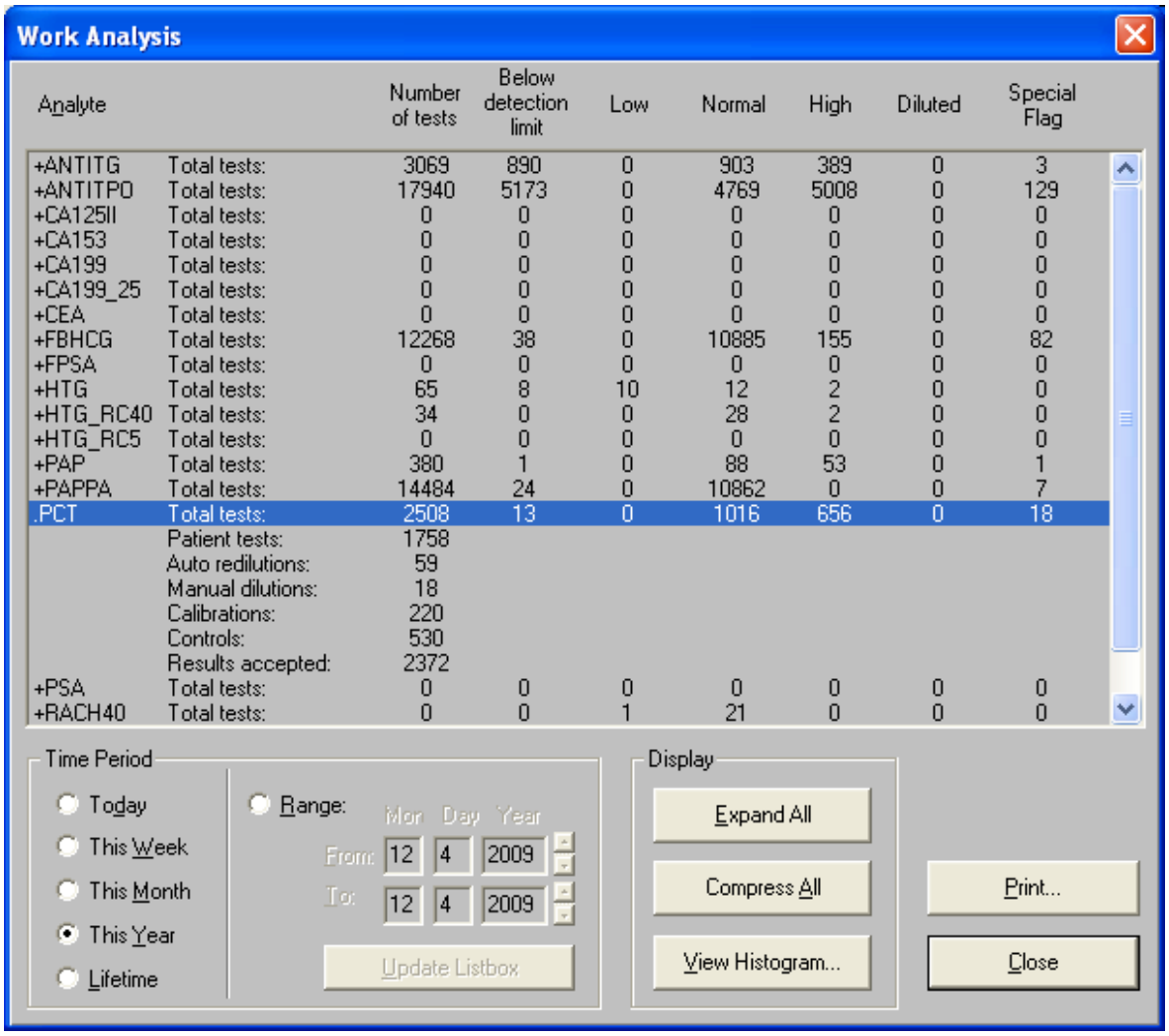
Compressed list

Each analyte is shown with the total number of patient samples, calibrators and controls that have been run in the period specified.



Expand list

The list can also be displayed in expanded format to provide information about the number of patients, controls, calibrators and diluted tests. These data are useful for calculating the costs of individual tests.



Definition of Time Period

You can specify the time period you want to consider and the corresponding date range.

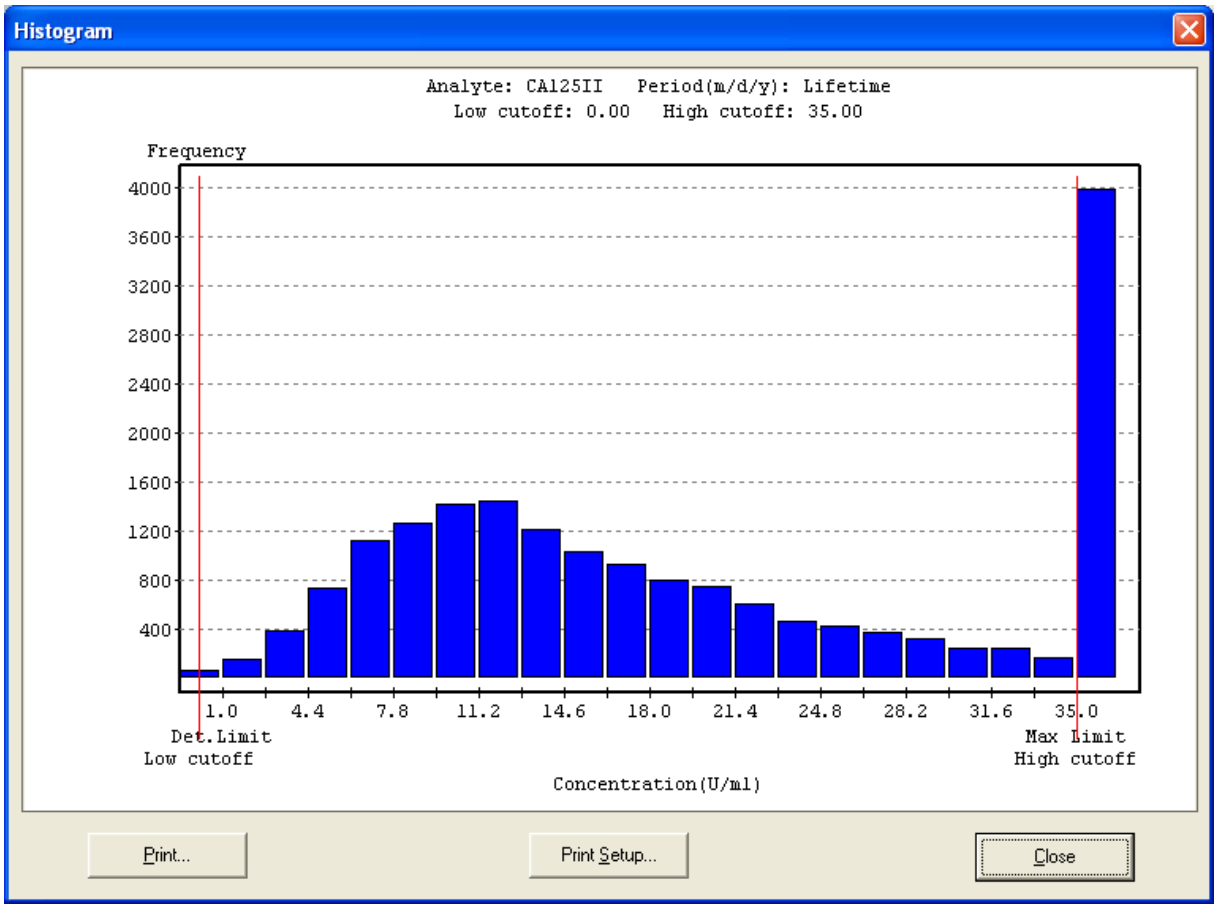
The following time periods are available:

- Current day **Today**
- Current week **This Week**
- Current month **This Month**
- Current year **This Year**
- Instrument lifespan **Lifetime**

View Histogram

Select an analyte from the list in the **Work Analysis** window.
Select **View Histogram**. The histogram of the selected analyte is displayed.

You can print the histogram by selecting **Print**.
Selecting **Print Setup** displays the standard WINDOWS printer setup.



5. Instrument Menu

5.1. Scanning the Carousel

Scanning the carousel enables the system to match the samples placed on the carousel with the samples registered in the work list, to identify dilution plates, SOLUTION bottles and reagent kits. Samples not recognized by the system will not be processed, for example samples without a barcode and without registered cassette/ position or poor barcode detection.
If carousel hood is opened for more than 2 minutes (to add or to remove samples, kit or dilution plate, etc.), the carousel is automatically scanned after closing to take into account all the modifications on the B·R·A·H·M·S KRYPTOR compact PLUS work surface.

After the carousel is scanned, the **System Status** window is updated to reflect the current status of the carousel.
The different colors for samples, SOLUTION bottles, wells in dilution plate and reagent kits in the carousel are described in **Chapter 2.5 Work Surface Color Codes.**

You can scan the carousel when the system is not pipetting. The carousel hood must be closed before scanning.

Select **Rescan Carousel** in the **Instrument** menu or you can also select the icon  from the tool palette or by typing **F1** on the keyboard.

The carousel is divided into 5 sections. Two types of tray can be placed in the carousel: sample tray and reagent tray.

Positions 1, 2, 3 are hybrid locations on which sample and reagent trays can be loaded. Positions 4 and 5 are only dedicated to sample trays.

When the carousel hood is open, it is possible to turn the carousel on its axis for easier access to the trays.

Each sample tray has a capacity of 16 tubes for a total carousel capacity of 64 tubes.

It is possible to use primary and secondary tubes with a hight of 60 to 120 mm and a diameter of 11 to 17 mm. Special tube holders are available for low-volume samples.
Calibrators and controls are also placed in the sample carousel for testing.

Each sample tray has also 2 positions for dilution plates or 4 positions for SOLUTION bottles on the upper part. Each tray can be removed for convenient loading and unloading of samples and consumables.

If you use barcode-labeled sample tubes, make sure that the barcode is fully visible through the long, narrow opening of the tube holder. Otherwise the barcode reader will not be able to identify the sample.

Each reagent tray has 4 kit positions. Up to 12 kits can be loaded on the carousel. An infra-red system is used to identify reagent tray during carousel scan. Reagent kits barcode identification through plexiglass window, is automatically detected during carousel scan.

Reagent tray is cooled to 2 ...8°C in the when placed in the carousel.

5.2. Starting, Pausing the Run

Selecting **Start Processing** in the **Instrument** menu will start the pipeting cycle.
You should start a run only after you have logged on, replenished the consumables, created the work list, loaded and preheated the reaction plate and placed the samples and reagent kits in the carousel. The instrument's protective hood must be closed.

The start command is also available from the icon  or **F2**.

Selecting **Pause Processing** in the **Instrument** menu will stop any new tests and pauses the instrument at the end of the task in process. To open the carousel hood, the pause button in front of the instrument must be pressed.
Samples can then be added to or removed from the carousel and consumable items can be replaced. Samples in the reaction plate are still measured during pause processing. However, pausing the instrument will prevent new samples from being dispensed into the reaction plate.

The pause command is also available from the icon  which is available after a **Start Process**

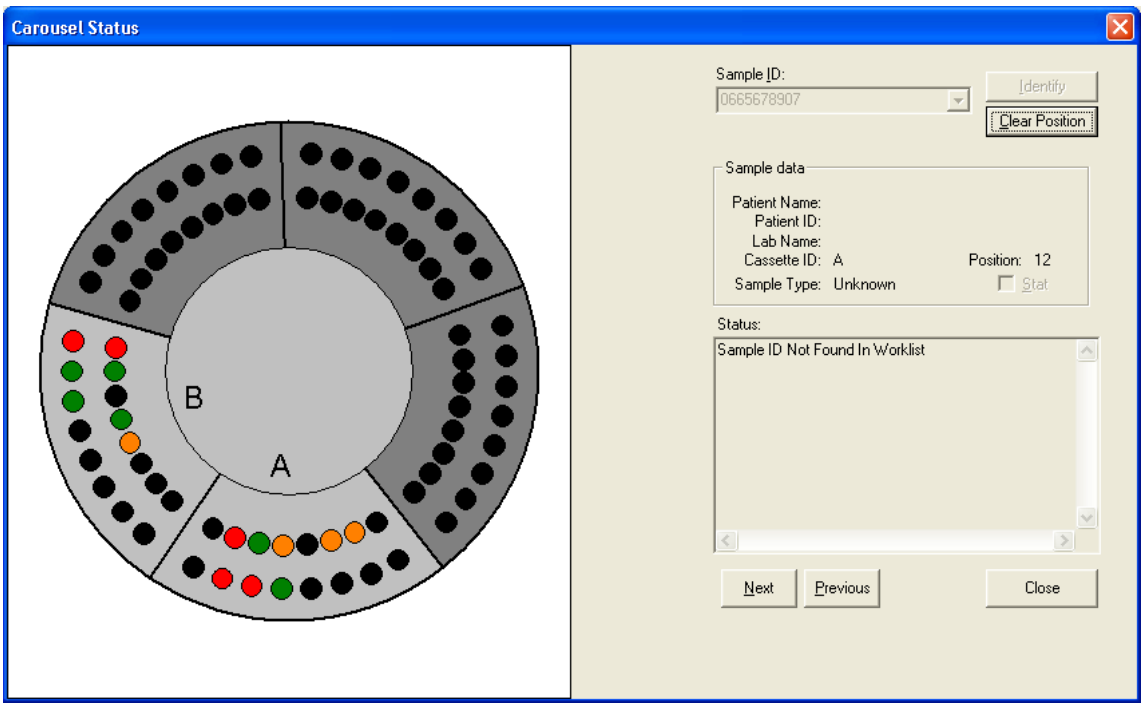
5.3. Query All

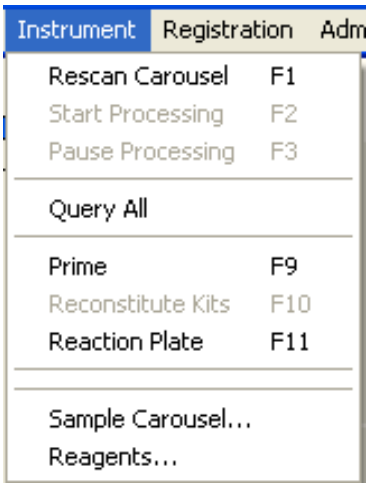
This function is used in B·R·A·H·M·S KRYPTOR compact PLUS LIS configuration.

One of the communication options between B·R·A·H·M·S KRYPTOR compact PLUS and LIS is the query mode that allows samples tubes detected on the carousel to be matched with the LIS work list.

This option is activated in the Administration Menu/LIS Interface (**7.8 LIS Interface**).

A query is made with each scan or start function. The "in query" samples are labeled in orange on the carousel screen at the end of the scan. If a sample was red, green or blue before being "in query", the previous color is kept as a circle around an orange center.





When holding the left mouse button over an "in query" sample on the screen, the test information is "sample not in worklist".

The sample stops to be "in query" as soon as the test is received from the LIS, and the color turns to green (or red if there is a problem).

In case of poor tube detection or missed samples in the LIS work list, the **Query All** function allows a new request to be repeated for all bar-coded samples placed on the carousel (except calibrators).

If the **Query All** function is used, an additional replicate is added to the work list for all the samples that have previously been queried.

Sample tubes that have already been identified by LIS will appear with an orange center.

Query All should only be used for troubleshooting purposes, i.e., when a query has not been received on LIS, due to a problem with the LIS system or a LIS connection.

5.4. Priming the System

Priming the system helps to eliminate air bubbles in the fluid system and to guarantee a reliable fluid system.

You should prime the system in case of pipeting problems, if the instrument has been sitting idle for an extended period of time (air bubbles might form) or if you have replaced the system buffer or water bottle.

Before the system is primed, make sure that there is a sufficient quantity of fluid in the system buffer or water bottle.

The instrument's protective hood must be closed before the priming process.

Select **Prime** from the **Instrument** menu. You can also select the icon  or press **F9**.

5.5. Reconstituting Reagents

Freeze-dried reagent kits installed in a reagent tray on the carousel need to be reconstituted.
The kit is highlighted in red in this case. The kit needs to be reconstituted and/or calibrated. For more information on kit status, click and hold the left mouse button once over the reagent kit selected. The **Requires Reconstitution** message is displayed or click on the left mouse button twice over the reagent kit. The **Reagent Status** window is displayed. The **Requires Reconstitution** message is displayed in the window.

If the reconstitution icon  is highlighted in the tool palette, the kit needs to be reconstituted.

5.6. Loading and Unloading the Reaction Plate

Once you have loaded the empty plate on the reaction plate support, close the plexiglass window and scan the barcode with the hand-held scanner. The reaction plate is automatically loaded in the reaction area.

When the reaction plate needs to be replaced, select **Reaction Plate** from the **Instrument** menu to move it from the reaction area. This enables you to remove the full plate and to load an empty plate.

When the reaction plate is loaded, the command will be prefixed by a check mark ✔. When the reaction plate is unloaded, no check mark is displayed.

This command is also available from the icon  , by pressing **F11**, or by clicking with the right mouse button on the reaction plate picture.

If the hand-held scanner is defective, it is possible to enter the plate identification manually.
(See **2.9 Manual entry of consumables and reagents**)

It is not possible to load an already used reaction plate.

5.7. Maintaining Consumables

The following consumable items on the instrument work surface need to be emptied, filled or replaced during the course of normal instrument operation.
The color codes for various consumables are explained in chapter **2.5 Work Surface Color Codes**.

B·R·A·H·M·S KRYPTOR compact SOLUTION 1 to 4

should be changed when empty or expired (4 weeks of stability on board). Volume and expiration date are managed by the software, thanks to barcode labels stuck on all SOLUTION bottles.

Caution: Residual volumes of the same SOLUTION must not be pooled.

The bottles are highlighted in red in the **System Status** window if their volume is too low or SOLUTION is expired and needs to be replaced. If the SOLUTION turns to red during a pipeting sequence, there is enough volume to finish the sequence
(wash sequence for SOLUTIONS 3 and 4, reconstitution sequence for SOLUTIONS 1 and 2).

For example, to change SOLUTION bottle 4:

The system automatically pauses at the end of the sequence, after detecting the empty SOLUTION bottle.

- ✓ Press the pause button in front of the instrument to open the carousel hood.
- ✓ Remove and replace bottle 4, barcode label must be visible to be correctly identified by the barcode reader.
- ✓ Select **Start Processing** in the **Instrument** menu or from the tool palette to identify the SOLUTION bottle at the end of the carousel scan and to resume test processing.

If the SOLUTION bottle is not identified because of poor barcode detection, it is possible to register the SOLUTION manually by right-click of the mouse in the position where the bottle will be placed.

IMPORTANT NOTE: In case of manual registration of a SOLUTION bottle, the software indicates the manual entry with a small hand on the SOLUTION bottle representation. Nevertheless, it is the responsibility of the user to pay special care to the SOLUTION bottle position in the tray compared to the position chosen on the screen.

The liquid system PBS buffer and water bottles

have to be filled when empty, and every 2 weeks at the latest for PBS buffer (15 days of stability after reconstitution in 5 liters of distilled water) and every week for distilled or demineralized water (during the weekly maintenance "cleaning of water bottle").

Liquid level of buffer and water bottle is managed by a floating sensor in the buffer and water intermediate tanks. When the floating sensor drops down, the fluidic system tries to refill the intermediate tank. After a certain time out, if the sensor is not back to its "full" position, then the liquid system PBS buffer bottle or water bottle is highlighted in red in the **System Status** window, and the bottle needs to be filled. Nevertheless, there is enough volume in the intermediate tank to finish the task in process.

To fill the liquid system buffer or water bottle:

The system automatically pauses at the end of the pipeting sequence, after detecting an empty liquid system buffer or water bottle.

No need to wait for the end of the pipeting sequence to fill in the bottles. There is enough volume in the intermediate tank to finish the task in process.

- ✓ Fill the liquid system buffer bottle with PBS or liquid system water bottle with distilled or demineralized water.
- ✓ Select **Start Processing** in the **Instrument** menu to resume test processing and intermediate tanks fill up.

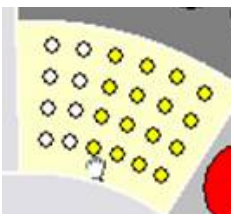
Dilution plates

have to be replaced when filled or expired (dilution plate validity is 365 days).

Replacement of dilution plate:

- ✓ Select **Pause Processing** in the **Instrument** menu or tool palette and press the pause button in front of the instrument to open the carousel hood.
- ✓ Remove the dilution plate from the upper part of the sample tray.
- ✓ Attach an adhesive biohazard cover to the full dilution plate.
- ✓ Insert a new dilution plate on the upper part of the sample tray.
- ✓ Close the carousel hood.
- ✓ Select **Start Processing** in the **Instrument** menu or tool palette to identify the new dilution plate at the end of the carousel scan and to resume test processing.

If the dilution plate is not identified because of poor barcode detection, it is possible to register it manually by right-click of the mouse in the position where the dilution plate will be placed.



IMPORTANT NOTE: In case of manual registration of a dilution plate, the software indicates the manual entry with a small hand on the dilution plate representation. Nevertheless, it is the responsibility of the user to pay special care to the dilution plate position in the tray compared to the position chosen on the screen.

The reaction plate

has to be replaced when filled and can be used at maximum for 7 days.

Replacement of reaction plate:

- ✓ When the reaction plate is full, you have to request the unloading of the plate by clicking on 
- ✓ Open the plexiglass window and push the metallic trigger.
- ✓ Remove the reaction plate.
- ✓ Attach an adhesive biohazard cover to the full reaction plate.
- ✓ Insert a new plate in the reaction area.
- ✓ Close the plexiglass window and scan the barcode with the hand-held scanner, the reaction plate will be automatically loaded.

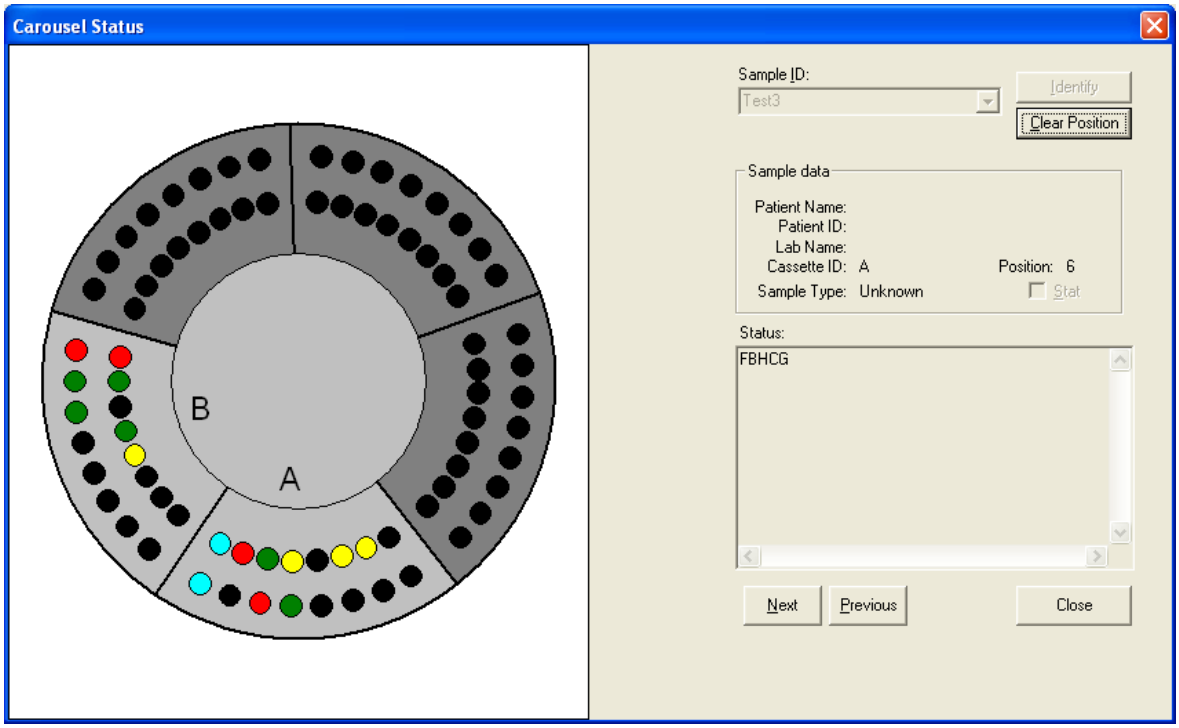
The system checks and automatically preheats the new plate.

If the hand-held scanner is defective, select **Reaction Plate** from the **Instrument** menu or tool palette and register the reaction plate identification manually.

5.8. Checking the Sample Carousel

Selecting **Sample Carousel** in the **Instrument** menu displays the **Carousel Status** window.
This window enables you to display information about each sample in the carousel.

Each sample status is color-coded (see **2.5 Work Surface Color Codes**).



To display sample data, click on a sample position using the left mouse button.
To display a previous position in the carousel, select **Previous**. To display a new position in the carousel, select **Next**.

The selected sample data are displayed in the **Carousel Status** window including:

- Sample ID
- Patient Name
- Patient ID
- Lab Name
- Cassette ID
- Position of the sample in the cassette
- Sample Type (unknown, standard, control, etc.)
- Stat: priority processing
- Sample status messages.

Fixed carousel positions and cassette IDs

Each sample cassette you place in the carousel is identified with an ID.
The **Cassette ID** listed in the window is the ID assigned to the cassette.
The **Position** is the sample location within the cassette.

Unidentified samples

A yellow sample position at the **Carousel Status** window indicates that the sample cannot be processed when the sample is not present in the work list or when two or more sample IDs are assigned to the same sample position in the cassette.

A sample is unidentified and shown as a black position when the system is unable to read the sample's barcode label. The label could be missing or torn. The sample tube may also be rotated in the cassette so that the label is not visible to the scanner. Whatever the cause, you must manually assign an ID to the sample at the **Carousel Status** window.

To assign a sample ID:

✓ Select the unidentified sample position depicted at the **Carousel Status** window. The selected position flashes.

✓ Enter the sample ID in the **Sample ID** entry box.

✓ Select **Identify**.

The system assigns the ID to the sample and updates the work list. The sample circle turns green if correctly identified. It is under the user's responsibility to make sure that the manually identified sample corresponds to the correct position in the sample cassette.

✓ Select **Close** to exit the window.

Clear position

You may need to clear a sample position in the carousel solely for tubes without a barcode.

✓ Select the specific sample position depicted at the **Carousel Status** window. The selected position flashes.

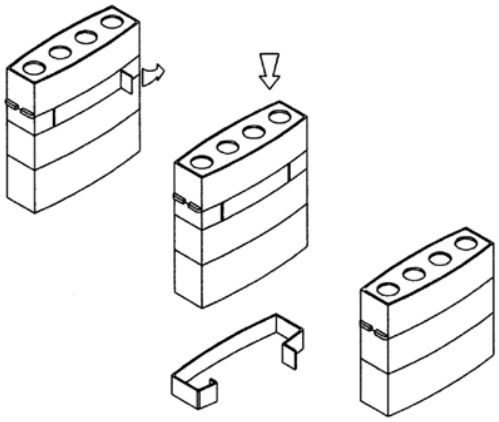
✓ Select **Clear Position**.

The sample position is cleared and the worklist updated. You can now assign a sample ID to the newly cleared sample position.

5.9. Maintaining Reagents

Install reagent kits

You can install reagent kits in 4 different locations on each reagent tray, installing one kit per location. Open the kit as shown on the following picture. Make sure that the Aluminium seal has not fallen on the surface of reagents and check it is not in the way of the tip. Take care, as well, to prevent foaming on the surface of reagents.



Place the reagent kit in the reagent tray, allowing the barcode label on the edge of the box to be visible through the plexiglass window.

Select **Rescan Carousel** in the **Instrument** menu or you can also select the icon  from the tool palette or type **F1** on the keyboard to allow scanning of the reagent kits barcode. After the carousel is scanned, the **System Status** window is updated to reflect the current status of the carousel.

If a barcode ID on the reagent kit cannot be automatically read, you can enter the barcode data manually.

There are two options for entering a barcode ID manually:

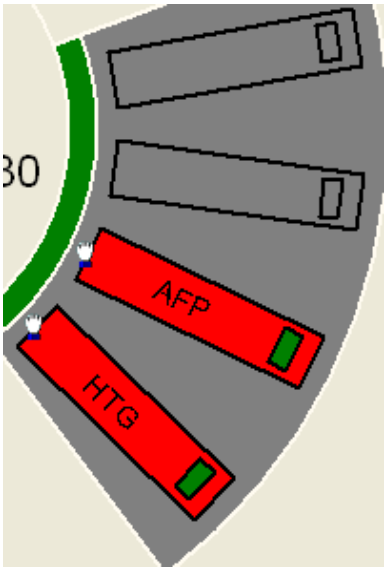
- ✓ Select a kit location with a double-click.
- ✓ Select **Manual Entry of Kit ID** in the **Reagent Status** window. The manual entry of barcode information window is displayed.
- ✓ Enter the ID number of the reagent kit in **Kit Barcode Data** by typing directly on the keyboard, or scanning the barcode on the side of the box with the hand-held scanner.
- ✓ Select **Install**.

or

- ✓ Click on the right mouse button to display the **Manual Entry of Barcode Identification** window on the **Reagent Area** picture.
- ✓ Enter the ID number of the reagent kit in the **Kit Barcode Data** by typing directly on the keyboard, or scanning the barcode on the side of the box with the hand-held scanner.
- ✓ Select **Install**.

Caution: Manual identification of consumables or sample tubes is under user responsibility. Entering incorrect data may lead to wrong result.

This option is to be used only in case of barcode reading fault while waiting for repair of problem cause.



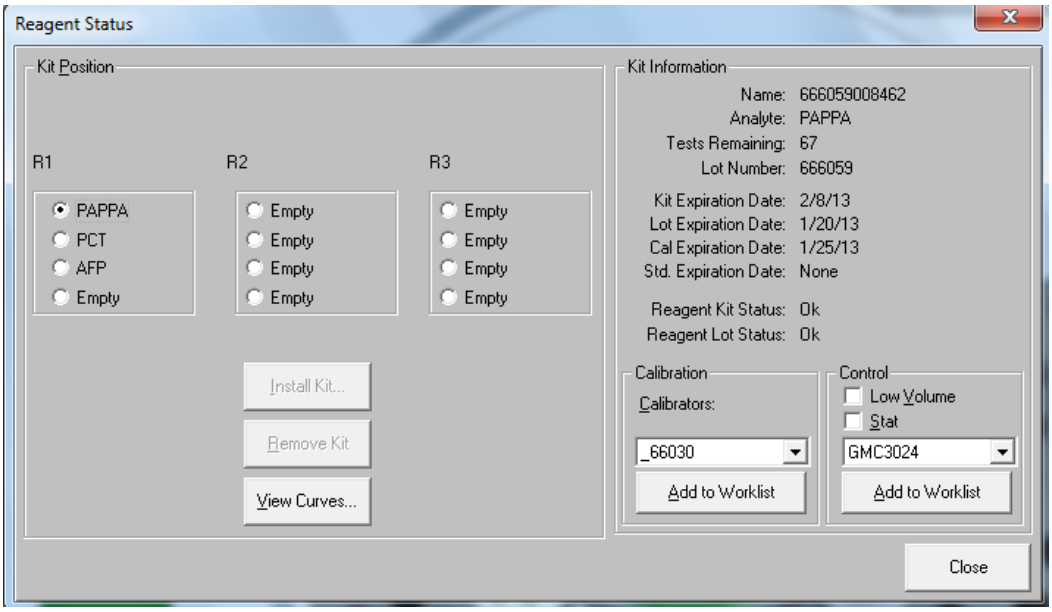
IMPORTANT NOTE: In case of manual registration of a reagent kit, the software indicates the manual entry with a small hand on the reagent kit representation. Nevertheless, it is the responsibility of the user to pay special care to the reagent kit position in the tray compared to the position chosen on the screen.

Selecting **Reagents** from the **Instrument** menu displays the **Reagent Status** window.

This window enables you to display

- information about the reagent kit installed in the reagent tray
- install reagent kits in the reagent tray
- calibrators for each reagent kit
- Display the standard curve history for each reagent kit

The **Remove Kit** button allows to clear the kit from the carousel status window when the reagent kit has been identified manually.



Display reagent kit information

When a kit is installed in the reagent tray, you can display information about the kit in the **Reagent Status** window.

Select a kit to display reagent kit information. If no kit is installed in the selected location of the reagent tray, then the **No kit loaded** message is displayed next to the **Reagent Lot Status**.

The following information is displayed about each reagent:

- Reagent's name = kit barcode identification
- Analyte name
- Number of tests remaining for the reagent kit
- Kit Lot Number
- Kit Expiry Date
- Lot Expiry Date
- Calibration Expiry Date
- Standard Expiry Date
- Reagent Kit Status
- Reagent Lot Status

Reagent area color codes

The reagent area color codes are described in **chapter 2.5.2 Reagent Area**

Remove reagent kits

When you want to remove a reagent kit from the reagent tray, you need to physically remove the kit from the specified location. But if the reagent kit has been identified manually, you have to use the **Remove Kit** button to clear the position on the carousel status screen.

Adding calibrators to work list

Calibrators adjust the analyte response curve. Each reagent or analyte needs to be regularly calibrated.

To order a calibrator for a reagent

✓ select the **Calibrator** drop-down arrow

✓ Then select a calibrator from the list and **Add to Worklist**

✓ Put the calibrator vial on the carousel

✓ Select **Start Processing**

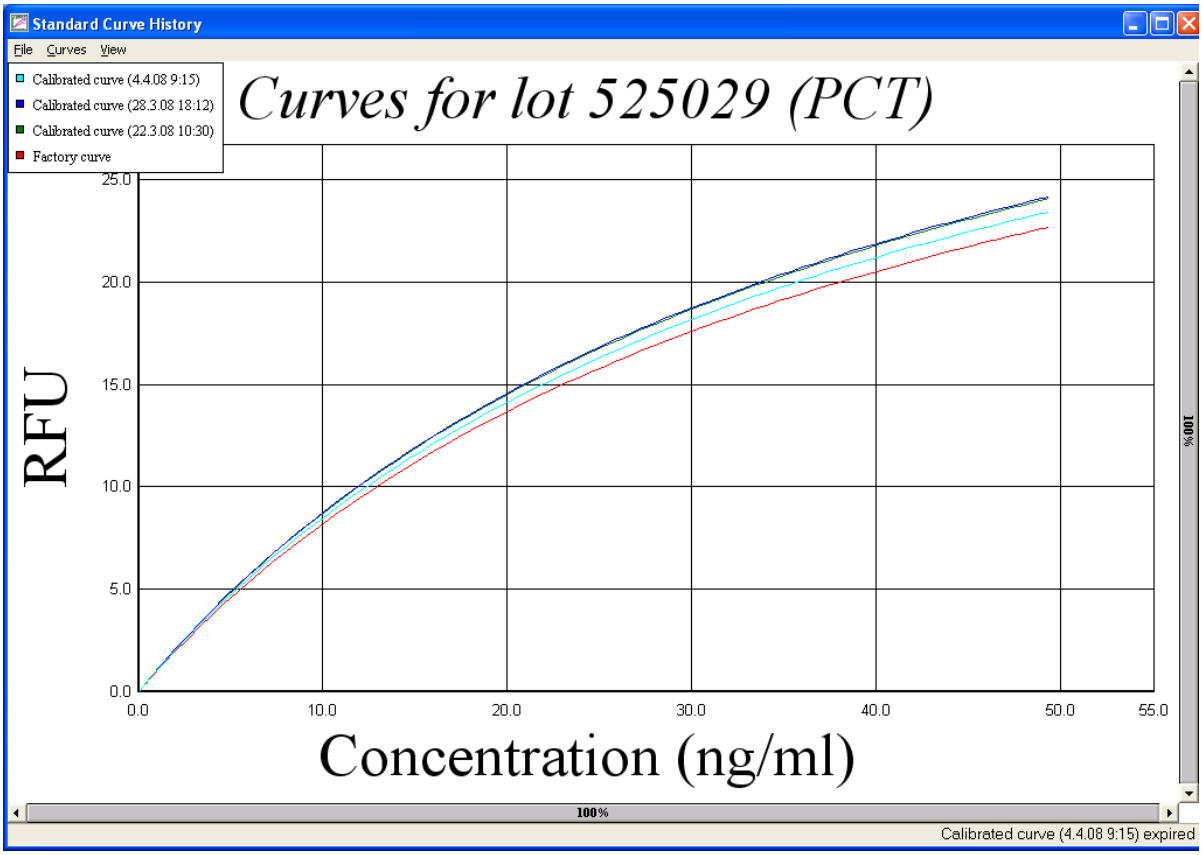
View standard curve history

Selecting **View Curves** in the **Reagent Status** window displays the standard curve history window. This window displays the curve calibration history for the selected reagent kit.

Selections in the **Curves** menu enable you to display or hide curves.

Selections in the **View** menu enable you to display or hide the X, Y axis title, chart title, and legend.

The graph can be printed by selecting **Print** from the **File** menu.



6. Registration Menu

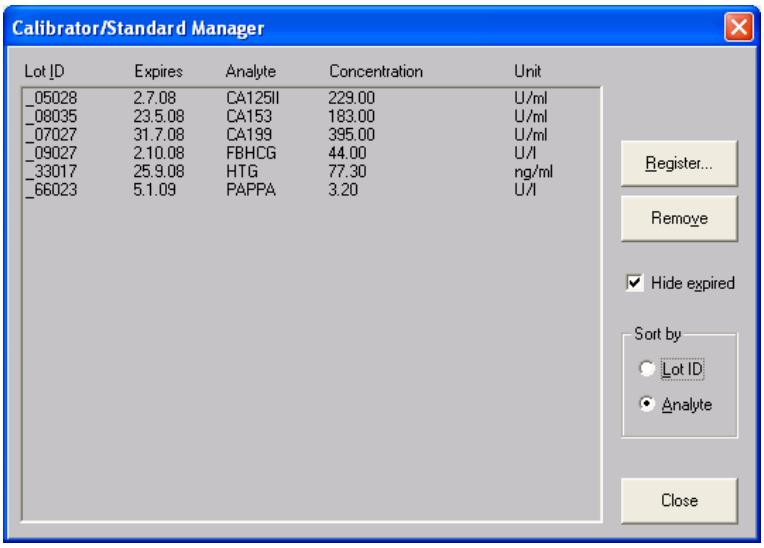
6.1. Registration of Calibrator or Standard

You have to use the hand held barcode reader and the barcode sheet supplied with the calibrator kit to register calibrators. The information is scanned from the sheet and entered automatically into the **Calibrator Lot Registration** window.

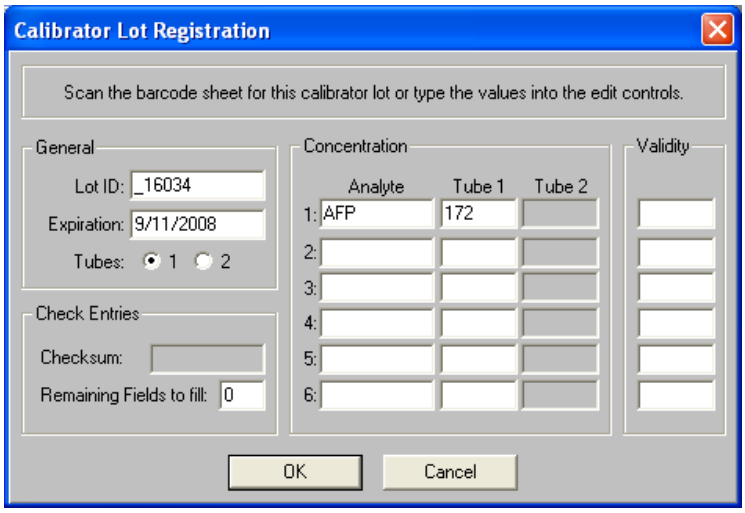
To register a calibrator, select **Calibrator/ Standard** from the **Registration** menu or

click on the icon  from the **tool palette**.

Select **Register** from the **Calibrator / Standard Manager** window.



Scan each barcode label on the sheet.



The information is entered into the **Calibrator Lot Registration** window.

When all the information has been scanned, the **Remaining Fields to fill** should be 0.

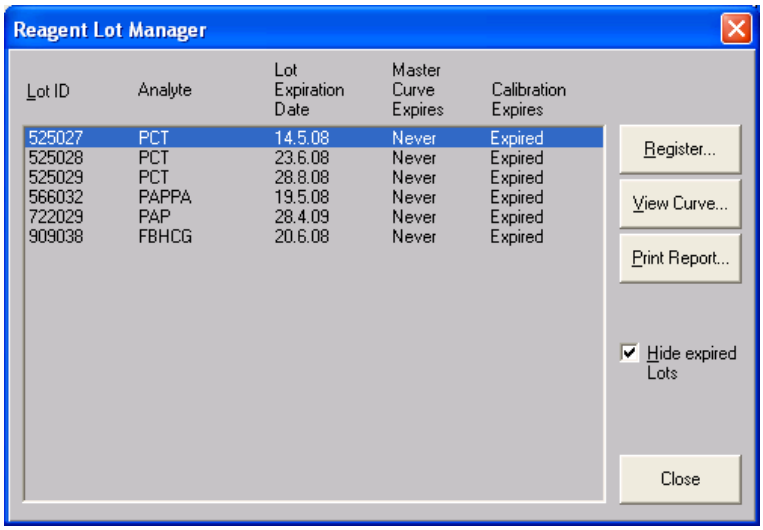
Select **OK**.

6.2. Registration of Control

See **Chapter 4.3.1 Registration of Controls when using default concentration units** and/or **Chapter 4.3.2 Registration of Controls when using laboratory specific concentration units**.

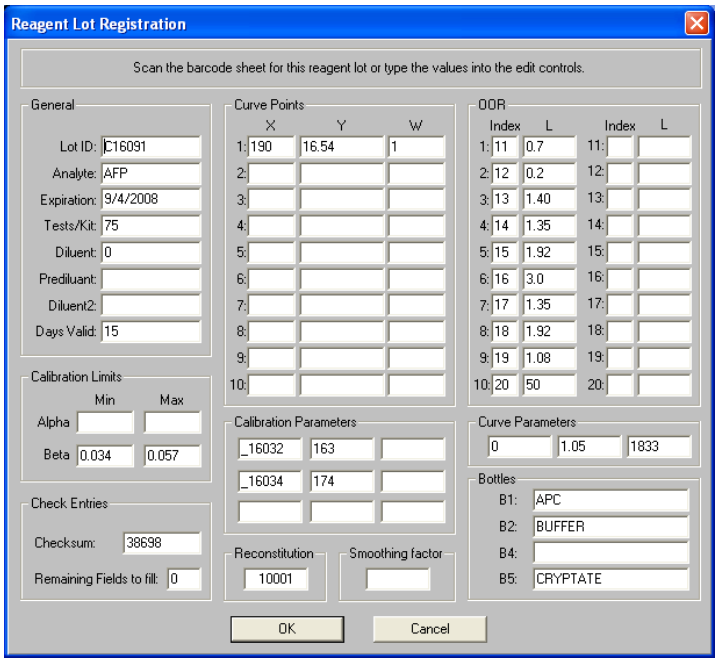
6.3. Registration of Reagent Lot

✓ To register a reagent, select **Reagent Lot** from the **Registration** menu or **Reagent Lot** icon  from the tool palette. The **Reagent Lot Manager** is displayed.



✓ Select **Register** from the **Reagent Lot Manager** window. The **Reagent Lot Registration** window is displayed.

✓ Scan each barcode label on the sheet.



Information is automatically entered into the **Reagent Lot Registration** window.

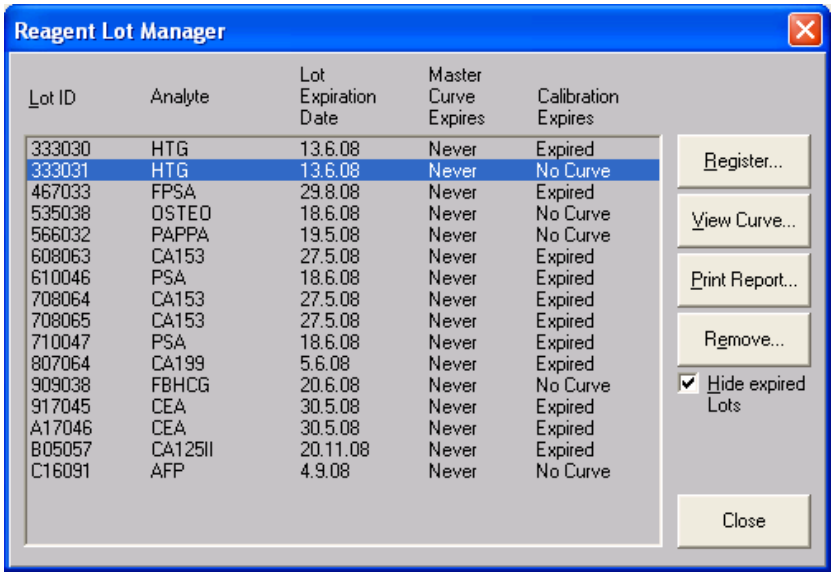
When all the information has been scanned, the **Remaining Fields to fill** should be 0.

✓ Select **OK**.

It is possible to remove a reagent lot that has never been calibrated.

The **Remove** button is only visible on the lots that can be deleted.

The action of this button has to be confirmed by the user.

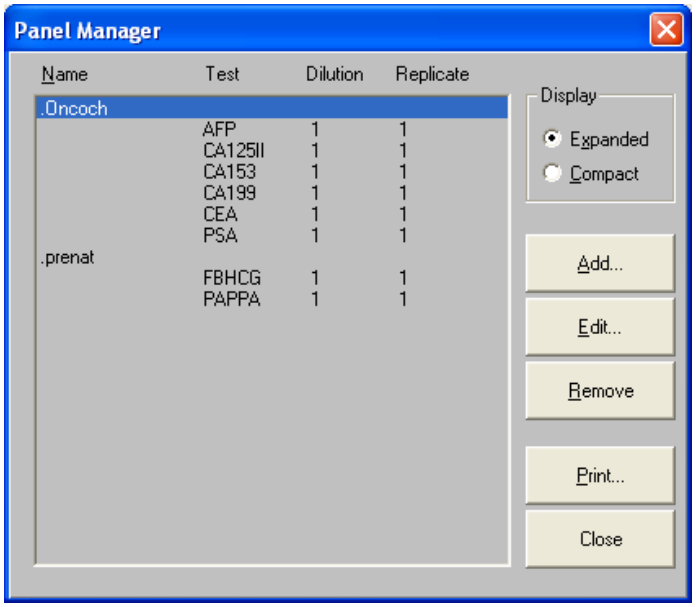


7. Administration Menu

7.1. Creating and Editing Panels

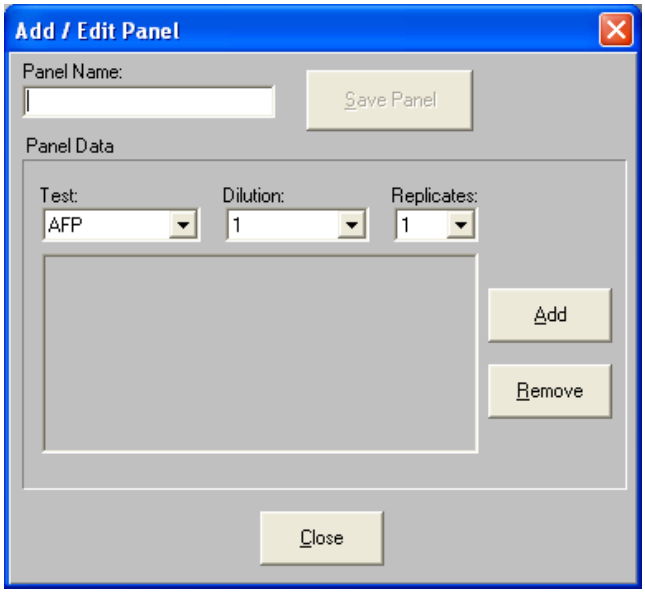
A panel is a group of tests gathered together under one name and entered into the work list as one test. They are a convenient method for entering common groups of tests into the work list. Once entered, they are no longer treated as a group. Each test is processed separately.

Selecting **Panels** from the **Administration** menu displays the **Panel Manager** window. This window enables you to create (**Add**), **Edit**, **Remove** and **Print** a panel.
It also enables you to display a panel in expanded or compact format.



Create a Panel

Selecting **Add** at the **Panel Manager** window displays the **Add/Edit Panel** window. This window enables you to create a panel. You can include as many tests as necessary in a panel.



You need to enter the name of the panel in the **Panel Name** field.
Specify the tests you want to include in the panel.
Select the drop-down arrow at the **Test** entry box. A list of available tests is displayed.
Select a test from the relevant list. The test is displayed in the **Test** entry box along with the recommended factor in the **Dilution** entry box and the replicates in the **Replicates** entry box.

To have the option of specifying a different dilution factor, select the drop-down arrow at the **Dilution** entry box. A list of available dilution factors is displayed. Select a dilution factor from the list and the factor is displayed in the **Dilution** entry box.

To have the option of specifying a different replicate, select the drop-down arrow at the **Replicates** entry box. A list of replicates is displayed. Select a replicate number from the list. The replicate is displayed in the **Replicates** entry box.

Select **Add** after each created test.
Save the panel by selecting **Save Panel**.

Remove a test from a panel

If you want to remove one test from a panel, be sure to select the test, click on **Remove** and **Save Panel**.

Edit a Panel

To edit a panel, select a panel at the **Panel Manager** window and select **Edit**. The **Add/Edit Panel** window is displayed and you are able to edit the necessary information.

Remove a panel

To remove a whole panel, select a **Panel** in the **Panel Manager** window and then **Remove** it.

Are you sure you want to remove this panel? will appear on the screen.

- ✓ Select **Yes** to delete the panel from the window.
- ✓ Select **No** to abandon the deletion.

Print a Panel

Select **Print** from the **Panel Manager** window.

Display in expanded or compact format

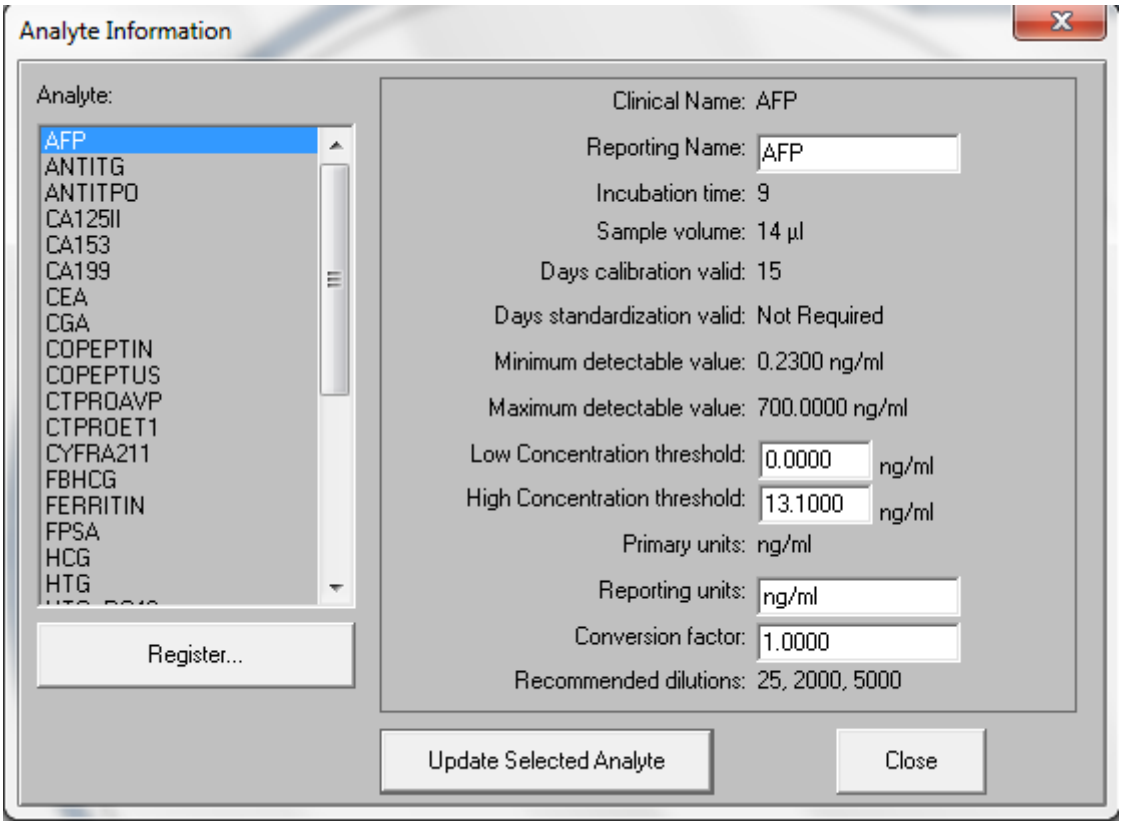
- When you display in **Expanded** format, all tests associated with each panel are listed.
- When you display in **Compact** format, the tests are not listed.

7.2. Registering and Updating Analytes

Selecting **Analytes** from the **Administration** menu displays the **Analyte Information** window.

This window enables you to display information about a specific test or analyte and update information about an analyte (white boxes).

The registration of new or updated analytes has to be done separately by the installation of K-DISK-ANA. The **K-DISK-ANA** including installation procedure is sent by the distributor every time a new version is available.



The following information displayed at the **Analyte Information** window can be changed and updated by the user:

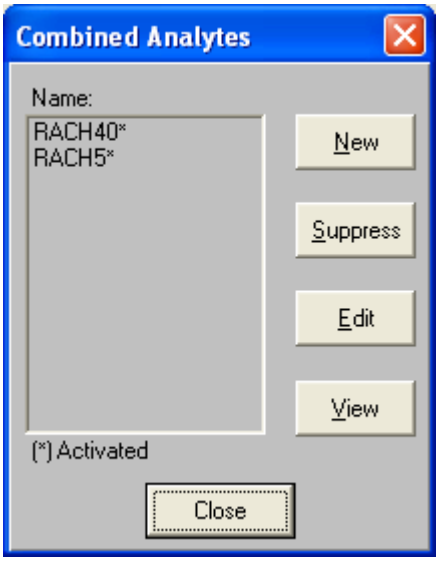
- **Reporting name**, used in the **Results** window and reports,
- **Reporting units**, used in the **Results** window and reports,
- **Low concentration threshold**
- **High concentration threshold**
- **Conversion factor**, multiplication factor to be applied
  Example:
  50 = concentration calculated on B·R·A·H·M·S KRYPTOR compact PLUS multiplied by 50,
  0.25 = concentration calculated on B·R·A·H·M·S KRYPTOR compact PLUS divided by 4

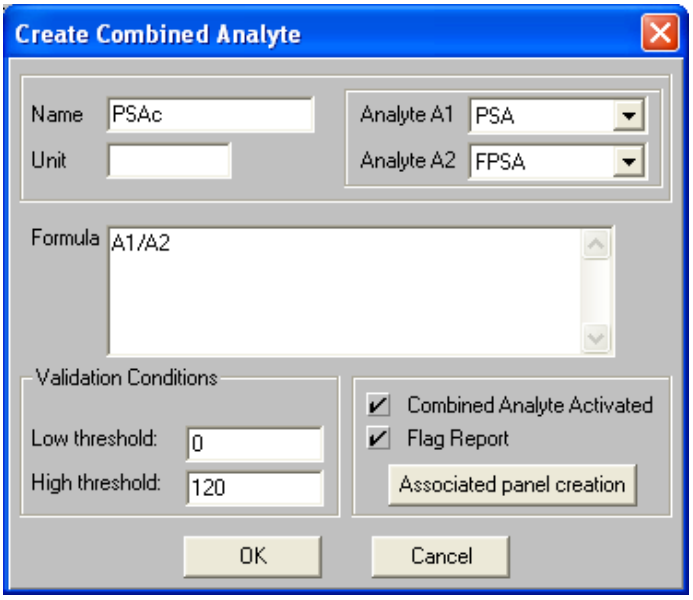
7.3. Combined Analytes

This function allows you to define a combined test based on two test results of various analytes, A1 and A2 (for example the FPSA/PSA ratio).

To run the function, go to **Administration** and select **Combined Analytes**.

Click on **New** to create a new combined test.





You have to enter the following information to define a new combined test:

- **Name**: The name of the combined test with a maximum of 8 characters
- **Analyte A1:** The first analyte involved in a combined test
- **Analyte A2:** The second analyte involved in a combined test
- **Unit:** Unit defined for the combined test result
- **Formula:** Defines the calculation mode generated with the results of tests involved in the combined mechanism
- **Validation conditions:** Definition of the result range for the acceptance of the combined test
- **Flag report**: If one of the tests used for the calculation is flagged, the combined test will be flagged as **Check Results.**
- **Combined Analyte Activated:** Each combined test can be activated individually.

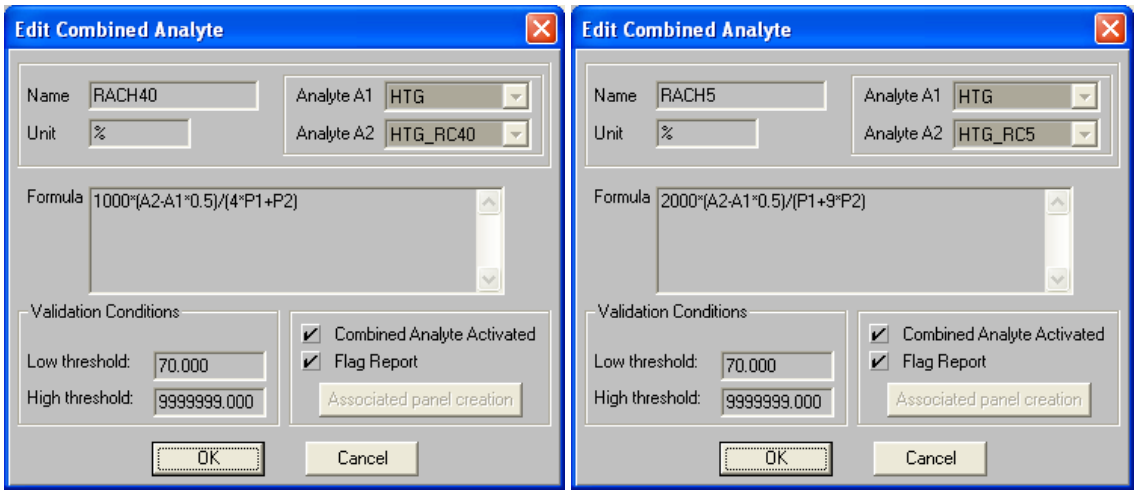
Combined test results are used in calculating the status provided that the analytes defined in the combined test remain in the **Need Resolution** status.

For each combined test “COMBINED_X”, two corresponding files “COMBINED_X.ini” and “COMBINED_X.for” are saved in the C:/Kryptor/data/combined directory to define the parameters and the formula.

A combined test can be protected by modifying the “protected” key in a section of the ini-file.

[Properties]
protected = 1

A special example for combined analytes is given for HTG testing. This section describes the calculation of the recovery test. The combined analyte definition for HTG is predefined by the software.



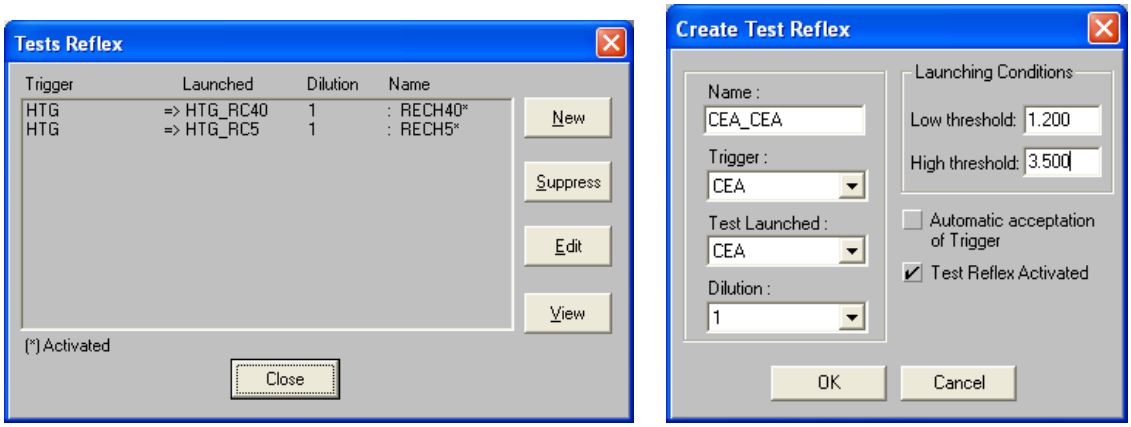
A RACH result will be calculated each time a couple of hTG and hTG_Rec will be measured. If both tests stay in “needs resol.” status, that RACH will have a result with status calculating. As soon as the two tests (hTG and hTG_Rec) will be validated, the RACH status will change to needs. Resoutionl or accepted if user validate it. There will be a RACH calculation for each combined measurement.

7.4. Reflex Testing

The reflex test allows the test launch conditions to be defined depending on the results obtained in another test.

To define a reflex test, go to **Administration** in the main menu and select **Reflex Testing**.

The **Tests Reflex** dialog box is opened and you can define a new test by selecting **New**.



To define a new test, you have to enter or consider the following information:

- **Name:** Define a name with not more than 8 characters.
- **Trigger:** The analyte launches the reflex.
- **Test launched**: The analyte of the test launched by the reflex mechanism.

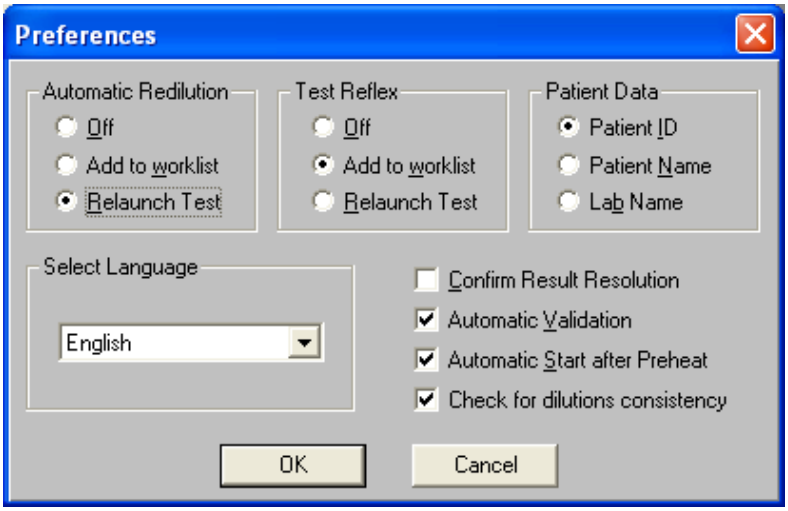
- **Dilution:** Dilution of the test launched
- **Launching conditions:** Specifies the dose range of the trigger test from which the reflex is launched.
- **Automatic acceptation of trigger:** When the reflex is launched, the trigger is accepted by the automatic validation mechanism. The trigger test is always flagged as **Reflex Test Launched**. If this option is checked, this flag is ignored for acceptance. If this option is unchecked, the trigger test remains in **Needs Resolution** status.
- **Test Reflex Activated**: Each reflex can be activated individually.

It is possible to able/enable a reflex test by:

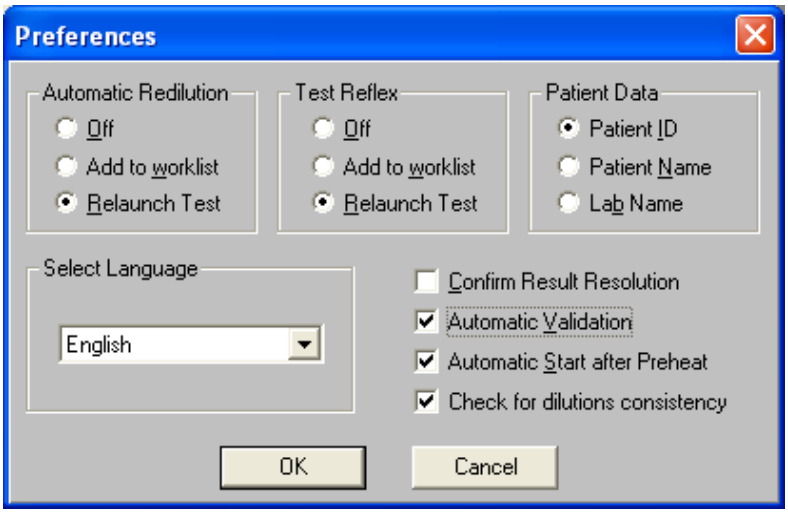
1. selecting the reflex in **Tests Reflex** window and clicking the right mouse button or
2. by clicking on the **Edit** button in the **Tests Reflex** window to edit the test reflex dialog box and select or unselect **Test Reflex Activated**.

Reflex launch

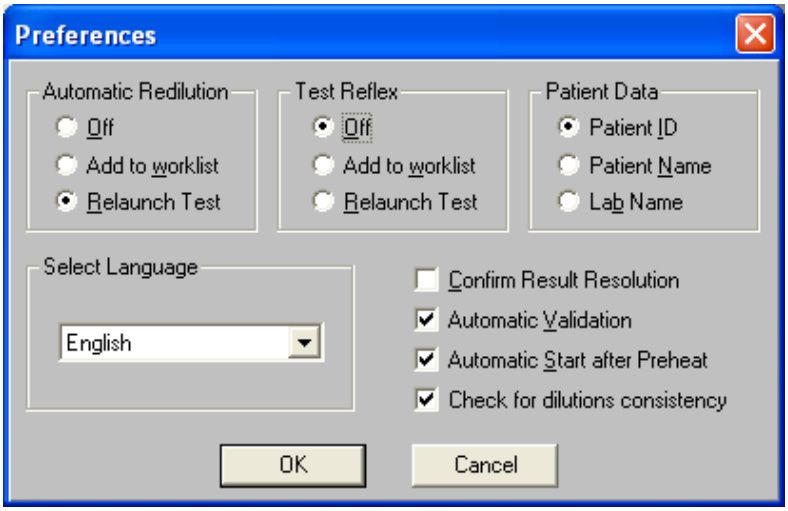
When a reflex test is launched during the pipetting process, the corresponding test is launched via the redilution reflex mechanism. Following the reflex options in the **Preferences** menu, the test is added to the work list or added to the IPC run list and pipetted as a matter of priority.
Note that the behavior of this mechanism is separate from the automatic redilution option.



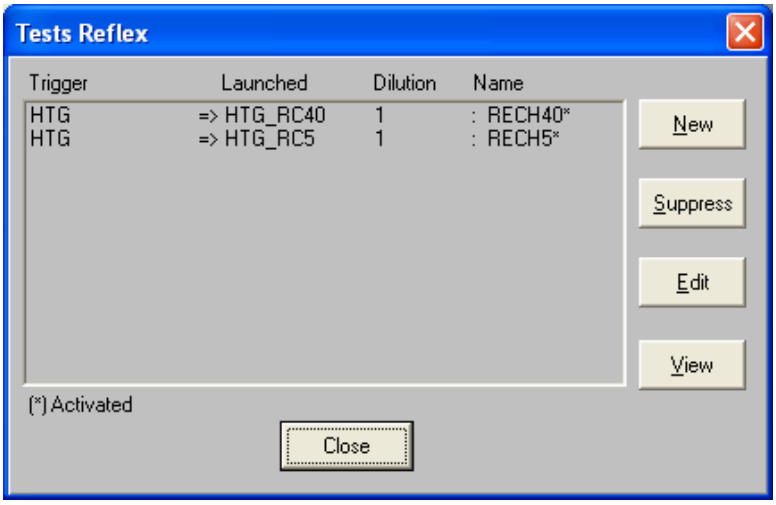
To launch the recovery test automatically by **Reflex Testing**, go to the **Administration, Preferences** main menu and select **Relaunch Test** in the **Reflex Test** section.
The reflex test is activated by default.

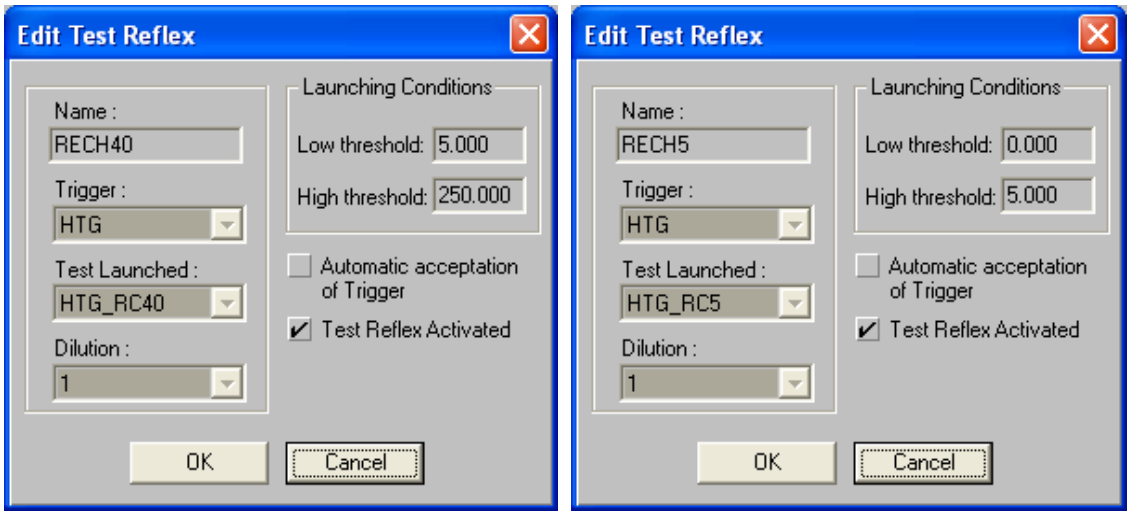


To suppress the automatic launch of the recovery test, go to the **Administration, Preferences** main menu and select **Off** in the **Test Reflex** section.



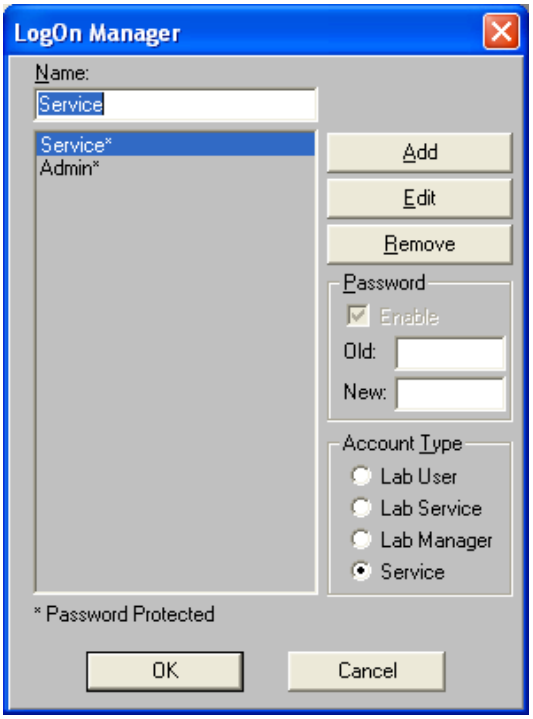
Reflex testing for HTG is a software-predefined example.




Edit Test Reflex
Name :
RECH40
Trigger :
HTG
Test Launched :
HTG_RC40
Dilution :
1
Launching Conditions
Low threshold: 5.000
High threshold: 250.000
Automatic acceptation of Trigger
Test Reflex Activated
OK
Cancel
Edit Test Reflex
Name :
RECH5
Trigger :
HTG
Test Launched :
HTG_RC5
Dilution :
1
Launching Conditions
Low threshold: 0.000
High threshold: 5.000
Automatic acceptation of Trigger
Test Reflex Activated
OK
Cancel

7.5. Maintaining User Accounts

B·R·A·H·M·S KRYPTOR compact PLUS can be used on different account levels. The account levels are divided into various software access allowances and some of them are password-protected.



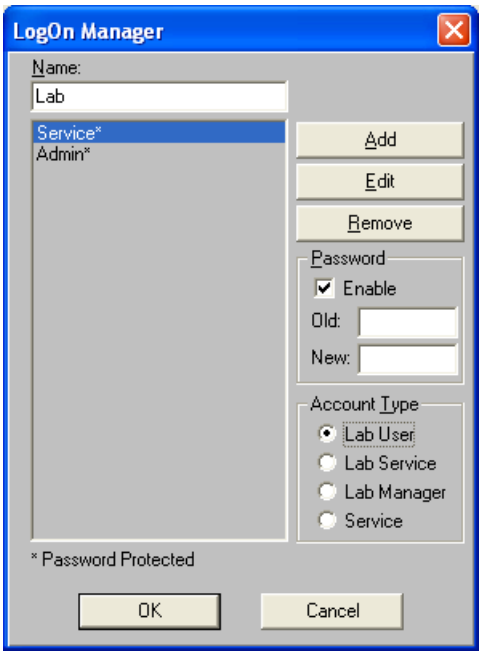
Menus	Service	Lab Manager	Lab User / Lab Service
System	Access	Access	Access
System-Service diagnostic	Access	-	-
Data	Access	Access	Access
Instrument	Access	Access	Access
Registration	Access	Access	Access
Administration	Access	Access	-

The laboratory administrator creates or modifies user accounts.

Create a user account

To create a user account,

- ✓ select **Administration, User Accounts**.
- ✓ Enter the user name and select the account type.
- ✓ If your account needs a password, enter it in the **Password, New** box. Only **Lab User** do not need a password. Password-protected accounts are marked with an asterisk (*).
- ✓ Select the **Add** and then the **OK** button.



Edit a user account

To edit a user account,

- ✓ select **Administration**, **User Accounts**, select the user name,
- ✓ enter the password in the **Password, Old** box, if the user account is protected.
- ✓ Select the **Edit** button.

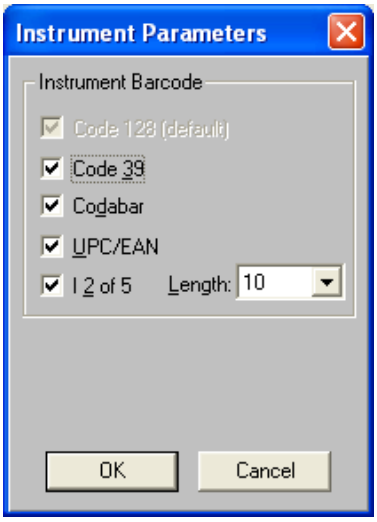
Remark: This modification removes user account protection.

Remove a user account

To remove a user account,

- ✓ select **Administration, User Accounts**, select the user name,
- ✓ enter the password in the **Password, Old** box, if the user account is protected.
- ✓ Select the **Remove** button.

7.6. Instrument Parameters



Instrument barcode

The barcode types that can be used on the B·R·A·H·M·S KRYPTOR compact PLUS system are listed here. This menu allows a barcode type to be suppressed on the system.

7.7. Specifications and Recommendations for the use of barcodes on KRYPTOR compact PLUS instruments

7.7.1. Introduction:

The KRYPTOR instruments are able to read several types of barcodes.

The symbology is one of the parameters to be taken into account for a good barcode reading but it's not the only one. The reading performances may be impacted by some other barcode parameters such as the resolution, the ratio, the paper quality, the paper brightness, the printing quality.

7.7.2. Specifications:

Available symbologies on KRYPTOR instruments:

Code 128

Code 39

Codabar

Code 2/5 interleaved

Code UPC/EAN

Other specifications:

Minimum resolution: 0.21 mm (size of narrowest bar (black or white bar))

Minimum ratio=2.5 (ratio of narrow bars to wide bars)

Maximum ratio=3.0

Silence section (blank section before and after the code): at least 10 times the resolution.

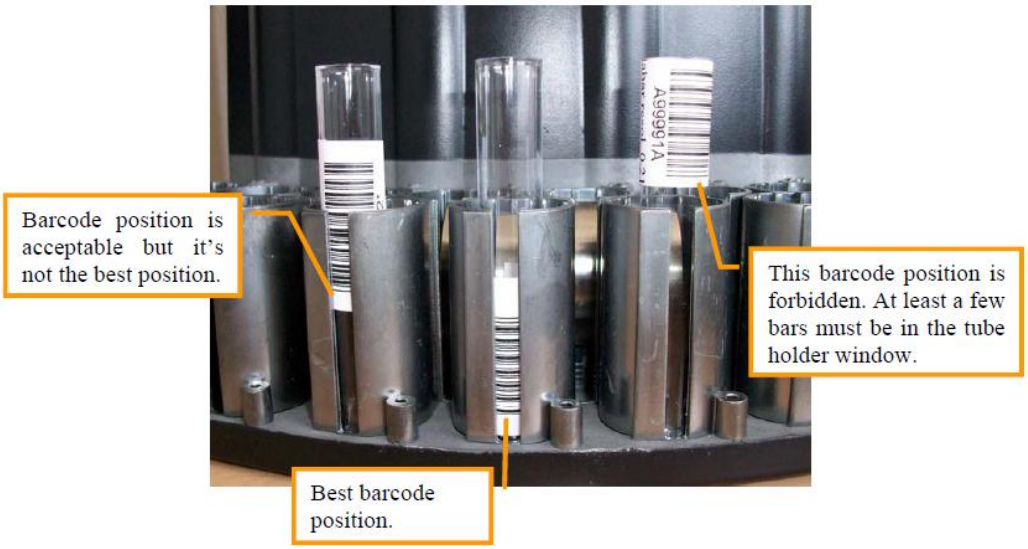
(a silent section before and after the code is mandatory for a good reading otherwise the code cannot be recognized).

7.7.3. Recommendations:

Barcode positioning:

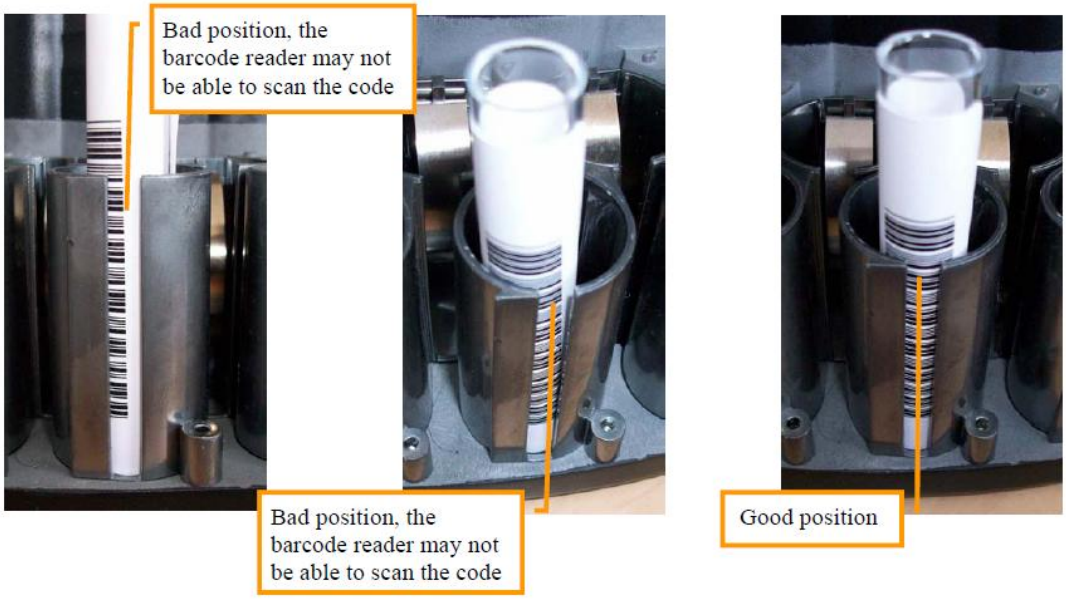
We recommend to stick the label 5mm above the bottom of the tube (if the code is long and the label is stuck too high the barcode reader may have some difficulties to read the bars located at the top, especially if the resolution is low (thin bars)).

At least a few bars of the barcode must be in the window formed by the tube holder: the window will determine the barcode position within the cassette. The code must not be stuck entirely above the tube holder because there is a risk of misidentification in this case (a tube in position 2 may be seen in position 3 for example).



Tube positioning:

The tube must be straight and the bars must be visible throughout the window width.



Paper Quality:

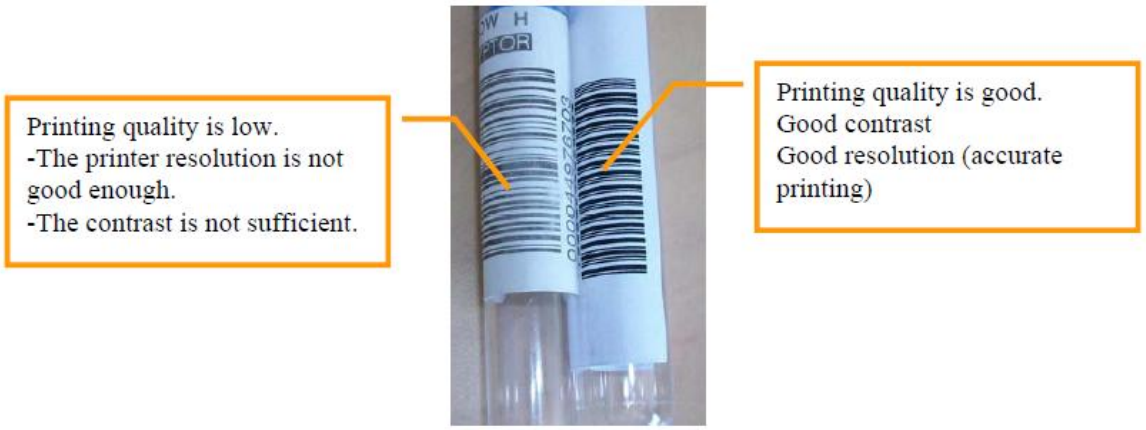
A paper having a too high ink absorption will give a blurred result and will decrease the amount of good readings (this problem will have a higher impact on barcodes having a low resolution).

Paper brightness:

The barcode readers are very sensitive to the light reflection. Even though the barcode reader is mechanically adjusted in order to limit the light reflection a too glossy paper may affect the reading performances of the codes.

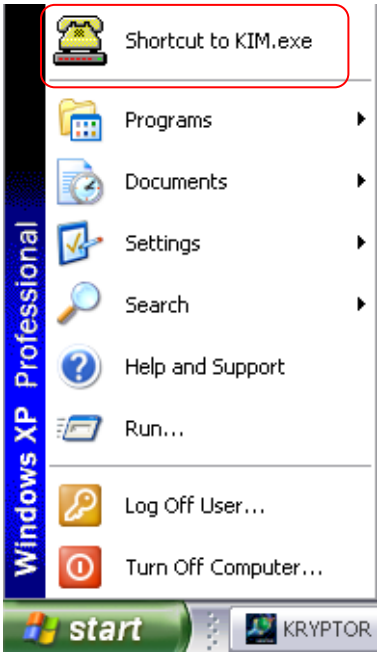
Printing Quality:

The printer quality has an influence on the reading performances. The best printers for barcodes are thermal printers (recommended for low resolution barcodes) but most of the time a laser printer is sufficient.



7.8. LIS Interface

The goal of the LIS interface is to achieve a bi-directional connection between B·R·A·H·M·S KRYPTOR compact PLUS and the Laboratory HOST system.
The communication between B·R·A·H·M·S KRYPTOR compact PLUS and the HOST is carried out using either a HPRIM or an ASTM protocol.

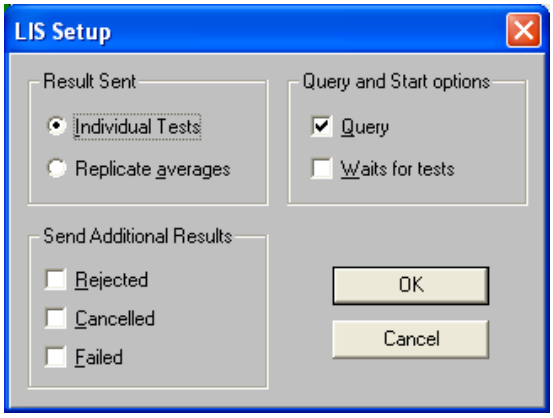


The program will be opened by clicking on **KIM** icon (Shortcut to KIM.exe) in the **Start** menu.

Query Mode

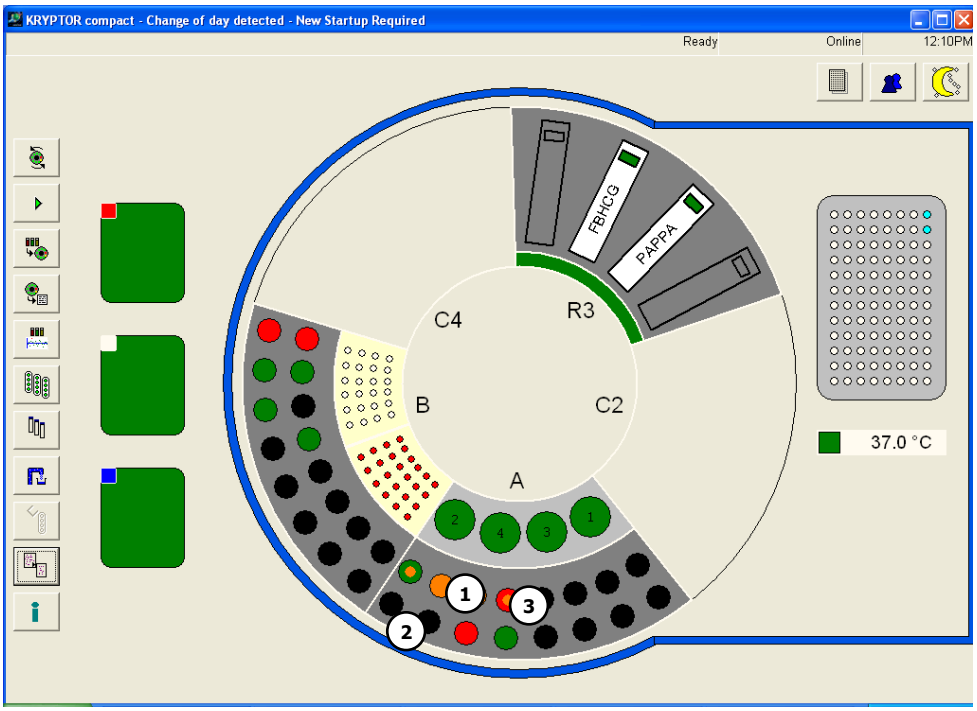
Query mode allows the carousel to be scanned and the list of samples found on board to be sent in order to request tests from LIS.

The mode is accessible from the **Administration**, **LIS Interface** menu.



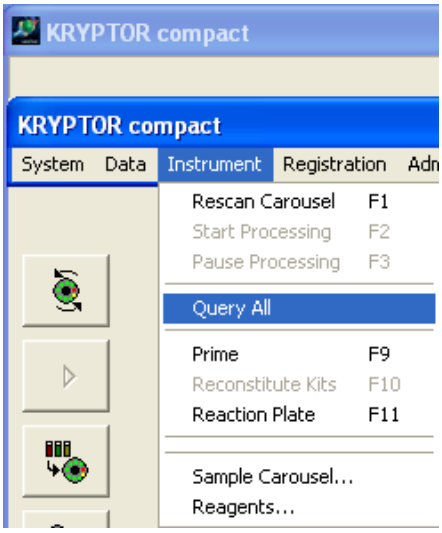
The query is requested by clicking on the **Scan**  or **Start**  icon.
A list of sample IDs is sent to LIS. This list contains all the barcodes of samples found on the carousel that have not been requested from LIS yet or with no test indicated in the work list.
A sample is called **In Query** if a request for a test was made from LIS.

In Query samples are labeled in orange on the **Carousel Status** screen at the end of a scan. If a sample was red, green or blue before being **In Query**, the previous color forms a circle around an orange center.



1. **Orange**: “In Query”, no tests ordered yet
2. **Green + Orange**: Test already ordered and query requested
3. **Red + Orange**: Problem with the tests already ordered and query requested

There is another option for requesting a query with the **Query All** function.
The list sent to LIS contains all sample IDs found on the carousel except calibrators, even those already requested by a previous scan.

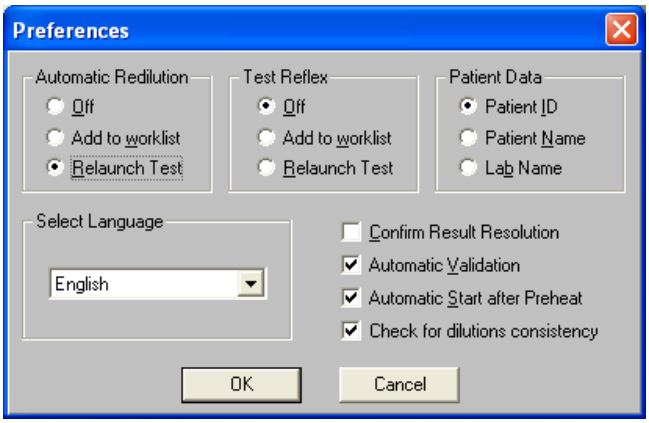


Query All is requested by selecting **Instrument, Query All**.

This function does not automatically start the pipetting. **Query All** should be used only for trouble-shooting purposes.

7.9. Preferences

Preferences enable you to customize various aspects of the software such as the language, automatic dilution or automatic validation.



Patient data preferences

This option allows you to select three possibilities regarding the information you prefer to see on the work list and result list.

Automatic redilution and reflex test

These choices are linked. Depending on your selection in the **Preferences** menu, the system will react in a specific way. In the following chart you find an overview of your possible choices and the resulting actions.

Selection			**Description**	
Automatic Redilution	Reflex Test	Message in Lower Menue Bar, Right	Dilution	Reflex Test
Off	Off	-	No dilution	No reflex test
	Add to work list	-	No dilution	Adds to work list, no automatic relaunch
	Relaunch test	Wait for reflex tests ...	No dilution	Automatic relaunch
Add to work list	Off	-	Adds to work list, no automatic relaunch	Off
	Add to work list	-	Adds to work list, no automatic relaunch	Adds to work list, no automatic relaunch
	Relaunch test	Do not take this combination		
Relaunch test	Off	-	Automatic dilution	No reflex test
	Add to work list	-	Automatic dilution	Adds to work list, no automatic relaunch
	Relaunch test	Wait for reflex tests ...	Automatic dilution	Automatic relaunch

Select the language

You can choose from 5 languages: French, English, German, Italian and Spanish.

Confirm the result resolution

Selecting **Confirm Result Resolution** in the **Preferences** window enables the system to display a prompt immediately after selecting a set of results to validate, rerun, or reject.
For example, if you want to reject a set of results, the system displays the following prompt:
"**Are you sure you want to reject tests?**"
Select **YES** to confirm the rejection; select **NO** to cancel the rejection.

Automatic validation

The results are automatically validated if the sample result is between the low and high concentration threshold. If it has only one flag, the sample result is not validated and remains in **Needs Resolution** status, highlighted with an asterisk. The user must check and validate the result according to the flag.

Automatic start after preheating

This choice allows you to install samples, identified on the work list, on the carousel whilst the reaction plate is being preheated. If the hood is closed, B·R·A·H·M·S KRYPTOR compact PLUS automatically starts at the end of the preheating period.

Check for dilution consistency

This option allows you to flag all of the dilution results in the result window before taking into account the dilution factor, which is N times lower than the detection limit of the analyte in question. N may vary depending on the measured analytes.

8. Trouble Shooting

8.1. Introduction

This chapter does not only contain information for the user, but also provides tips that support the work of the hotline.

The trouble-shooting guide contains error messages that may appear on the results, but do not invalidate them. The error messages alert the user during the result validation.

The flag numbers do not appear in the results display. They are related to the software, but may be transferred to the HOST system as part of a LIS configuration.

In the following chapters error messages will be described to provide you with possible causes and how to trouble shoot.

- Error messages from the result list.
- Calibration error messages.
- Quality Control error messages.
- Patient sample error messages.

8.2. Error Codes in the result list

Flag numbers 45 and 46, preceded by an underscore, are visible in the **Results flag** box only with “Service” logon.

Flag N°	Results Windows Messages	Messages in Session Log	Result Provided, Status
0	"System Warning: Low Laser Power"	Yes	Yes, Needs Resolution
1	"System Error: Reaction Plate position"	Yes	No, cancelled or failed
2	"System Warning: Reagent Cooler out of Range"	Yes	Yes, Needs Resolution
3	"System Warning: Incubator Out of Range"	Yes	Depends on the temperature
4	"System Error: Missed Reading"	Yes	No, cancelled or failed
6	"System Error: Insufficient Sample Volume"	Yes	No, Failed
7	"System Error: Insufficient Reagent Volume"	Yes	No, Failed
9	"System Warning: Late T0/TM"	Yes	No, Rediluted*
11	"System Warning: Late TE"	Yes	No, Rediluted*
12	"System Error: Pipetting"	Yes	No, Pending
13	"System Error: Clot Detected"	Yes	Failed
14	"System Error: Pipetting in Sample area"	Yes	No, Pending
15	"System Error: Pipetting in Dilution area"	Yes	No, Pending
16	"System Error: Pipetting in Reagent area"	Yes	No, Pending
17	"System Error: Pipetting in Wash area"	Yes	No, Pending
18	“System Error: Pipetting in Reaction area”	Yes	No, Pending
19	"System Warning: Heated Tip Out of Range"	Yes	Yes, Needs Resolution
20	"System Error: Interrupted"	Yes	Cancelled

Flag N°	Results Windows Messages	Messages in Session Log	Result Provided, Status
21	**"System Warning: Not Performed"**	No	depends on how serious the problem is
24	**"Check Results"**	No	Yes, Needs Resolution
25	**"Math Error"**	No	cancelled or failed
26	**"Reflex Test Launched"**	No	Yes, Needs Resolution
29	**System Error: Clot detected or insufficient sample volume**	Yes	No, Failed
30	**"Data Error: Unknown Error"**	No	Yes, Needs Resolution
31	**"Data Error: Ratio"**	No	No, Cancelled
32	**"Data Error: Response"**	No	No, Failed
33	**"Data Warning: Abnormal"**	No	No, Rediluted*
34	**"Data Warning: Out of Range"**	No	No, Rediluted*
35	**"Data Warning: Detection Limit"**	No	low, Needs Resolution
36	**"Data Error: Above max. Range"**	No	No, Needs Resolution
38	**"Data Warning: Calibrator Warning"**	Yes	Yes, Needs Re Resolution
39	**"Data Warning: Below Normal"**	No	Yes, Needs Resolution (depends on settings in Administration /Analytes)
40	**"Data Warning: Above Normal"**	No	Yes, Needs Resolution (depends on settings in Administration /Analytes)
42	**"Concentration not Consistent with Dilution Used"**	No	Yes, Needs Resolution
43	**"Sample Pipetting Problem - Check Sample"**	No	Yes, Needs Resolution
44	**"Data Warning: Abnormal Kinetics"**	No	Rediluted* or cancelled
45	**"_Data Warning: Second Response Used"**	No	Yes, Needs Resolution
46	**"_Data Warning: Short Lived Fluorescence"**	No	Yes, Needs Resolution
48	**"Data Warning: Control out of 2 SD range"**	No	Yes, Needs Resolution
51	**“Inconsistent incubation time”**	No	Yes, Needs Resolution
52	**“System Error: Missed flashes”**	Yes	Yes, Needs Resolution
69	**“Pre-incubating”**	No	Yes, information only
70	**System error: Pre-incubation has failed**	Yes	No, Failed
	* Only if automatic redilution is activated in the **Administration, Preferences** menu		

8.2.1. Description of Error Codes in the result list

Flag 0: System Warning: Low Laser Power
During a reading for this test, the average ADC value for all flashes was lower than 13000. The reading was actually completed with no missed flashes.
Possible causes: • Low laser energy, end of laser life • Bad positioning of the optical fiber • Photodiode board failure • Damaged cable from reader head to reader interface board
Action: No emergency action but calls the hot line.

Flag 1: System Error: Reaction Plate position
The reaction plate was not positioned correctly during any one of the readings of this test.
Possible causes: • Problem on X-Y-translator • Problem on X & Y optical home sensor • Obstacle in the path • Problem on ILS sensors on Plexiglas door and external reaction door.
Action: • Request a reader initialization in **Daily Maintenance** (chapter **System Menu**) or restart the system completely. • Unload the reaction plate, check that the reaction plate was correctly loaded and load a new reaction plate. • If the problem persists, ask a technical intervention.

Flag 2: System Warning: Reagent Cooler Out Of Range
The reagent area's cooler temperature sensor ADC out of the 2 - 8°C range at the time the reagents were sampled for this test. The result should not be affected if this problem happened during a run, except if reagent kits have been allowed on board with this problem persisting for several days.
Possible causes: • Room temperature (between 18 - 26°C) out of specification • Reagent cassette failure
Action: • Check if the room temperature is within specification (18 - 30°C) • Check the fan below the drip pan of the carousel: if there is no air extraction, something may block the fan or there is a fan failure. • Reagent Cassette failure • If the problem persists, call the hot line.

Flag 3: System Warning: Incubator Out Of Range
This warning appears when the reaction temperature is out of the 37 - 40°C range after the preheating or after the pipetting. Pipetting sequence goes on, but all tests still incubating are flagged "System Warning: Incubator Out Of Range". The pipetting does not start if the temperature is below 35.7°C or over 38,5.
Possible causes: • Room temperature (between 18 - 30°C) out of specification • Heater failure • Temperature sensor failure
Action: • Stop the B·R·A·H·M·S KRYPTOR compact PLUS and wait a few minutes before switching on the instrument. • Adjust the room temperature within the specification (between 18 - 30°C). • If the problem persists, call the hot line.

Flag 4: System Error: Missed Reading
If more than 5 flashes are missing the software is not able to calculate the reading and the test will be flagged with missed reading flag
Possible causes: • Laser failure. • Laser energy below photodiode sensitivity limit. • Photodiode board maladjustment or failure • Damaged cable from reader head to reader interface board
Action: • Call your hot line.

Flag 6: System Error: Insufficient Sample Volume
The tip goes to the Zmax without liquid detection in the sample tube, the sample cup or the calibrator vial. Or the the Tip shock below Zmax
Possible causes: • Not enough volume (or dead volume) in the sample cup, calibrator vial or reagent bottles • Zmax adjustment. (Zmax too high) • Conductivity trouble
Action: Check if the trouble occurs on one or several samples tubes, cup or calibrator vials. If it concerns one tube : • check the liquid level in the sample cup, the sample tube or the calibrator vial. • check the tube positioning in the carousel. If it concerns several tubes : • Check the Zmax adjustment. • Liquid detection failure (Tip board) : call the Hot Line for a Technical intervention

Flag 7: System Error: Insufficient Reagent Volume
Tip goes to the Zmax without liquid detection in the reagent kit (conjugates bottles). Or there is a Tip shock below Zmax .
Possible causes: • Not enough volume or no liquid in reagent bottles. • Zmax adjustment. (Zmax too high) • Conductivity trouble
Action: • Check the liquid level in reagent bottles Call the Hot Line for a Technical intervention to : • Check Zmax adjustment. • Liquid detection failure (Tip board)

Flag 9: System Warning: Late T0/TM
The first reading of this test has been performed within an off-specification time limit, causing the cancellation or the relaunch of the assay.
Possible causes: • Problem on XY translator • Reader head • Obstacle in the path in the reaction area • Instrument too busy
Action: • Check the presence of messages related to each other in the XIPClog.txt . • If the problem occurs more than once in a series, shut down, and then restart the instrument after 1 or 2 minutes. If the problem persists, Call the Hot Line to launch an intervention. • If the problem occurs sporadically while a significant work list is loaded on B·R·A·H·M·S KRYPTOR compact PLUS, the problem is not relevant. It is then advisable to relaunch the sample displaying this message.

Flag 11: System Warning: Late TE
The reading of this test has been performed within an off-specification time limit, causing the cancellation or the relaunch of the assay.
Possible causes: • Problem on XY translator • Reader head • Obstacle in the path in the reaction area • Instrument too busy
Action: • If the problem occurs more than once in a series, shut down, and then restart the instrument after 1 or 2 minutes. If the problem persists, launch an intervention. Check the absence of hard dots on the linear motion in the reaction area. • If the problem occurs sporadically while a significant work list is loaded on B·R·A·H·M·S KRYPTOR compact PLUS, the problem is not relevant. It is then advisable to relaunch the sample displaying this message.

Flag 12: System Error: Pipetting
A mechanical error occurs during the pipetting sequence of this test. It could be an error in any of the Theta, Z, or carousel mechanisms.
Possible causes: • Not enough volume • Zmax adjustment. (Zmax too high) • Conductivity trouble • The tip found an obstacle before ZLs • The tip reached the bottom of the tube without finding any liquid • Fluidic hood and / or Carousel hood is open • A shock is detected during the pipetting sequence before the ZLL. • It can also be due to a bad communication.
Action: • Check the tube and remove the cap. Make sure that nothing is obstructing the path Remark: In that case the carousel hood is open and the run is interrupted. • The tube is probably empty otherwise check the liquid level in vial. Remark: In that case test is in pending status. • Zmax adjustement. • If following pop-up appears <Error: tip level sense baseline. Contact technical support>, the carousel hood is open and the run is interrupted.

Flag 13: System Error: Clot Detected
A clot is detected during sample aspiration, either in a tube on the carousel or from a dilution plate.
Possible causes: • Sample itself • Clot detector board • Zmax too close to the tube bottom
Action: • Clean the tip (fish line, Secure tip cleaning from the monthly maintenance). • Check the sample and relaunch the test. • Change the tip if the clot persist. • If the trouble persist, call the Hot Line

Flag 14: System Error: Pipetting in Sample area
There is a Tip shock above Zmax when descending in a sample tube, a sample cup or a calibrator vial.
Possible causes: • Obstacle in the path (Cap…) • Bad sample tube positioning • Carousel positioning • Pipetor arm adjustment
Action: • Check obstacle in the path (Cap…) • Check the sample tube positioning • Check the carousel positioning • Check the pipetor arm adjustment

Flag 15: System Error: Pipetting in Dilution area
The tip is physically stopped at or above Zmax (even if above ZLL) when descending into a dilution well. The tip is physically stopped when moving up out of a dilution well.
Possible causes: • Bad dilution plate positioning • Carousel positioning • Pipetor arm adjustment
Action: • Check the dilution plate positioning • Check the carousel positioning • Check the pipetor arm adjustment

Flag 16: System Error: Pipetting in Reagent area
There is a Tip shock above Zmax. The tip is physically stopped when moving up out of a reagent kit bottle.
Possible causes: • Obstacle in the path (reagent area lid…) • Bad reagent kit positioning • Carousel positioning • Pipetor arm adjustment
Action: • Check obstacle in the path (reagent area lid, aluminium foil…) • Check the reagent kit positioning • Check the carousel positioning • Check the pipetor arm adjustment

Flag 17: System Error: Pipetting in Wash area
The tip is physically stopped above Zmax or ZLL when descending into the washbowl, wash cup or any of the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles. The tip detects the liquid too close to Zmax and therefore insufficient room for the subsequent liquid in any one of the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles. The tip descends to Zmax in any one of the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles without detecting any liquid. The tip is physically stopped when moving up out of the washbowl, wash cup or any one of the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles.
Possible causes: • Poor area adjustments • Problem with washing SOLUTIONS (volume is too low or too high, cap still present)
Action: • Check if the B·R·A·H·M·S KRYPTOR compact SOLUTION bottles are present, open and if sufficient liquid remains. • Liquid detection failure (Tip board) • Check if there is any obstruction on the path. If the problem persists, call the hot line.

Flag 18: System Error: Pipetting in Reaction Area
The tip cannot move down to the reaction tray for dispensing or move up after dispensing.
Possible causes: • Obstacle in the path • Pipetor arm adjustment
Action: • Check if there is any obstruction on the path. If the problem persists, call the hot line.

Flag 19: System Warning: Heated Tip Out of Range
The heated Tip temperature is Out Of Range during the pipetting sequence (36 - 41°C).
Possible causes: • Heated Tip failure • Heated tip board failure • Bubbles in the system
Action: • Prime the system to remove bubbles (Start the **Prime** function on the main screen or use **F9)** • Replace the complete Tip (Tip and board). • If the problem persists, call the hot line.

Flag 20: System Error: Interrupted
The test is pipetted and incubation initiated but it is interrupted while test is in progress (B·R·A·H·M·S KRYPTOR compact PLUS status: Ready/Counting or Pipetting/Counting).
Possible causes: • Test cancelled by the user • XIPC closed while the test is in progress • Instrument is switched off while the test is in progress
Action: • Reboot the system. • If the problem persists, call the hot line.

Flag 21: System Warning: Not Performed
The test was entered in the work list on a previous date but was not carried out on that date.
Action: • Start testing or delete it from the work list.

Flag 24: Check Results
This flag appears on the calculation of combined analytes, when at least one of both analytes (A1 and/or A2) generates a warning about the sampling.
Action: • The software is working properly. If the "**Flag port**" option is checked, any flag on the individual tests A1 and A2 generates a "**Check results**" message on the combined result which makes it only acceptable manually. If this option is not checked, the combined test will be automatically accepted as soon as all the tests composing the A1 and A2 tests groups are validated (i.e. no Need Resolution, Counting or Detecting) and at least one accepted result exists for each analyte A1 and A2.

Flag 25: Math Error
This flag appears on the calculation of combined analytes in case of a problem of the combined formula or a problem of the combined calculation itself (i.e: division by 0). Error also appears when closing the interface during pipetting/counting phase. In case of double determination the result will be calculated as an average only.
Action: • Rerun the sample and make sure not to close the interface during pipetting/counting phase. • If problem persists, call the hotline

Flag 26: Reflex Test Launched
This flag appears when the reflex mechanism is activated in **Administration**, **Preferences** menu. This flag indicates that an analyte has been defined as "Trigger" in the reflex test definition window in **Administration**, **Reflex Testing**.
Action: • It is not a problem, this is an information.

Flag 29: System Error: Clot detected or insufficient sample volume
Message occurs when a clot is detected too close to sample's zmax. The current test will be flagged in red.
Action: • Clean the tip (fish line, Secure tip cleaning from the monthly maintenance). • Check the sample and relaunch the test. • If the trouble persists, call the Hot Line.

Flag 30: Data Error: Unknown Error
DLL file is corrupted or missing.
Action: • Call the hot line.

Flag 31: Data Error: Ratio
No signal has been detected at 620 nm, leading to an impossibility to calculate the ratio (denominator = 0). The flag **"Missed reading"** is also issued when the "Ratio" appears.
Possible causes : • Laser failure • Laser energy below photodiode sensitivity limit • Photodiode board maladjustment or failure • Damaged cable from reader head to reader interface board
Action : • Call the hot line.

Flag 32: Data Error: Response
A problem has hindered the concentration calculation.
Possible causes : • Corrupt Analyte.ini file. • Abnormal reaction kinetics.
Action : • Check the presence and content of the files used for this assay (Analyte.ini; CRV; …).

Flag 33: Data Warning: Abnormal
Counts on B channel are too low. They must not be less than 20 % of calibrator counts at T0.
Possible causes: • Sample absorbance is too high to provide a reliable result. • Cryptate conjugate is not dispensed in the case of a pipetting problem not detected by the instrument. • The laser or the reader head performance has fallen since the last calibration. • Several bubbles (for example from the sample).
Action: • Start the **Prime** function on the main screen or use **F9**. Relaunch the test pure and/or in dilution. • Check the samples for bubbles. • Check sample and reaction plate for dust. • Check if there are any bubbles in the reaction plate. • If the problem persists, call the hot line.

Flag 34: Data Warning: Out of Range
The test is detected "**Out of Range**" during the detection phase (high concentration above the maximal detectable range) at the beginning of the incubation period.
Action: • Automatic dilution is started depending on the **Preferences** configuration in the **Administration** menu.

Flag 35: Data Warning: Detection Limit
The test is calculated below the "**Minimum Detectable Value**" at the end of the incubation period. This value is indicated in the **Administration, Analytes** menu.
Action: • No action is necessary.

Flag 36: Data Error: Above Max Range
The test is not detected "**Out of Range**" during the detection phase but it is calculated above the "**Maximum Detectable Value**" at the end of the incubation period. This value is indicated in the **Administration, Analytes** menu.
Action: • Relaunch the test manually with a small dilution factor (1/2 or 1/5).

Flag 38: Data Warning: Calibrator Warning
The test was processed on the last day on which the calibration is valid.
Action: • Start a calibration not later than the following day.

Flag 39: Data Warning: Below Normal
The test is calculated below the "**Low Concentration Threshold**" at the end of the incubation period. This value is indicated in the **Administration, Analytes** menu.
Action: • No action is necessary.

Flag 40: Data Warning: Above Normal
This value is indicated in the **Administration, Analytes** menu. The test is calculated above the "**High Concentration Threshold**" at the end of the incubation period.
Action: • No action is necessary.

Flag 42: Concentration not Consistent With Dilution Used
The dilution used is too high in relation to the assessed concentration.
Action: • Relaunch the test with another dilution. Use a lower dilution factor.

Flag 43: Sample Pipetting Problem - Check Sample
This message appears at the end of the incubation period. It indicates an antigen default during the pipetting sequence.
Possible causes: • Poor positioning of samples in the carousel • Bubbles in the fluid system or the tip
Action: • Check the sample for bubbles or foam and relaunch the test.

Flag 44: Data Warning: Abnormal Kinetics
Abnormal kinetics between T0 and Tmarching or T0 and Tend
Possible causes: • Poor positioning of the reaction plate • Pipetting problem (bubbles in fluid line) • Small bubbles are present on dispensing the samples • Contaminants are present in the sample or in the tip • Reader head • Problem on XY translator • Inadequate instrument performance when counting (bad laser – incorrect PMT threshold setting).
Action: • Prime the system and relaunch the test. • Check the samples for bubbles. • Check sample and reaction plate for dust. • Check if there are any bubbles in the reaction plate. • If the problem persists, call the hot line.

Flag 45: _Data Warning: Second Response Used
The measurements taken for this test during the Out of range detection phase show unexpected long-lived fluorescence. Note : This message is only displayed if the user is registered with the SAV level.
Possible causes: • Highly haemolized sample. • Serum that shows a high absorbance or a strong natural fluorescence. • Partial cryptate pipetting.
Action: • No action is necessary.

Flag 46: _Data Warning: Short-lived Fluorescence
The measurements taken for this test during the Out of range detection phase show unexpected short-lived fluorescence. Note : This message is only displayed if the user is registered with the SAV level.
Possible causes: • Serum that shows a strong natural fluorescence. • This message occurs frequently in patients with a renal failure.
Action: • No action is necessary.

Flag 48: Data Warning: Control out of 2 SD range
Control is out of specified 2 SD range
. **Possible causes:** • Problem with control vial (reconstitution, storage) • Problem with current calibration • Problem with reagent
Action: • Repeat measurement with a new aliquot of the control • Recalibration of the reagent • Use of a fresh reagent box and reconstitution of a fresh control vial **For more information see chapter** 8.4 Quality Control error messages

Flag 51: Inconsistent incubation time
Discordance between the Start time and the End time of the kinetics If the gap between the TCount and the TCalc is upper to the incubation time + 4 minutes, the test is flagged "Inconsistent incubation time".
. **Possible causes:** • Switch between summertime and wintertime • XPC time clock was changed during a run. • KRYPTOR software was closed during a run
Action: • Check in the result list the time of “end of test” and ”start of test”. If the real incubation time = theoretical incubation time + <4 minutes=> the result can be accepted. If not check if system is disconnected. • Close the KRYPTOR compact PLUS program or restart the computer.

Flag 52: "System Error: Missed Flashes"
• Some flashes are missing but the instrument is able to process the readings if less than 5 flashes are missing.
. **Possible causes:** • Laser failure. • Laser energy below photodiode sensitivity limit. • Photodiode board maladjustment or failure • Damaged cable from reader head to reader interface board
Action: • Call the hotline for a technical intervention

Flag 69: "Pre-incubating"
Pre-incubation test, awaiting phase II incubation
Possible causes: • No action necessary, information about pre-incubation only

Flag 70: System error: Pre-incubation has failed
The pre-incubation has failed and the phase II cannot be proceed
Possible causes: • Pipetting problem during the phase II. • No reagent unit on board at the end of the pre-incubation • The carousel hood is still open at the end of the pre-incubation • Kit discrepancy because the diluent is empty (Insufficient reagent volume) • B·R·A·H·M·S KRYPTOR compact SOLUTION 3 and 4 are empty • Water or Buffer bottles are empty • The waste bottle is full.

8.3. Calibration error messages

Schedule of the tests: KRYPTOR checks each one of the following points one by one. A message will be displayed with the first failed test, but it is still necessary to check that the other tests are correct.

- A replicate is missing
- Beta (or Alpha) Out of range
- CV of RT0 is too high
- Curve is too far from the master curve
- CV is too high
- CV of OOR limits is too high

Problem	**A replicate is missing**
Origin	One of the replicates has not the “Needs Resolution” status.
What to do	• Check in the session log if there is an error message • relaunch the calibration with a new calibrator tube

Problem	**Beta Out Of Range**
Origin	If the Ratio at T0 (RT0) is out of range : • The silica window may be dirty • The reader head lens may be dirty • The cryptate pipetting has been incomplete • The instrument ratio is incorrectly adjusted.
What to do	• Clean the silica window • Relaunch a calibration. • If the problem persists, call the hot line

Problem	**CV of RT0 is too high**
Origin	• Due to a pipetting problem.
What to do	• Check the presence of a message in the Session log. • Clean the silica window, and start a priming process. • Relaunch a calibration. • If the problem persists, unload the reaction plate, and check whether there are bubbles, splashes, scratches or insufficiently filled wells (it is normal for the first wells to be less filled because of evaporation and also for the two first points of the calibration (S0)). • If the problem persists, call the hot line

Problem	Curve is too far from the master curve
Origin	1) Dots are close to 0: no reaction, due to the absence of material, of cryptate pipetting, of calibrator, or of XL. 2) Dots are too low, but above 0: concentration of antigen or of conjugates is too low; the reader window or the reader lens is too dirty. 3) The new curve is too high: antigen or conjugate concentration is too high. 4) If the 2 dots are very far from each other, refer to the CV is too high section. 5) The problem occurs on several parameters.
What to do	1) • Check the presence of messages in the Session log. • Check the kit and the calibrator for bubbles and particles. • Perform a priming process and relaunch a calibration. • If the problem persists, call the hot line 2) • Check the calibrator and the kit for bubbles or particles, and check the liquid level. • Clean the silica window, perform a priming process and relaunch the calibration. • If the problem persists, call the hot line 3) • Unload the reaction plate in order to check the distribution and there are not scratches, and check the fluidic system for bubbles or leak. • Relaunch a new calibration after a priming process. • If the problem persists, call the hot line 4) If the 2 dots are very far from each other, refer to the CV is too high section. 5) Technical intervention is necessary. Call the hotline

Problem	CV is too high
Origin	• Due to a pipetting problem.
What to do	• Check the presence of a message in the Session log. • Perform a priming process, and then relaunch a calibration. • If the problem persists, check the fluidic system for bubbles. Unload the reaction plate, and check whether there are bubbles, splashes, scratches or insufficiently filled wells (it is normal for the first wells to be less filled because of evaporation). • If the problem persists, call the hot line

Problem	CV of OOR limits is too high
Origin	• Due to a pipetting problem.
What to do	• Check the presence of a message in the Session log. • Perform a priming process, and then relaunch a calibration. • If the problem persists, check the fluidic system for bubbles. Unload the reaction plate, and check whether there are bubbles, splashes, scratches or insufficiently filled wells (it is normal for the first wells to be less filled because of evaporation).

8.4. Quality Control error messages

Problem	Data Warning: Control out of 2 SD range
Origin	• Problem with control vial (reconstitution, storage) • Stability of control or reagent kit • Problem with the current calibration • Problem with the reagent kit
What to do	• if it is a multiparametric control : check if the trouble occurs on all parameters: If yes: the trouble can come from the control vial or the aliquot of the control (reconstitution, storage…). In this case, use another aliquot and if the trouble is reproducible, reconstitute another control vial. If the problem occurs on one parameter of a multiparametric control the reason can be the age of the control. • If the trouble occurs on one parameter, it can be a drift observed on a single reagent lot. Check the reagent (bubbles, aluminium foil, expiration date…). Check if there is a calibration drift. First, use another aliquot and if the trouble is reproducible, perform another reagent kit calibration. Use another reagent kit lot or another control lot if available

8.5. Patient sample error messages

If the problem only concerns a small number of samples:

- ✓ Check the samples' aspect (icteric, highly hemolytic, foaming, with bubbles…)
- ✓ Check if serum, plasma or another liquid is used and if this fits to the manufacturer specifications.
- ✓ Does the tube looks different (height, diameter) from the usual tubes.
- ✓ Is the anteriorly of this patient known?
- ✓ Does the patient follow a particular treatment?

- ✓ Check if there is an error message in **the result list**
- ✓ Check if there is an error message in **the detail log** (system/session log menu)
  - Samples are rediluted and cancelled
  - Result is too low
  - CV is too high
  - Concentration is not consistent with the dilution used
  - Suspected contamination problem

Many rediluted samples cancelled:

Does the problem concern one or several kits?

- ✓ Check the kit for bubbles or aluminium foil
- ✓ Replace the kit.

If the problem concerns several samples

- ✓ unload the reaction plate and assess the distribution in it. If distribution is performed according to order but with bubbles, check in the fluidic system, the presence of bubbles,
- ✓ Check if the water and the buffer bottles are not inverted.
- ✓ Shut down the instrument, wait 1 or 2 minutes, and then restart it.

Result is too low:

Can be due to an absence of pipetting or a partial pipetting.

- ✓ Ensure that there are no bubbles and that the tube is straight in its rack.
- ✓ Restart the assay and check the tip penetration into the tube.

Can be also due to a stability problem with the used kitbox especially if it needs to be reconstituted.

- ✓ So use a fresh kit, launch a control and redetermine the effected sample.
- ✓ Check the correct distribution in the reaction plate at the end of the day.

CV is too high:

Two different values, one of them is too low:

✓ See recommendations for **Result is too low**.

2 significantly different values from low with a CV that is too high:

✓ check that the different values have been obtained on the same kit, with the same dilution.

✓ Rerun the sample

✓ If the problems occurs frequently please call the hotline

Concentration is not consistent with the dilution used:

This may be due to a sample with a kinetics that does not enable KRYPTOR compact PLUS to determine the most appropriate dilution rate.

✓ Several dilution rates have to be tried, but never deliver a rate that is too low with a dilution.

✓ You can also attempt to dilute the sample manually (for manual dilutions, check that the specific kit diluent does not have a given concentration).

Contamination problem:

After a high result, if you observe an overvaluing of a sample pipetted immediately after, you can consider a carry over problem. This carry over may be due to a tip contamination or an insufficient pressure in the fluidic system.

✓ Perform a secure tip cleaning in the monthly maintenance.

✓ Perform a carry over test (Order a Carry over set - Reference number: 84194) if you can do so.

✓ If problem persists call the hotline

Pipetting/Reading sequence:

During pipetting/reading sequence it is forbidden to close interface to avoid to lost samples results or to have bad behavior of results list management.

8.6. Degraded Mode

When one of the following sensors has a malfunction the local hotline can disable it to finalize the ongoing measurement protocol. The sensors listed are installed to warrant safe routine use. As the sensor malfunctions do not affect the patient result they can be disabled. In these exceptional cases the user has to follow the precautions described below. This allows use of the instrument until service engineer intervention.

After the local hotline has disabled a sensor, the window “Securities disabled” appears on the interface.

When you click on the window, detail of sensors disabled is shown.

Specific conditions to use the instrument

Caution: The user must be careful when using the instrument because the securities are off and some specific conditions are mandatory. The user must follow the advice given.

Fluidic Hood:

The tip and the carousel may move while the fluidic hood is open. The user must be vigilant at each requested action on the interface (starting a pipett ing sequence, a carousel scan, maintenances, etc ...).

Lower Barcode Reader:

Sample tubes and reagent kits must be identified by manual entry. Refer to **Chapter 2.9 Manual entry of consumables and reagents** for precautions.

Upper Barcode Reader:

Sample cassettes are not detected. Their positions are imposed on the carousel in positions 4 and 5. The dilution plates and SOLUTIONS 1-4 must be identified manually. Refer to the **Chapter 2.9 Manual entry of consumables and reagents** for precautions. Consumables status (liquid level, dilution wells available,) will be managed as usual.

Plexi Door:

The Plexi door is the clear flap which is lowered when loading a new reaction plate. The software no longer identifies if it is open or closed. Check that the plexi door is closed before loading the reactionplate to prevent damage to the reaction plate carriage.

Reader Front Door:

This door is used to load the reaction plate and the software no longer identifies if it is open or closed. Check that the door is closed after loading the reaction plate to avoid allowing light into the reaction area and maintaining temperature control of the incubator.

The Silica Window:

This is the Reader Head Window and the heating of the reader head window is disabled. There are no special precautions to be applied in addition to daily maintenance.

Clot Detection:

The clot detection for samples is disabled, check samples before placing them on the carousel.

Waste Status:

The liquid level in the Waste bottle as well as in the waste collector placed below the washbowl is no longer managed. The status of the waste is in green color on the screen. Check waste level before starting a pipetting sequence. Check that no liquid comes out underneath the instrument.

IRDA Communication:

IRDA is used to inform the system about temperature of the reagent cassettes. The temperature is still controlled accurately but it is not reported to the system which leads to display of the alarm “System Warning: reagent cooler out of range” on all test results. The temperature status of the reagent cassette appears in red on the screen. When IRDA communication is OFF, the position of the reagent cassette is imposed at location 1 of the carousel. The identification of the reagent cassette is R1. Reagent kits are always detected through the lower bar code reader.

9. How to find archived sample results - FIAView and Database Export

9.1. Introduction

A backup of databases is made every week during the “weekly maintenances” to archive all sample results.

At any moments, the user can come back on sample results from several months ago by using two tools: the FIAView and the database Export.

In this chapter the following points are described:

- The Backuser
- The Snapshot
- Use FIAView
- Use Database Export

The differences between the snapshot and the backup of the databases lie in the following point: the backup is performed once a week during maintenances, leading to the cleaning of the databases in use through a backup of data that are older than 3 days. The snapshot, on the other hand, is requested by the hotline in order to identify problems, and can be performed at any moment on the device.

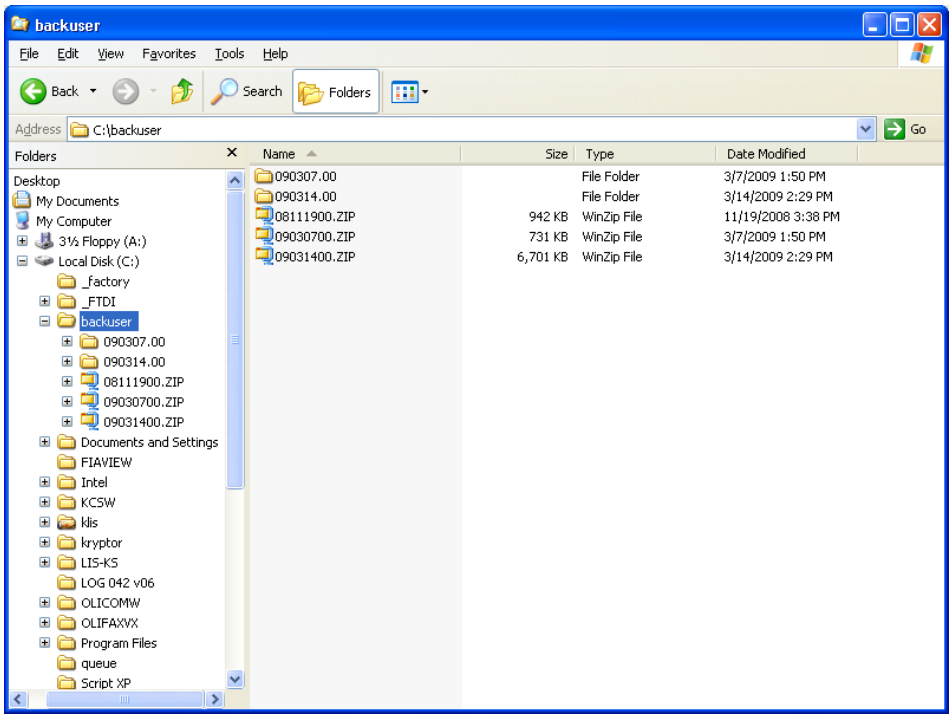
9.2. Backuser

Every week, KRYPTOR maintenance enables to perform a “databases backup”.
This backup consists in storing in a subdirectory the databases that refer to the assay results only.
The name of this directory and this .zip file consist of the date of the backup and a unique two digit number which corresponds to the number of backups performed every day: YYMMDDnn. The first time a snapshot is taken per day, the two digit number will be 00.
Subsequent backusers on the same day will be sequenced accordingly: 01, 02, 03...

YY=year
MM=month
DD=day
nn=backup order within the same day

To find this file again, go to Start\Program\Service\Explorer.exe, and then go to the C:\ Backuser directory.
In this backuser folder, the results between the last maintenance and D-3 (D is the day when maintenance is performed) are stored.

Example: The backuser 09030700.zip contains all data prior to 07 March 2009.

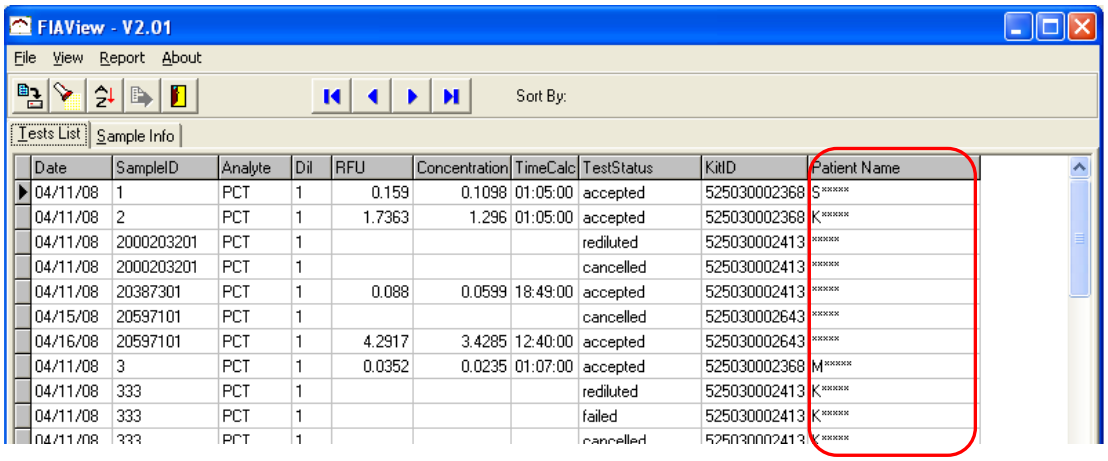


9.3. Snapshot

The snapshot corresponds to a picture of all B·R·A·H·M·S KRYPTOR compact PLUS data at the time of its execution. It is used as a trouble-shooting tool to help the hotline. With snapshot-recovered data, the hotline can look at all instrument files. The snapshot can be produced regardless of whether the instrument is running / is in online status or not.

The local hotline can access snapshots via modem or files that are saved on a floppy or USB stick and sent by mail or email.

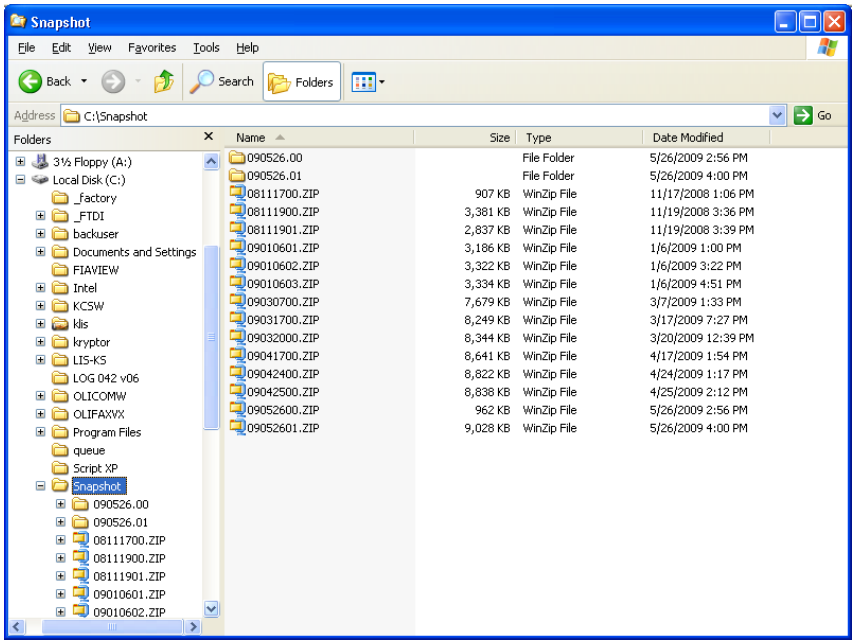
When a snapshot is taken, the patient name is automatically replaced by the name's first letter followed by 5 stars, which enables to keep the confidentiality of the patient data during the file analysis through the hot line.



To create a snapshot, click on the **Start** button and then click on **KRYPTOR Snapshot**.

Wait until the end of the procedure, the data are automatically saved in a sub-directory, which is found in the **C:\Snapshot** directory as a new zip file.

The file name consists of the date followed by a unique two digit number: YYMMDDnn.
The first time a snapshot is taken per day, the two digit number will be 00.
Subsequent snapshots on the same day will be sequenced accordingly: 01, 02, 03...



9.4. Use FIAView

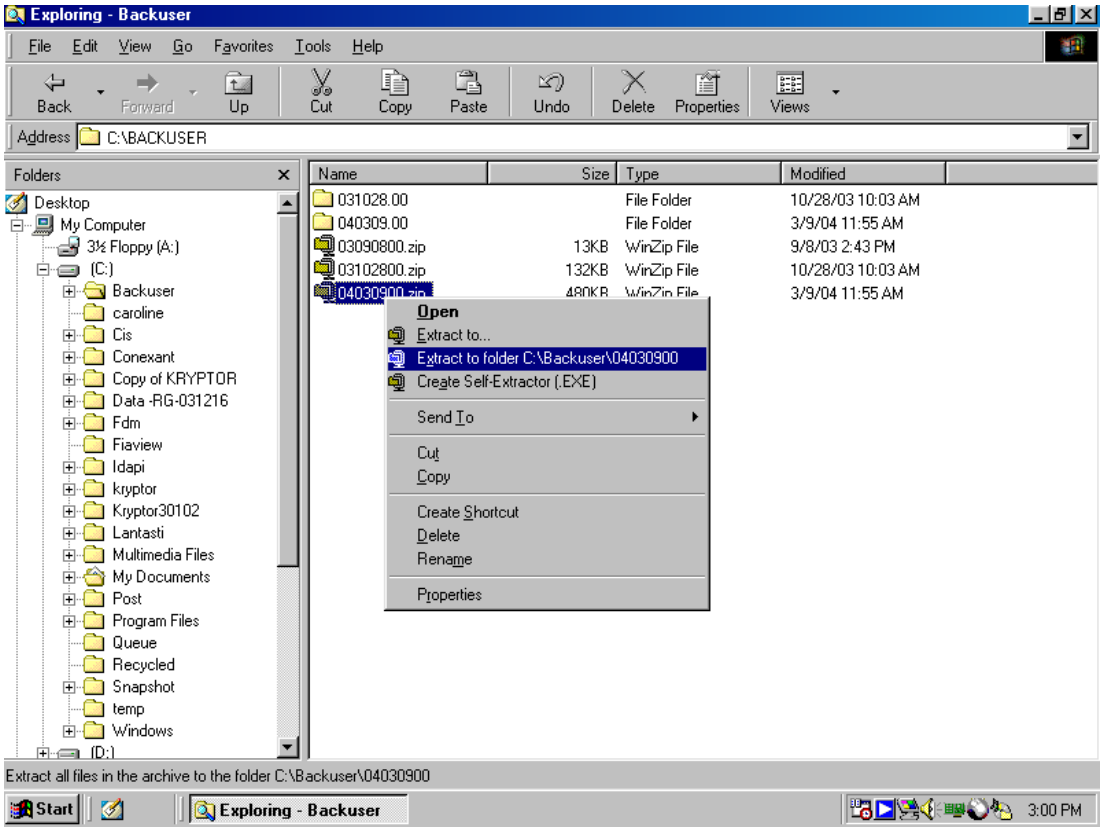
FiaView is an application that enables to edit in a “readable” form all the databases backed up during weekly maintenances. The file is named Backuser (databases backup).

9.4.1. Extract a Backuser

Note: Before reading a Backuser on FiaView, you need to unzip the Backuser.

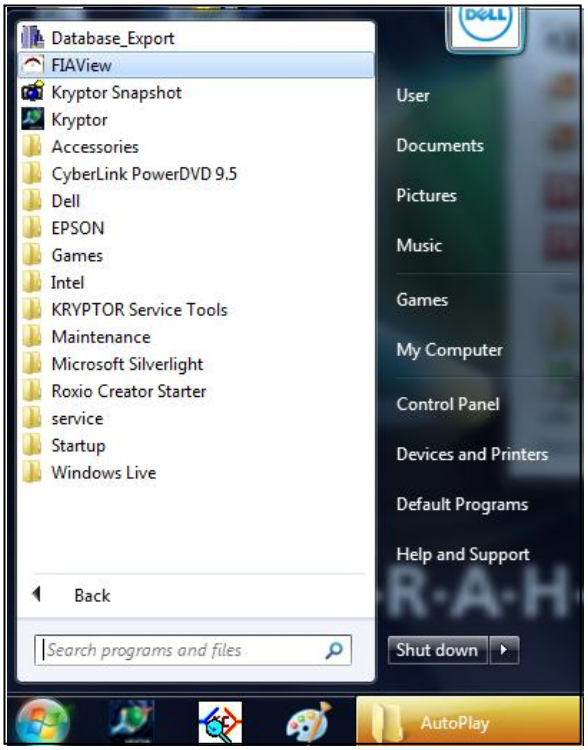
To unzip a Backuser:
- ✓ Go to C:\ Backuser
- ✓ Select the Backuser you want to visualize.
- ✓ Click with the right mouse button
- ✓ Click on 

(see picture below)
- ✓ An unzipped file will be automatically created.



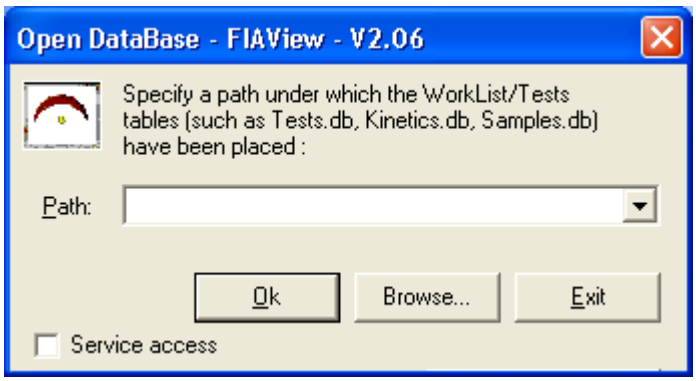
9.4.2. Open Databases

Click on the **Start** button, then select **FIAView** or **START**, **Programs**, **FIAView**.

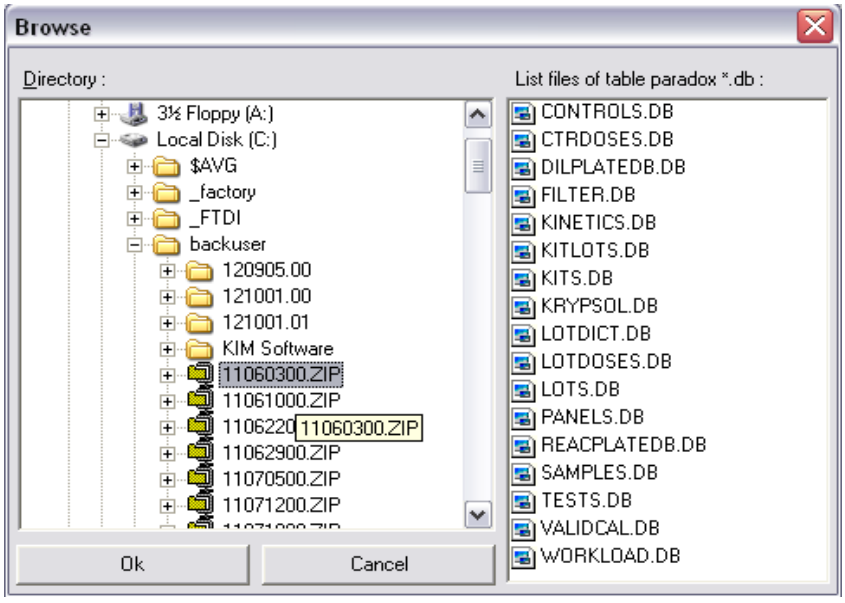


✓ When you are asked to enter a password click on **Cancel**.

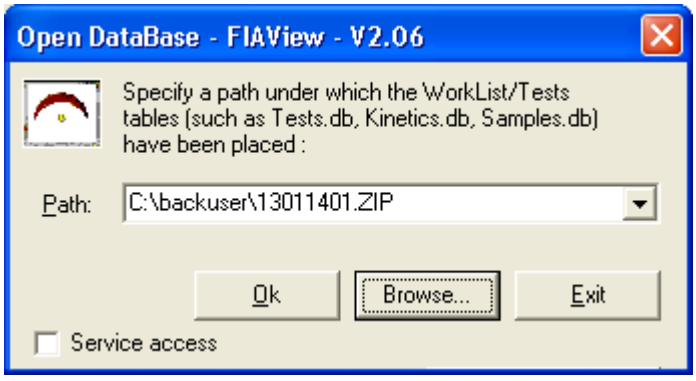
The following window will appear: The indication in the path box corresponds to the location of the previously opened databases.



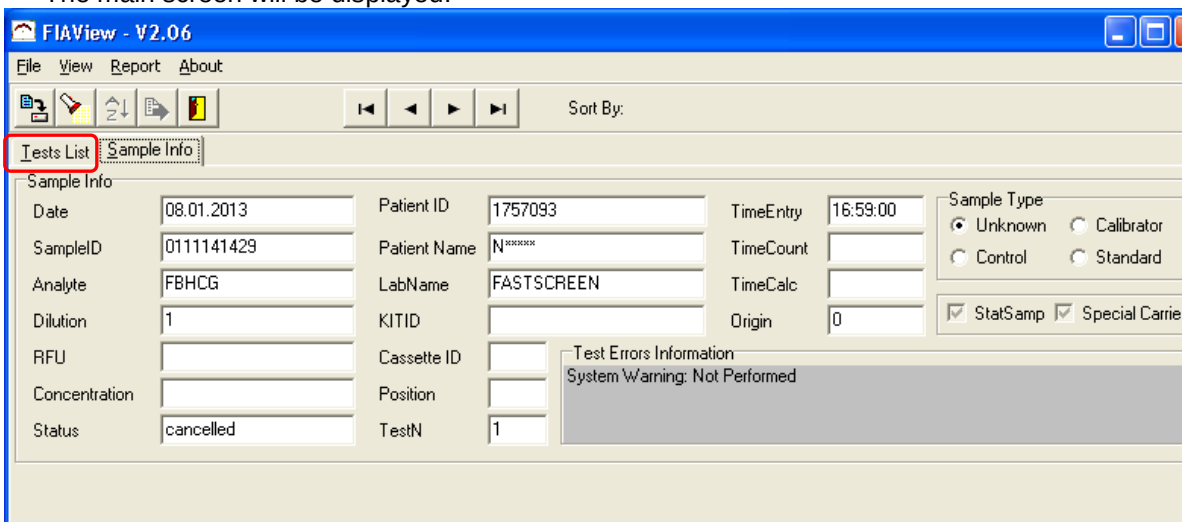
✓ Click on **Browse** in order to select the path to access the data you want to edit.
The left-hand side allows you to select the directories that you want: to choose. Double-click on the relevant directory and then first on the **zip-file** in which all databases are located.



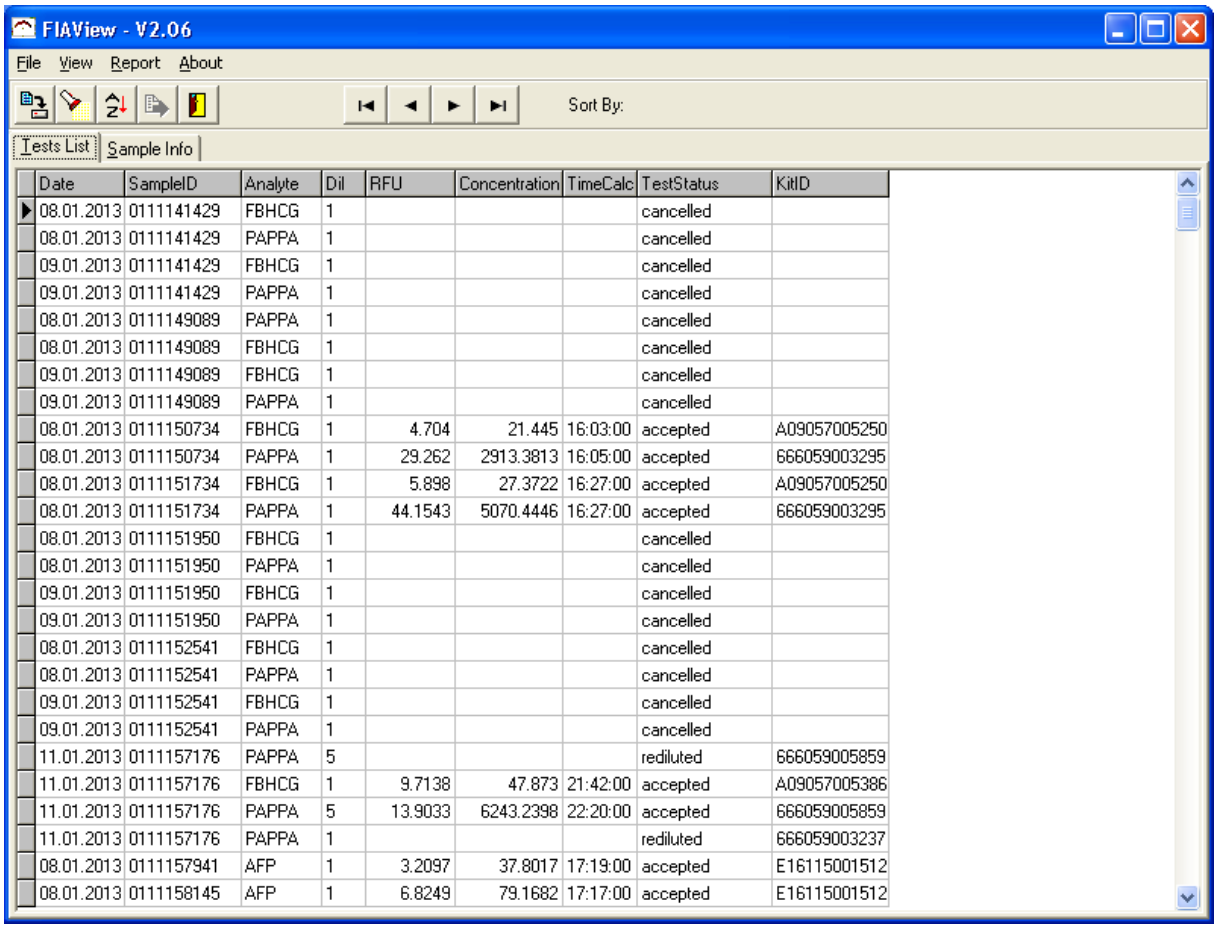
✓ Click on **Ok**



✓ Click on **Ok** in the Open database window to read the databases.
✓ The main screen will be displayed.

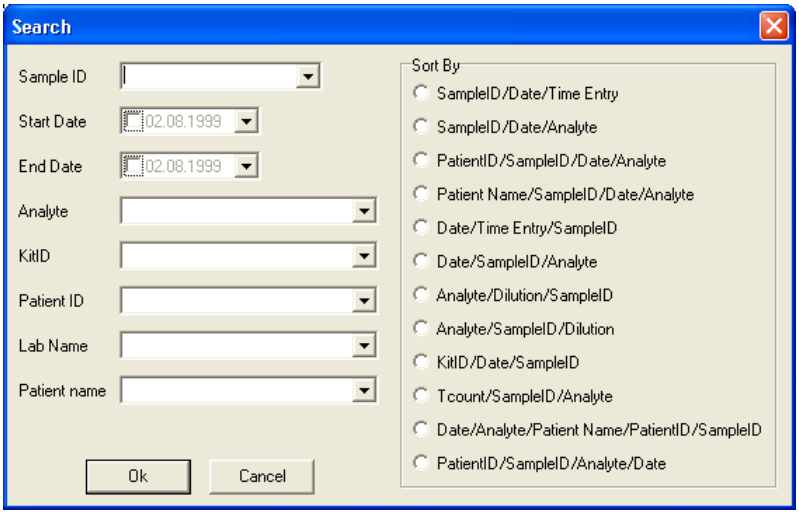


✓ Choose the tabulator **Tests list** to show the data contained in the file that you have selected.



Date	SampleID	Analyte	Dil	RFU	Concentration	TimeCalc	TestStatus	KitID
08.01.2013	0111141429	FBHCG	1				cancelled	
08.01.2013	0111141429	PAPPA	1				cancelled	
09.01.2013	0111141429	FBHCG	1				cancelled	
09.01.2013	0111141429	PAPPA	1				cancelled	
08.01.2013	0111149089	PAPPA	1				cancelled	
08.01.2013	0111149089	FBHCG	1				cancelled	
09.01.2013	0111149089	FBHCG	1				cancelled	
09.01.2013	0111149089	PAPPA	1				cancelled	
08.01.2013	0111150734	FBHCG	1	4.704	21.445	16:03:00	accepted	A09057005250
08.01.2013	0111150734	PAPPA	1	29.262	2913.3813	16:05:00	accepted	666059003295
08.01.2013	0111151734	FBHCG	1	5.898	27.3722	16:27:00	accepted	A09057005250
08.01.2013	0111151734	PAPPA	1	44.1543	5070.4446	16:27:00	accepted	666059003295
08.01.2013	0111151950	FBHCG	1				cancelled	
08.01.2013	0111151950	PAPPA	1				cancelled	
09.01.2013	0111151950	FBHCG	1				cancelled	
09.01.2013	0111151950	PAPPA	1				cancelled	
08.01.2013	0111152541	FBHCG	1				cancelled	
08.01.2013	0111152541	PAPPA	1				cancelled	
09.01.2013	0111152541	FBHCG	1				cancelled	
09.01.2013	0111152541	PAPPA	1				cancelled	
11.01.2013	0111157176	PAPPA	5				rediluted	666059005859
11.01.2013	0111157176	FBHCG	1	9.7138	47.873	21:42:00	accepted	A09057005386
11.01.2013	0111157176	PAPPA	5	13.9033	6243.2398	22:20:00	accepted	666059005859
11.01.2013	0111157176	PAPPA	1				rediluted	666059003237
08.01.2013	0111157941	AFP	1	3.2097	37.8017	17:19:00	accepted	E16115001512
08.01.2013	0111158145	AFP	1	6.8249	79.1682	17:17:00	accepted	E16115001512

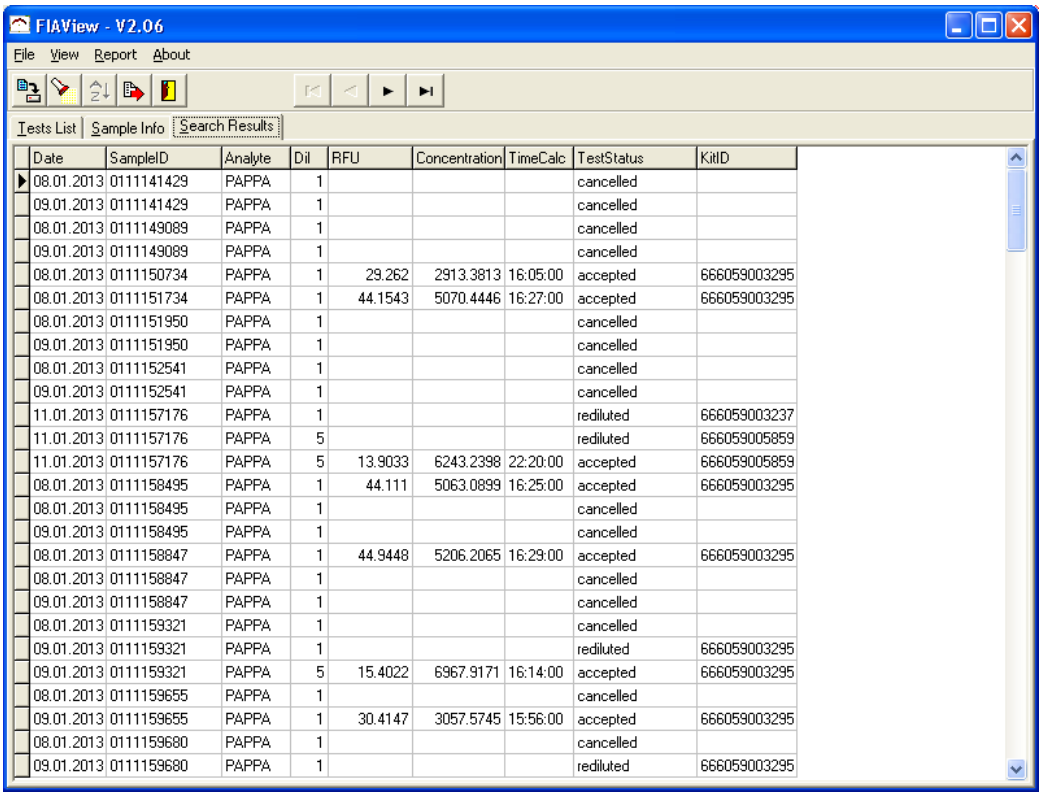
✓ Search for the relevant sample by clicking on the following icon: 
✓ The following window will be displayed:



This function enables you to:

- Look for a sample (Sample ID)
- Define a period of time (Start Date and End Date)
- Edit the result for a specific analyte (Analyte)
- Display all obtained results for a specific reagent lot (Kit ID)
- Look for a patient file (Patient ID)
- Look for a patient (Patient Name)
- Look for a laboratory (Lab Name)

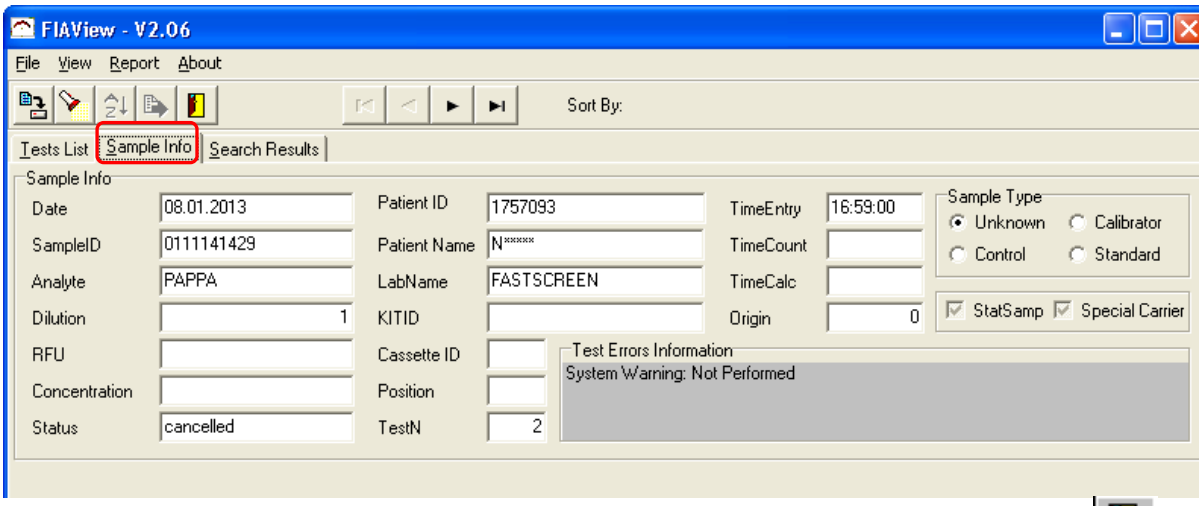
Once the research is finished, the following window is displayed with the tests you want to see.



Date	SampleID	Analyte	Dil	RFU	Concentration	TimeCalc	TestStatus	KitID
08.01.2013	0111141429	PAPPA	1				cancelled	
09.01.2013	0111141429	PAPPA	1				cancelled	
08.01.2013	0111149089	PAPPA	1				cancelled	
09.01.2013	0111149089	PAPPA	1				cancelled	
08.01.2013	0111150734	PAPPA	1	29.262	2913.3813	16:05:00	accepted	666059003295
08.01.2013	0111151734	PAPPA	1	44.1543	5070.4446	16:27:00	accepted	666059003295
08.01.2013	0111151950	PAPPA	1				cancelled	
09.01.2013	0111151950	PAPPA	1				cancelled	
08.01.2013	0111152541	PAPPA	1				cancelled	
09.01.2013	0111152541	PAPPA	1				cancelled	
11.01.2013	0111157176	PAPPA	1				rediluted	666059003237
11.01.2013	0111157176	PAPPA	5				rediluted	666059005859
11.01.2013	0111157176	PAPPA	5	13.9033	6243.2398	22:20:00	accepted	666059005859
08.01.2013	0111158495	PAPPA	1	44.111	5063.0899	16:25:00	accepted	666059003295
08.01.2013	0111158495	PAPPA	1				cancelled	
09.01.2013	0111158495	PAPPA	1				cancelled	
08.01.2013	0111158847	PAPPA	1	44.9448	5206.2065	16:29:00	accepted	666059003295
08.01.2013	0111158847	PAPPA	1				cancelled	
09.01.2013	0111158847	PAPPA	1				cancelled	
08.01.2013	0111159321	PAPPA	1				cancelled	
09.01.2013	0111159321	PAPPA	1				rediluted	666059003295
09.01.2013	0111159321	PAPPA	5	15.4022	6967.9171	16:14:00	accepted	666059003295
08.01.2013	0111159655	PAPPA	1				cancelled	
09.01.2013	0111159655	PAPPA	1	30.4147	3057.5745	15:56:00	accepted	666059003295
08.01.2013	0111159680	PAPPA	1				cancelled	
09.01.2013	0111159680	PAPPA	1				rediluted	666059003295

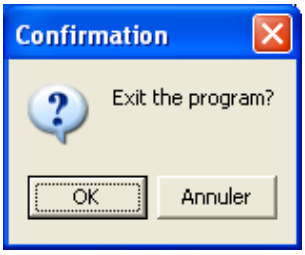
Description of the displayed table:	
Date :	Date when the sample is added in the worklist
SampleID :	Sample identification
Analyte :	Analyte name
Dilution :	Dilution used
RFU :	Relative Fluorescence Unit
Concentration :	Sample concentration.
Timecalc :	Time when the result of the sample is calculated
Test Status :	Test status
KitID :	Kit identification

For more information about a sample result, select the sample and click on the menu **Sample Info**.



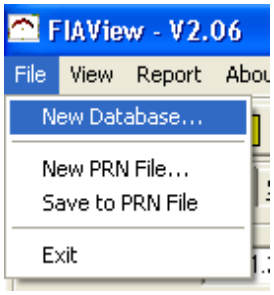
To exit the program, the *Exit* function in the **File** menu is equivalent to the following icon: 

Before leaving FiaView, the application proposes to confirm the exit by clicking on **OK** or to cancel it by **Annuler**.



Instead of leaving the program and start it again to have a look on other data, you can choose to open a new database.

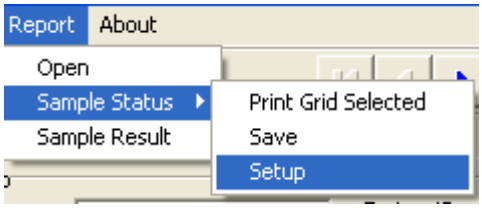
To open a new database, select the **File** menu and then click on **New Database**.



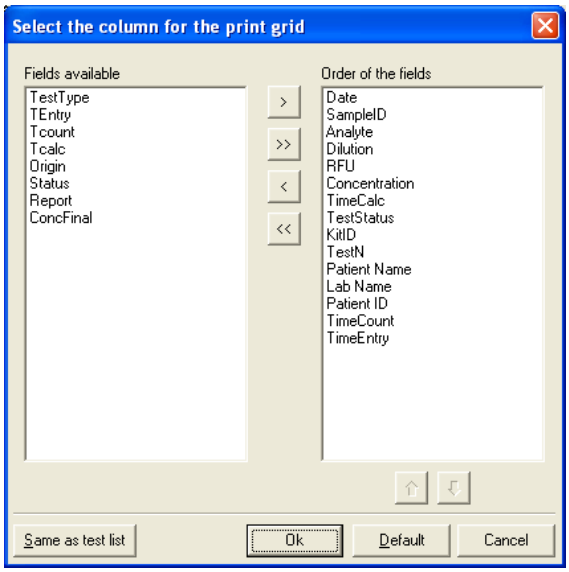
9.4.3. Print Sample Status Report

You can use FIAView to customize the print report.

Select **Report**, **Sample Status**, **Setup**.



The **Printer setup** window is displayed.



Description of the fields available:	
SampleID :	Sample identification
Date :	Date when the sample is added in the worklist
Tentry :	Elapsed time in seconds from 01/01/1904 until the sample is added in the worklist
Analyte :	Analyte name
Dilution :	Dilution used
TestN :	Number of tests ordered per Sample ID
KitID :	Kit identification
Tcount :	Elapsed time in seconds from 01/01/1904 until the sample is dispensed in the reaction plate
Timecalc :	Elapsed time in seconds from 01/01/1904 until the result of the sample is calculated
Test Status :	Test status
Errors :	Error code
Origin :	Origin of the test ordered (LIS, redilution, manual, user rerun, automatic rerun…)
Report :	Information useful for application specialist
RefDose :	Previous value of the test (only information value sent by the LIS)
Concentration :	Sample concentration.
RFU :	Relative Fluorescence Unit

To add the **Fields available** to the **Order of the fields** that are printed you have the following buttons:

Select all the fields

Select one field

Unselect one field

Unselect all the fields

You can also only print the default data list.

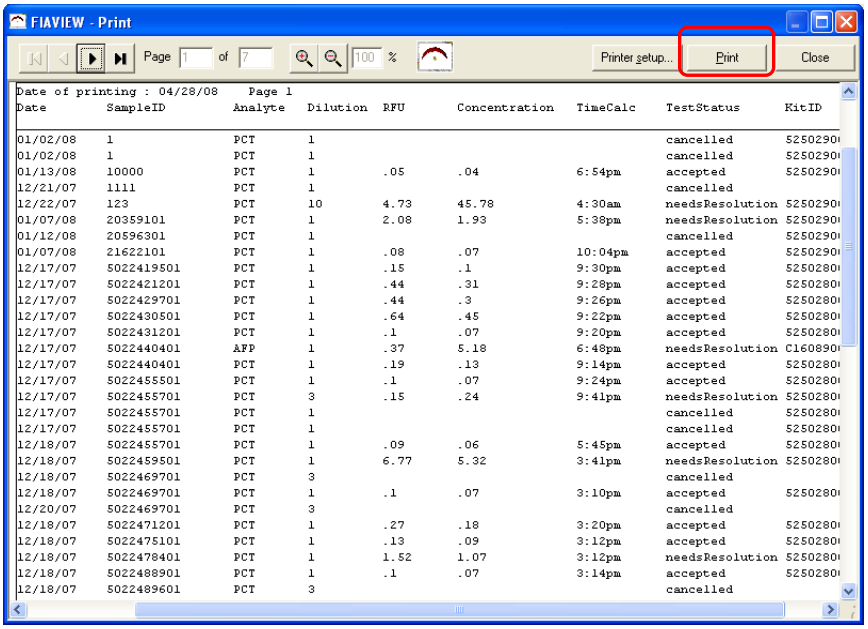
The buttons are:

- **OK**: To validate the configuration

- **Cancel**: To cancel all modification
- **Default**: To reset the “Order of the Fields” to the default settings.
- **Same as test list**: To configure the printing as for the main screen

The configuration is memorized until the next modification.

To print the report, select **Report**, **Sample Status**, **Print Grid** to obtain a preview of the print and then click on **Print**.



Date of printing : 04/28/08 Page 1

Date	SampleID	Analyte	Dilution	RFU	Concentration	TimeCalc	TestStatus	KitID
01/02/08	1	PCT	1				cancelled	5250290
01/02/08	1	PCT	1				cancelled	5250290
01/13/08	10000	PCT	1	.05	.04	6:54pm	accepted	5250290
12/21/07	1111	PCT	1				cancelled	
12/22/07	123	PCT	10	4.73	45.78	4:30am	needsResolution	5250290
01/07/08	20359101	PCT	1	2.08	1.93	5:38pm	needsResolution	5250290
01/12/08	20596301	PCT	1				cancelled	5250290
01/07/08	21622101	PCT	1	.08	.07	10:04pm	accepted	5250290
12/17/07	5022419501	PCT	1	.15	.1	9:30pm	accepted	5250280
12/17/07	5022421201	PCT	1	.44	.31	9:28pm	accepted	5250280
12/17/07	5022429701	PCT	1	.44	.3	9:26pm	accepted	5250280
12/17/07	5022430501	PCT	1	.64	.45	9:22pm	accepted	5250280
12/17/07	5022431201	PCT	1	.1	.07	9:20pm	accepted	5250280
12/17/07	5022440401	AFP	1	.37	5.18	6:48pm	needsResolution	C160890
12/17/07	5022440401	PCT	1	.19	.13	9:14pm	accepted	5250280
12/17/07	5022455501	PCT	1	.1	.07	9:24pm	accepted	5250280
12/17/07	5022455701	PCT	3	.15	.24	9:41pm	needsResolution	5250280
12/17/07	5022455701	PCT	1				cancelled	5250280
12/17/07	5022455701	PCT	1				cancelled	5250280
12/18/07	5022455701	PCT	1	.09	.06	5:45pm	accepted	5250280
12/18/07	5022459501	PCT	1	6.77	5.32	3:41pm	needsResolution	5250280
12/18/07	5022469701	PCT	3				cancelled	
12/18/07	5022469701	PCT	1	.1	.07	3:10pm	accepted	5250280
12/20/07	5022469701	PCT	3				cancelled	
12/18/07	5022471201	PCT	1	.27	.18	3:20pm	accepted	5250280
12/18/07	5022475101	PCT	1	.13	.09	3:12pm	accepted	5250280
12/18/07	5022478401	PCT	1	1.52	1.07	3:12pm	needsResolution	5250280
12/18/07	5022488901	PCT	1	.1	.07	3:14pm	accepted	5250280
12/18/07	5022489601	PCT	3				cancelled	

9.5. Database Export

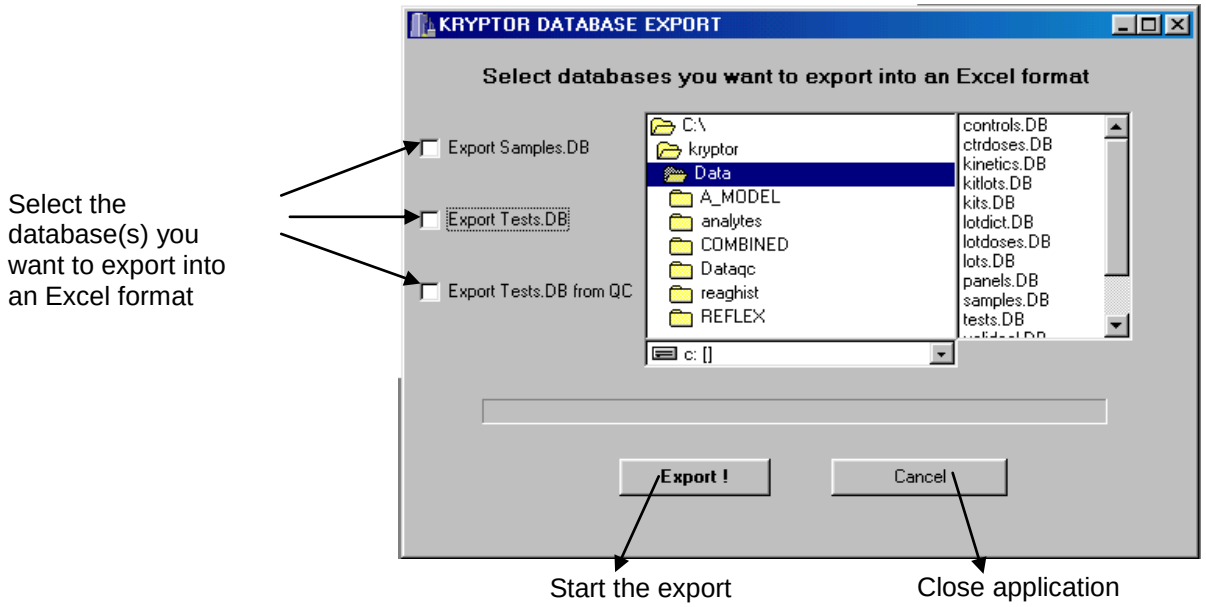
9.5.1. Introduction

Database Export is a utility that enables the user to convert 3 types of B·R·A·H·M·S KRYPTOR compact PLUS data into an Excel file.

You will work with the following databases:

- Tests.DB (patient identification and patient results)
- Samples.DB (patient identification)
- Tests.DB from QC (control identification and results).

To open Database Export, click on **Start** and select **Database-export** in the pull-down menu.



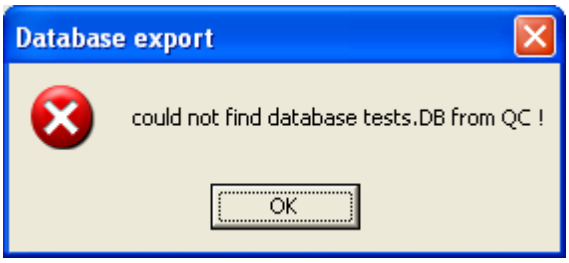
The default directory will be the one displayed on screen. Keep this configuration so that you can export your databases.

Note: Before starting the export process, check that the Kryptor application is closed. After this, “tests.DB”, “samples.DB” and “tests.DB from QC” will be accessible.

9.5.2. Choice of directory

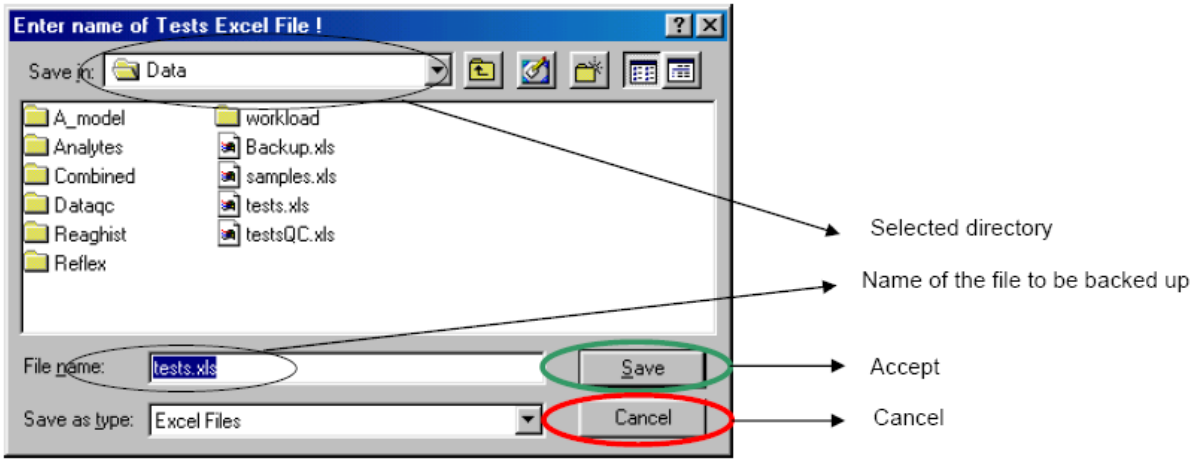
You must specify the directory where the database to be exported is located.

If the program does not find the database wished , the following message will be displayed:



9.5.3. Backup of files to be exported

During the database export process, the software will ask you to back up the file you want to export. The default file name is the selected database's name.



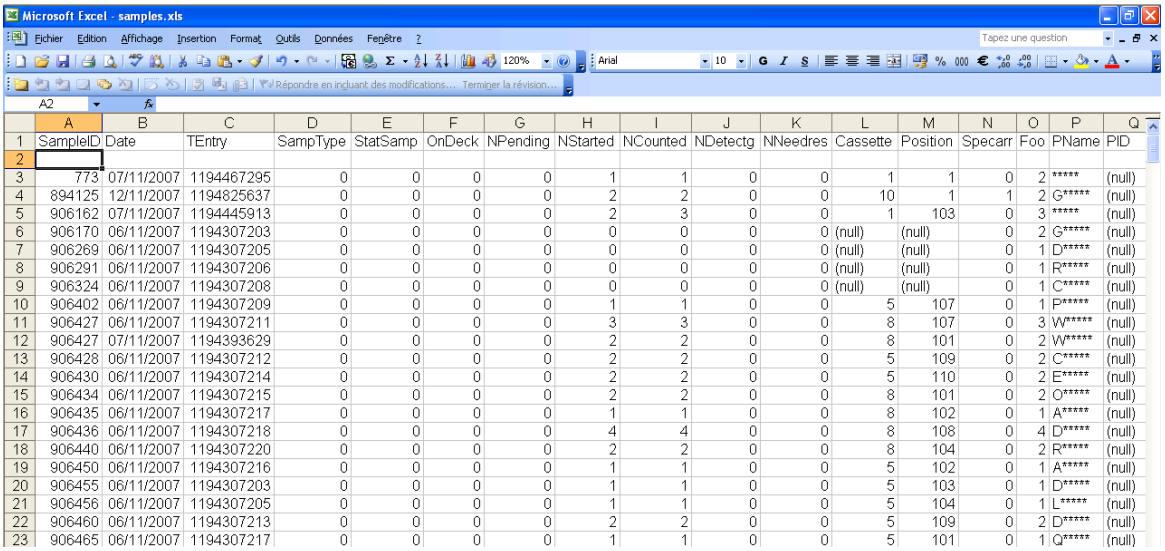
Note: If the file name already exists, a message confirming the file replacement will appear.

9.5.4. Results

Copy the files on a floppy disk or a memory stick and read them on a computer which has the Excel application.

You will obtain a table such as the one below (example):

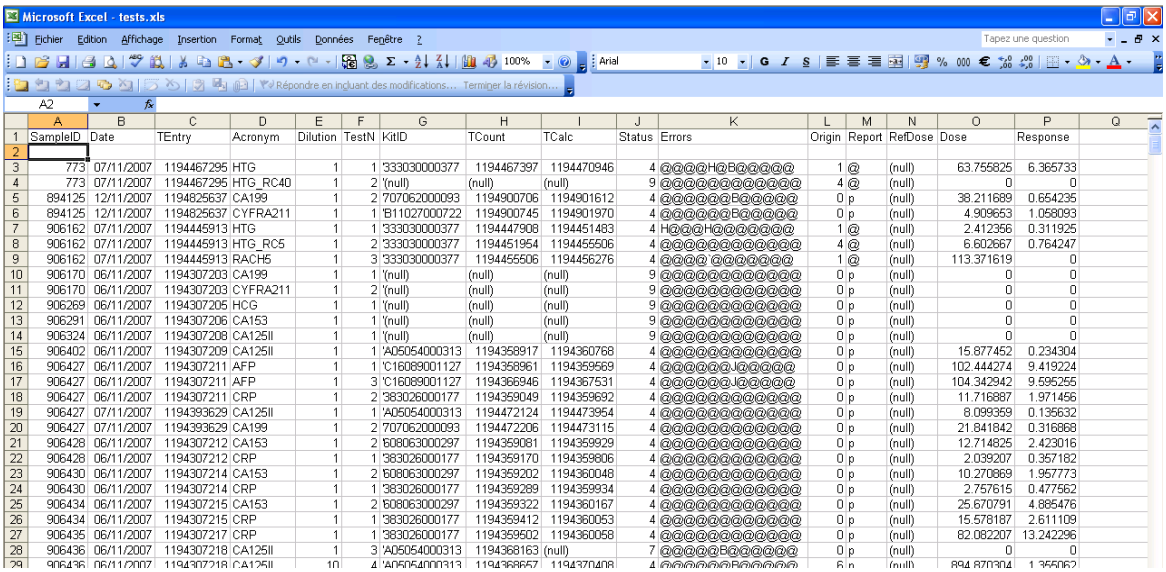
Example Samples.DB



SampleID	Date	TEntry	SampType	StatSamp	OnDeck	NPending	NStarted	NCounted	NDetectg	NNeedres	Cassette	Position	Specarr	Foo	PName	PID
773	07/11/2007	1194467295	0	0	0	0	1	1	0	0	1	1	0	2	*****	(null)
894125	12/11/2007	1194825637	0	0	0	0	2	2	0	0	10	1	1	2	G*****	(null)
906162	07/11/2007	1194445913	0	0	0	0	2	3	0	0	1	103	0	3	*****	(null)
906170	06/11/2007	1194307203	0	0	0	0	0	0	0	0	(null)	(null)	0	2	G*****	(null)
906269	06/11/2007	1194307205	0	0	0	0	0	0	0	0	(null)	(null)	0	1	D*****	(null)
906291	06/11/2007	1194307206	0	0	0	0	0	0	0	0	(null)	(null)	0	1	R*****	(null)
906324	06/11/2007	1194307208	0	0	0	0	0	0	0	0	(null)	(null)	0	1	C*****	(null)
906402	06/11/2007	1194307209	0	0	0	0	1	1	0	0	5	107	0	1	P*****	(null)
906427	06/11/2007	1194307211	0	0	0	0	3	3	0	0	8	107	0	3	W*****	(null)
906427	07/11/2007	1194393629	0	0	0	0	2	2	0	0	8	101	0	2	W*****	(null)
906428	06/11/2007	1194307212	0	0	0	0	2	2	0	0	5	109	0	2	C*****	(null)
906430	06/11/2007	1194307214	0	0	0	0	2	2	0	0	5	110	0	2	E*****	(null)
906434	06/11/2007	1194307215	0	0	0	0	2	2	0	0	8	101	0	2	O*****	(null)
906435	06/11/2007	1194307217	0	0	0	0	1	1	0	0	8	102	0	1	A*****	(null)
906436	06/11/2007	1194307218	0	0	0	0	4	4	0	0	8	108	0	4	D*****	(null)
906440	06/11/2007	1194307220	0	0	0	0	2	2	0	0	8	104	0	2	R*****	(null)
906450	06/11/2007	1194307216	0	0	0	0	1	1	0	0	5	102	0	1	A*****	(null)
906455	06/11/2007	1194307203	0	0	0	0	1	1	0	0	5	103	0	1	D*****	(null)
906456	06/11/2007	1194307205	0	0	0	0	1	1	0	0	5	104	0	1	L*****	(null)
906460	06/11/2007	1194307213	0	0	0	0	2	2	0	0	5	109	0	2	D*****	(null)
906465	06/11/2007	1194307217	0	0	0	0	1	1	0	0	5	101	0	1	Q*****	(null)

Description of samples.db:	
SampleID :	Sample identification
Date :	Date when the sample is added in the worklist
TEntry :	Elapsed time in seconds from 01/01/1904 until the sample is added in the worklist
SampType :	Sample type (Unknown, Calibrator, Control, Standard)
StatSamp :	Stat sample (Y/N)
OnDeck :	Sample on carousel board (Y/N)
NPending :	Number of tests pending per Sample ID
NStarted :	Number of tests pippeted per Sample ID
NCounted :	Number of tests in counting phase per Sample ID
NDetectg :	Number of tests in Out Of Range detection phase per Sample ID
NNeedres :	Number of tests in « Need resolution » status per Sample ID
Cassette :	Cassette identification on which sample is placed
Position :	Position of the sample in the cassette
SpeCarr :	Sample in micro-cup (Y/N)
Foo :	Information for software development.
PName :	Patient Name
PID :	Patient ID
LabName :	Lab Name
Notes :	Comments area

Example Tests.DB



Microsoft Excel - tests.xls

	SampleID	Date	TEntry	Acronym	Dilution	TestN	KitID	TCount	TCalc	Status	Errors	Origin	Report	RefDose	Dose	Response
3	773	07/11/2007	1194467295	HTG	1	1	'333030000377	1194467397	1194470946	4	@@@@H@B@@@@@	1	@	(null)	63.755825	6.365733
4	773	07/11/2007	1194467295	HTG_RC40	1	2	'(null)	(null)	(null)	9	@@@@@@@@@@@@	4	@	(null)	0	0
5	894125	12/11/2007	1194825637	CA199	1	2	'707062000093	1194900706	1194901612	4	@@@@@@B@@@@@	0	p	(null)	38.211689	0.654235
6	894125	12/11/2007	1194825637	CYFRA211	1	1	'B11027000722	1194900745	1194901970	4	@@@@@@B@@@@@	0	p	(null)	4.909653	1.058093
7	906162	07/11/2007	1194445913	HTG	1	1	'333030000377	1194447908	1194451483	4	H@@@H@@@@@@@	1	@	(null)	2.412356	0.311925
8	906162	07/11/2007	1194445913	HTG_RC5	1	2	'333030000377	1194451954	1194455506	4	@@@@@@@@@@@@	4	@	(null)	6.602667	0.764247
9	906162	07/11/2007	1194445913	RACH5	1	3	'333030000377	1194455506	1194456276	4	@@@@ @@@@@@@	1	@	(null)	113.371619	0
10	906170	06/11/2007	1194307203	CA199	1	1	'(null)	(null)	(null)	9	@@@@@@@@@@@@	0	p	(null)	0	0
11	906170	06/11/2007	1194307203	CYFRA211	1	2	'(null)	(null)	(null)	9	@@@@@@@@@@@@	0	p	(null)	0	0
12	906269	06/11/2007	1194307205	HCG	1	1	'(null)	(null)	(null)	9	@@@@@@@@@@@@	0	p	(null)	0	0
13	906291	06/11/2007	1194307206	CA153	1	1	'(null)	(null)	(null)	9	@@@@@@@@@@@@	0	p	(null)	0	0
14	906324	06/11/2007	1194307208	CA125II	1	1	'(null)	(null)	(null)	9	@@@@@@@@@@@@	0	p	(null)	0	0
15	906402	06/11/2007	1194307209	CA125II	1	1	'A05054000313	1194358917	1194360768	4	@@@@@@@@@@@@	0	p	(null)	15.877452	0.234304
16	906427	06/11/2007	1194307211	AFP	1	1	'C16089001127	1194358961	1194359569	4	@@@@@@J@@@@@	0	p	(null)	102.444274	9.419224
17	906427	06/11/2007	1194307211	AFP	1	3	'C16089001127	1194366946	1194367531	4	@@@@@@J@@@@@	0	p	(null)	104.342942	9.595255
18	906427	06/11/2007	1194307211	CRP	1	2	'383026000177	1194359049	1194359692	4	@@@@@@@@@@@@	0	p	(null)	11.716887	1.971456
19	906427	07/11/2007	1194393629	CA125II	1	1	'A05054000313	1194472124	1194473954	4	@@@@@@@@@@@@	0	p	(null)	8.099359	0.135632
20	906427	07/11/2007	1194393629	CA199	1	2	'707062000093	1194472206	1194473115	4	@@@@@@@@@@@@	0	p	(null)	21.841842	0.316868
21	906428	06/11/2007	1194307212	CA153	1	2	'608063000297	1194359081	1194359929	4	@@@@@@@@@@@@	0	p	(null)	12.714825	2.423016
22	906428	06/11/2007	1194307212	CRP	1	1	'383026000177	1194359170	1194359806	4	@@@@@@@@@@@@	0	p	(null)	2.039207	0.357182
23	906430	06/11/2007	1194307214	CA153	1	2	'608063000297	1194359202	1194360048	4	@@@@@@@@@@@@	0	p	(null)	10.270869	1.957773
24	906430	06/11/2007	1194307214	CRP	1	1	'383026000177	1194359289	1194359934	4	@@@@@@@@@@@@	0	p	(null)	2.757615	0.477562
25	906434	06/11/2007	1194307215	CA153	1	2	'608063000297	1194359322	1194360167	4	@@@@@@@@@@@@	0	p	(null)	25.670791	4.885476
26	906434	06/11/2007	1194307215	CRP	1	1	'383026000177	1194359412	1194360053	4	@@@@@@@@@@@@	0	p	(null)	15.578187	2.611109
27	906435	06/11/2007	1194307217	CRP	1	1	'383026000177	1194359502	1194360058	4	@@@@@@@@@@@@	0	p	(null)	82.082207	13.242296
28	906436	06/11/2007	1194307218	CA125II	1	3	'A05054000313	1194368163	(null)	7	@@@@@B@@@@@@	0	p	(null)	0	0
29	906436	06/11/2007	1194307218	CA125II	10	4	'A05054000313	1194368657	1194370408	4	@@@@@@@B@@@@@	6	p	(null)	894.870304	1.355062

Description of tests.db:	
SampleID :	Sample identification
Date :	Date when the sample is added in the worklist
Tentry :	Elapsed time in seconds from 01/01/1904 until the sample is added in the worklist
Analyte :	Analyte name
Dilution :	Dilution used
TestN :	Number of tests ordered per Sample ID
KitID :	Kit identification
Tcount :	Elapsed time in seconds from 01/01/1904 until the sample is dispensed in the reaction plate
Timecalc :	Elapsed time in seconds from 01/01/1904 until the result of the sample is calculated
Test Status :	Test status
Errors :	Error code
Origin :	Origin of the test ordered (LIS, redilution, manual, user rerun, automatic rerun…)
Report :	Information useful for application specialist
RefDose :	Previous value of the test (only information value sent by the LIS)
Concentration :	Sample concentration.
RFU :	Relative Fluorescence Unit

9.5.5. Possible errors:

If the user tries to export the samples.DB file while the instrument is running, the following message will appear:

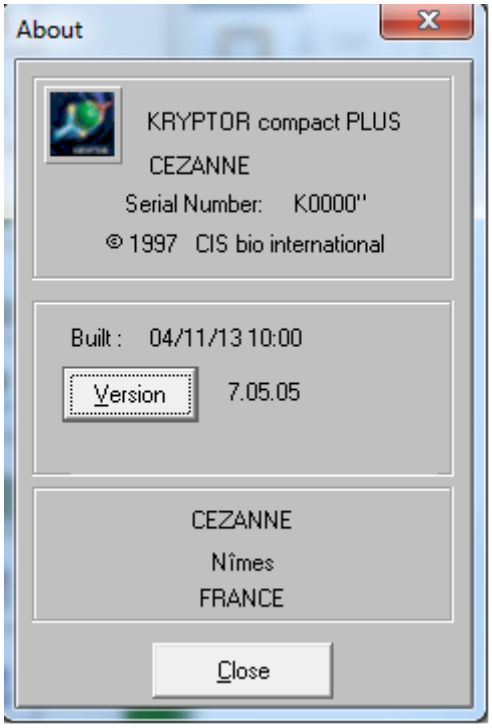
In this case, you can close the Kryptor application and export databases afterwards

10. Instrument Specifications

10.1. Technical Specifications

All instrument specifications given below are confirmed by B·R·A·H·M·S GmbH.

B·R·A·H·M·S KRYPTOR compact PLUS serial number can be accessed through the **Help / About** menu on the external PC interface or on the signal plate located on the top of the instrument.



10.1.1. Technical Specifications´ Overview

	Reader Module	Pipetor Module
Height:	630 mm	630 mm
Width: (add 200 mm for the fluidic system)	280 mm	460 mm
Depth:	610 mm	750 mm
Weight:	26 kg	28 kg
Noise:	55 dBA	55 dBA
Power requirements:	100 - 240 V AC 50/60Hz single phase	100 - 240 V AC 50/60Hz single phase
Current Rating:	<250 VA	<250 VA
Power input:	465 VA for KRYPTOR compact PLUS Reader Module, Pipetor Module, screen and XPC	465 VA for KRYPTOR compact PLUS Reader Module, Pipetor Module, screen and XPC
Transient Overvoltage category:	II	II
Pollution degree:	2	2
Class:	I	I
Current Rating for UPS	1000 VA	1000 VA

10.1.2. Transport and placement conditions

	Reader Module	Pipetor Module
Temperature:	18…30°C	18…30°C
Humidity:	20-85% non-condensing	20-85% non-condensing
Altitude:	must be used below 2.000 meters	must be used below 2.000 meters
Clearance distance	Behind 5 cm Left Side 10 cm Right Side 20 cm Disconnecting device should be accessible.	Behind 5 cm Left Side 10 cm Right Side 20 cm Disconnecting device should be accessible.
Transport conditions	-20… 70°C	-20… 70°C
Long term storage	0… 50°C	0… 50°C

10.1.3. Laser

The laser inside the instrument emits an invisible radiation whose characteristics are the following:

Laser Type	LTB	SRS
Beam Deviation(mrad)	3*3	5*8
Pulse Length (ns)	2.5	<3.5
Max Peak Power (kW)	100	45
Repetition Rate (Hz)	20	20

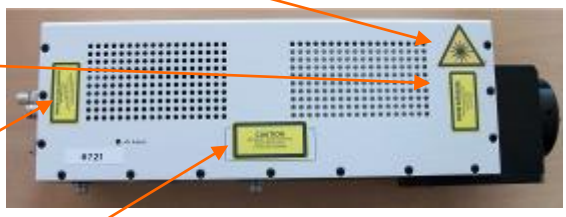
10.2. Location of Signs and Symbols

<table>
<tr><th>Sign</th><th>Location</th><th>Risk/ Warning</th></tr>
<tr><td>CAUTION-CLASS 3B INVISIBLE LASER RADIATION WHEN OPEN
AVOID EXPOSURE TO THE BEAM</td><td>Reader head shielding
  </td><td rowspan="3"><u>Optical risk</u>
Class 3B laser
Do not look into the laser beam
Always keep the laser connected to the optical fiber.
Make sure the other extremity of the optical fiber is connected either to the reader head or a joulemeter.
Do not open the casing of the laser</td></tr>
<tr><td>CAUTION-CLASS 3B INVISIBLE LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED
AVOID EXPOSURE TO THE BEAM</td><td>Side panel of access to the laser</td></tr>
<tr><td>Laser Radiation
Avoid Exposure To Beam
Class 3B Laser Product
Invisible laser radiation is emitted from this aperture

Caution – Laser Radiation
Avoid Exposure To Beam
Class 3B Laser Product
Peak power: 100kW ; 2.5ns ; 337 nm
IEC 60825-1:1993

LASER APERTURE</td><td>LTB Laser
 
Invisible laser radiation is emitted from this aperture</td></tr>
<tr><td> 
AVOID EXPOSURE
INVISIBLE LASER RADIATION
IS EMITTED FROM
THIS APERTURE

INVISIBLE LASER RADIATION
AVOID EXPOSURE TO BEAM
Class 3B laser product
3 ns pulse duration, 200 µJ max. pulse energy
4 mW max. avg. power, 337 nm emitted wavelength
Classified to IEC60825-1: 2001-08

CAUTION
INVISIBLE LASER RADIATION
WHEN OPEN AVOID
EXPOSURE TO BEAM</td><td>SRS Laser
  </td></tr>
</table>

Laser

Symbol	Explanation
	Laser
	Carousel Barcode Readers Max. power.: 1.3 mV Signal: 650 nm Class II
	Laser Max. power: 3.0 mV Signal: 337 nm Class 3B

Reader Head

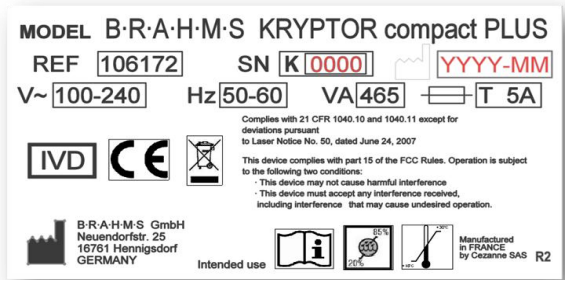
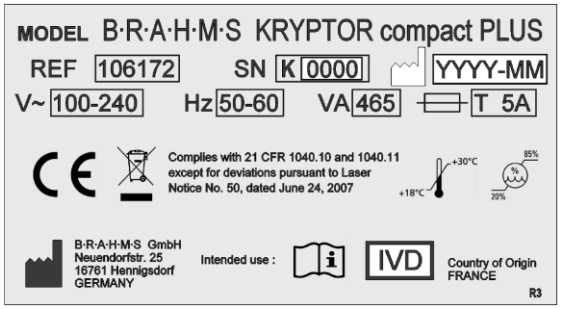
Caution: Class 3B invisible laser radiation when open and interlocks defeated**.** Avoid exposure to the beam

Symbol	Explanation
	Laser
	Electric

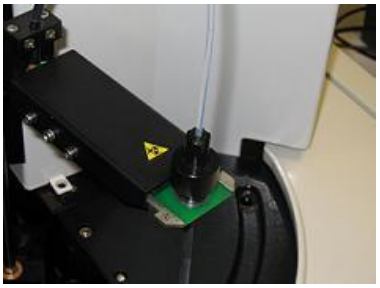
Reaction Area:

Symbol	Explanation
	Thermal hazard

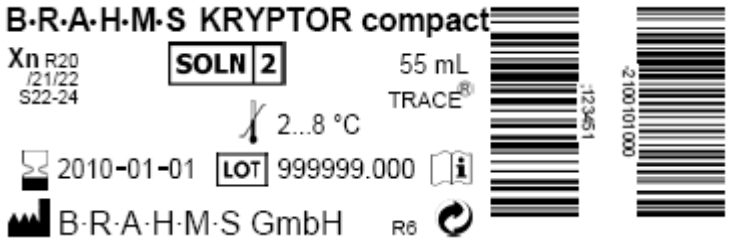
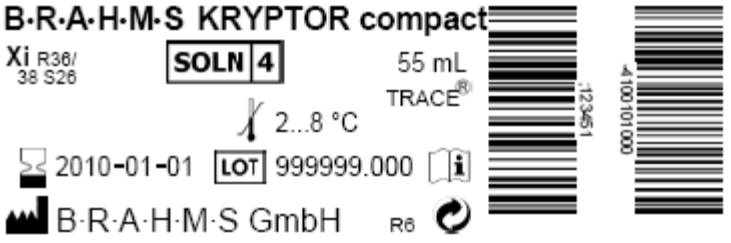
Back of KRYPTOR compact PLUS

Symbol	Explanation
1)  2)  	Rear top of B·R·A·H·M·S KRYPTOR compact PLUS 100-240V 5 A (depending on the manufacturing date of the instrument you will find ID Plate 1) or 2) on the instrument)

Pipetor Arm and Fluidic System:

Symbol	Explanation
	Biologic hazard
	Sample Probe Sample probe to take samples and reagents
	Waste bottle
	Fluidic connectors

Labeling of B·R·A·H·M·S KRYPTOR SOLUTIONS:

Symbol	Explanation
 **Xn R 20/21/22 S 22-24**	Labeling B·R·A·H·M·S KRYPTOR compact SOLUTION 2 Harmful Harmful by inhalation, in contact with skin and if swallowed. Do not breathe in the aerosole. Avoid contact with skin.
 **Xi R 36/38 S 26**	Labeling B·R·A·H·M·S KRYPTOR compact SOLUTION 4 Irritant Irritant to eyes and skin, rinse immediately with plenty of water and seek medical advice.

10.3. Safety Instructions

The safety instructions given in this manual help the user to avoid personal accidents, material damage and environmental contamination.
Only qualified and trained personnel should use this in-vitro device in accordance with the GMP guidelines. Please observe the local health and safety regulations as well.
System users must be familiar with the use as described in the manual and with maintenance procedures.
Please pay attention to all warnings and safety instructions given in this manual.
Remove safety equipment only if necessary and described in the relevant instruction, and replace it immediately after taking the necessary action.
Use only the SOLUTIONS specified for maintenance and cleaning.
Follow the safety instruction for reagents and SOLUTIONS.

Please read the safety instructions very carefully before operating the B·R·A·H·M·S KRYPTOR compact PLUS
analyzer. Contact your local hot line if you have any doubts or questions.

The system must be installed by trained service engineers. All the performance specifications are checked on installation. Please refrain from all attempts to install, repair or modify the instrument by unauthorized personnel.

Caution: Use of controls or adjustment or performances of procedures other than those specified herein may result in hazardous radiation exposure.

B·R·A·H·M·S KRYPTOR compact PLUS analyzer is a class 2 laser product.

Do not look at the lasers in the sample carousel barcode reader and in the manual barcode reader. Avoid direct eye exposure.

10.3.1. Biological Hazard

When working with human serum, controls and calibrators all accessible parts of the analyzer must be considered as biohazardous. The pipette tip, sample cassettes, reagent cassettes, carousel drip pan, and analyzer deck should be routinely disinfected.
Concerning all areas exposed to patient potential infectious material or to user contact follow the cleaning requirements and use 5% Hypochloride solution for decontamination. (See chapter maintenance.)
It is strongly recommended to wear gloves and a special coat.

Dilution plate

Before removing the dilution plate, attach the adhesive cover film to the plate.
The adhesive covers are supplied with the dilution plates.

Reaction plate

Before removing a reaction plate, attach the adhesive cover film.

Calibrator, controls

Read the safety instructions in the instructions for use.

Sample probe

Clean up any fluid that may have leaked and check whether there is any evidence of leakage between the plastic connector (fluidic line) and the top of the probe. Contact the hot line in the event of a leak.

Waste disposal

Please dispose of the reagents and the waste in accordance with the local authority specifications.

10.3.2. Chemical Hazard

B·R·A·H·M·S KRYPTOR compact SOLUTION 1 to 4

For detailed information, read the safety instructions given in the instructions for use.
Safety data sheets are available from your local hot line on request.

10.3.3. Electrical Hazard

Electrical security

Do not connect the B·R·A·H·M·S KRYPTOR compact PLUS to a power supply before ensuring that the voltage setting is correct. The analyzer can be used with a power supply (mains) voltage of 100.0 - 240.0 V~ / 50 - 60 Hz (automatic switch). Verify the voltage of the local power supply (mains) to be used. Make sure the analyzer is correctly set for the power supply (mains) actually being used. Always plug the analyzer into a grounded outlet. Operating technicians and maintenance personnel are urged to follow sound electrical safety practices at all times. Although all metal parts of the analyzer are at ground potential (zero voltage), they should never be touched with one hand while touching a plumbing fixture, radiator, AC-operated device or other grounded object with the other. Before opening the analyzer, remove the power cable from the power outlet. Do not replace components or attempt any repairs with the analyzer switched on.
Do not operate the analyzer in an atmosphere containing explosive gases since components of the analyzer could generate sparks.
Avoid spilling fluid on or into the analyzer at any time. All spills should be wiped up promptly.
If the equipment is used in a manner not specified by B·R·A·H·M·S, the protection provided by the equipment may be impaired.

Electromagnetic compatibility

Changes or modifications not expressly approved by B·R·A·H·M·S GmbH could void the user's authority to operate the equipment.

B·R·A·H·M·S KRYPTOR compact PLUS is compliant with class B product requirements as defined in IEC 61326-2-6 standard.

The B·R·A·H·M·S KRYPTOR compact PLUS complies with the emission and immunity requirements described in EN 61326-2-6.
The electromagnetic environment should be evaluated prior to operation of the device.
Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

11. Remote Assistance

11.1. Information on Modem Connection

Information on Modem Connection for B·R·A·H·M·S KRYPTOR compact PLUS Automates

The B·R·A·H·M·S KRYPTOR compact PLUS offers the possibility of a remote connection via a modem. With a modem and appropriate software (pcAnywhere) the user will have the following options and advantages:

- Remote control of the B·R·A·H·M·S KRYPTOR compact PLUS , e. g. in case of problems or difficulties in operation
- Online error diagnosis, e. g. by means of the „FIAView“ software utility
- Online troubleshooting, e. g. software errors, remedy of calibration problems
- Online software updates
- Quick availability of snapshots for further error analysis by the International Hot Line
- Online user training

The use of a modem connection offers the following benefits:

- Prevention/reduction and better planning of on-site service visits (less materials and effort required for servicing – decreased service & maintenance costs)
- Reduced system downtime by means of direct error analysis and, if possible, remedy
- Increased customer satisfaction

Online access to those systems equipped with a modem is designed in such a way that login is possible only after authorisation by the user (clearance for each individual case), and only to the B·R·A·H·M·S KRYPTOR compact PLUS connected. Access to the system without the user's awareness is thus ruled out. The user can monitor all online activities at any time, or break the online connection if he wishes to.

With regard to the implementation of B·R·A·H·M·S KRYPTOR compact PLUS remote service via modem, B·R·A·H·M·S GmbH guarantees to the customer that the following principles will be adhered to:

Data Protection and Confidentiality

B·R·A·H·M·S GmbH regards itself as committed to respect the personal rights and privacy of all persons with whom it maintains direct or indirect business contacts. As company operating in the health care sector, B·R·A·H·M·S GmbH considers it a matter of course that health-related information in particular shall be treated with utmost sensitivity, under observance of all applicable legal requirements.
Processing of patient-specific data during maintenance and servicing of the diagnostic systems is neither planned nor intended.
The International Hot Line pledges to respect the privacy and anonymity of information provided by the laboratories and distributors in their communications with them. Data is securely stored and not shared with any third party. In case any personal data has to be transmitted, it will be deleted immediately upon the completion of the remote servicing activity.

System Access

B·R·A·H·M·S GmbH shall ensure that

- the system cannot be accessed without the customer's positive action of running the pcAnywhere utility. The remote hot liner must type a password defined upon pcAnywhere installation.
- every attempt will be made to prevent interception of transmitted data by unauthorised third parties.

11.2. FAQs Concerning B·R·A·H·M·S KRYPTOR compact PLUS Modem Access

How to use it?

The connection is monitored with a user-friendly interface named pcAnywhere. The software can be purchased via B·R·A·H·M·S GmbH and is easily installed and configurated following the instructions enclosed in the service manual.

Is a dedicated telephone line required?

The telephone line could be shared with other applications (phone, other PC…) but it must be a direct line, not via switchboard.

Who will pay for the communication?

The hot line (national or International Hot Line) is calling the B·R·A·H·M·S KRYPTOR compact PLUS, therefore the hot line is billed for the call. No costs are charged to the lab/hospital.

Who has modem access to my B·R·A·H·M·S KRYPTOR compact PLUS?

Access can only be given by the B·R·A·H·M·S KRYPTOR compact PLUS user. The modem configuration will lock access from external calls. pcAnywhere is launched by the B·R·A·H·M·S KRYPTOR compact PLUS user using password authentification before connection and closed by the user following intervention.

Can I disable the modem?

Yes, the integrated modem can be disabled (hardware + driver) using the MS WINDOWS administration menu. Please refer to the WINDOWS documentation.
You also could easily disconnect manually the phone line via your PC.

Is the LIS accessible through the modem connected to my B·R·A·H·M·S KRYPTOR compact PLUS?

Serial connection: The link between B·R·A·H·M·S KRYPTOR compact PLUS and LIS is through ASTM protocol. The only request accepted by the LIS is a query on sample ID. No file access to LIS or virus contamination is possible.
RJ45 network: Any drive visible on B·R·A·H·M·S KRYPTOR compact PLUS can be accessible with pcAnywhere. As networks shall be adequately protected and drive access carefully defined, please refer to your administrator to limit B·R·A·H·M·S KRYPTOR compact PLUS XPC access to the network.

Is the B·R·A·H·M·S KRYPTOR compact PLUS available for routine work during the remote connection?

Yes, modem connection allows survey and data collection during routine work and other normal B·R·A·H·M·S KRYPTOR compact PLUS operations.

12. Abbreviations

Abbreviation	Explanation
ADC	Analog Digital Converter
ASTM	(American Society for Testing and Materials) Connection protocol for LIS
CV	Coefficient of Variation
DSP	Digital Signal Processor
HOST	Corresponds to the main system (server) in the LIS connection
HPRIM	Type of message coding for LIS connection
KC	KRYPTOR compact PLUS
K-DISK-ANA	B·R·A·H·M·S KRYPTOR compact PLUS CD ROM including analyte.ini files
KIM	Kryptor Interface Module
LED	Light-emitting diode
LIS	Laboratory Information System
OOR	Out of Range
PBS	Phosphate Buffer Saline (Liquid system)
PMT	Photon Photomultiplier
T0	Readings at time zero
T1	Readings at a precise time defined for certain analytes
TE =Tend	Readings at the end of the incubation period
Tmarching	Readings during the OOR detection phase
TRACE	Time Resolved Amplified Cryptate Emission
XIPC	KRYPTOR compact PLUS software on the external PC
XPC	External PC (User Interface)
ZLL	Vertical position, from which detection starts (Liquid level)
Zmax	Maximum low position in vertical movement
ZTr	Secure, vertical position for traveling from one area to another

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