Alinity c Total Bilirubin (Bili Total)-20

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BIENNIAL REVIEW:

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SUPERSEDES: Procedure titled _____

INTENDED USE

The Alinity c Total Bilirubin assay is used for the quantitation of total bilirubin in human serum or plasma of adults and neonates on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Red blood cells at the end of their circulating lives are broken down in the reticuloendothelial system, mainly the spleen. The resulting heme is converted to bilirubin upon removal of iron. This process accounts for about 80% of the 500 µmol (292 mg) of bilirubin formed daily. Other sources of bilirubin include the breakdown of myoglobin and cytochromes and the catabolism of immature red blood cells in the bone marrow.

Once formed, bilirubin is transported to the liver bound to albumin. This fraction of bilirubin is referred to as indirect or unconjugated bilirubin. In the liver, bilirubin is conjugated to glucuronic acid (mono- and di-glucuronides) by the enzyme uridyl diphosphate glucuronyl transferase to form conjugated bilirubin. Conjugated bilirubin or direct bilirubin is excreted via the biliary system into the intestine, where it is metabolized by bacteria to a group of products known collectively as stercobilinogen. Elimination is almost complete and serum levels are normally negligible.

Total bilirubin is the sum of the unconjugated and conjugated fractions. Total bilirubin is elevated in hepatitis, cirrhosis, hemolytic disorders, several inherited enzyme deficiencies, and conditions causing hepatic obstruction.

Neonatal bilirubin quantitation is used to monitor diseases causing jaundice in the newborn, chiefly erythroblastosis fetalis (also called hemolytic disease of the newborn or HDN). HDN is caused by maternal alloimmunization to RhD, antibodies involving additional blood groups, and ABO incompatibility.[1]

The average full-term newborn infant has a peak serum bilirubin concentration of 5 to 6 mg/dL (86 to 103 µmol/L). Physiologic jaundice is seen at serum bilirubin concentrations from
7 to 17 mg/dL (120 to 291 µmol/L). Serum bilirubin concentrations greater than 17 mg/dL may be pathologic. The primary concern is the potential for bilirubin encephalopathy or kernicterus. The term "kernicterus" was introduced in the early 1900s to refer to the yellow staining of the basal ganglia observed in infants who died with severe jaundice.[2]

Additional causes of neonatal jaundice are hematoma/hemorrhage, hypothyroidism, Crigler-Najjar syndrome, obstructive jaundice, galactosemia, sepsis, syphilis, toxoplasmosis, cytomegalovirus, rubella, glucose-6-phosphate dehydrogenase (G-6-PDH) deficiency, pyruvate kinase deficiency, and spherocytosis.[1], [2]

PRINCIPLES OF THE PROCEDURE

Traditional methods of measuring bilirubin are based on the reaction of bilirubin with a diazo reagent to form the colored compound azobilirubin. The diazo reaction can be accelerated by the addition of various chemicals. For example, Malloy-Evelyn[3] used methanol, Jendrassik-Gróf[4] used caffeine, and Walters-Gerarde[5] used dimethyl sulfoxide (DMSO). Modifications of these methods included the addition of surfactants as solubilizing agents.[6]

Total (conjugated and unconjugated) bilirubin couples with a diazo reagent in the presence of a surfactant to form azobilirubin. The diazo reaction is accelerated by the addition of surfactant as a solubilizing agent. The increase in absorbance at 548 nm due to azobilirubin is directly proportional to the total bilirubin concentration.

Methodology: Diazonium Salt

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity c Total Bilirubin Reagent Kit 04V51

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	04V5121	04V5131
Tests per cartridge	275	360
Number of cartridges per kit	10	10
Tests per kit	2750	3600
R1	52.9 mL	68.1 mL
R2	16.8 mL	21.0 mL
R1 Active ingredients: Surfactants (4.53%), HCl (9.33 g/L).		
R2 Active ingredients: 2,4-dichloroaniline (0.81 g/L), HCl (5.563 g/L), Sodium nitrite (0.345 g/L), Surfactant (1.96%).		

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[7], [8], [9], [10]

The following warnings and precautions apply to: R1	
	
DANGER	Contains sodium borohydride, hydrochloric acid, polyoxyethylene lauryl ether, and polyethylene glycol octylphenyl ether.
H360	May damage fertility or the unborn child.
H314	Causes severe skin burns and eye damage.

H290	May be corrosive to metals.
H401*	Toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
Prevention	
P201	Obtain special instructions before use.
P234	Keep only in original container.
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
P273	Avoid release to the environment.
Response	
P308+P313	IF exposed or concerned: Get medical advice / attention.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower.
P310	Immediately call a POISON CENTER or doctor / physician.
P390	Absorb spillage to prevent material damage.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

The following warnings and precautions apply to: R2


DANGER	Contains hydrochloric acid and polyoxyethylene lauryl ether.
H314	Causes severe skin burns and eye damage.
H290	May be corrosive to metals.
Prevention	
P234	Keep only in original container.
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower.
P310	Immediately call a POISON CENTER or doctor / physician.
P390	Absorb spillage to prevent material damage.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or/and SDS folder.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Reagents are shipped on wet ice.

- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- Do not invert reagent cartridges prior to use.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	21 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10**.

INSTRUMENT PROCEDURE

The Alinity c Total Bilirubin assay file must be installed on the Alinity c analyzer prior to performing the assay.

The Alinity c Total Bilirubin assay file is also known as Bili Total assay file.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) =
(Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	17.1	µmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	Protect from light.*11*
Plasma	Collection tubes	Protect from light.*11*
	Acceptable anticoagulants are:	The use of tubes containing sodium fluoride/ potassium oxalate is not recommended due to the potential for hemolysis with this anticoagulant.
	Lithium heparin (with or without gel barrier)	
	Sodium heparin	
	EDTA	
Matrix Comparison Data Analysis		

This study was performed on the ARCHITECT c System.

Serum vs. plasma matrices were compared utilizing a Least-Squares Linear Regression analysis for glass serum tube (x-axis) vs. various tube types (y-axis).

Tube Type	N	Correlation Coefficient	Slope	Intercept (mg/dL)	Intercept (µmol/L)
Serum Separator Tube (SST)	30	0.9999	1.00	-0.01	-0.17
K2 EDTA Plasma Tube (non-gel)	30	0.9995	1.07	-0.15	-2.57
Lithium Heparin Plasma Tube (non-gel)	30	0.9998	1.00	-0.01	-0.17
Lithium Heparin Plasma Tube (Plasma Separator Tube–PST) with gel	30	0.9999	1.00	0.00	0.00
Sodium Heparin Plasma Tube (non-gel)	30	0.9999	0.99	-0.01	-0.17

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	20 to 25°C	1 day[12]
	2 to 8°C	7 days[12], [13]
	-20°C	6 months[12], [14]
	-80°C	6 months[14]

Specimens should be protected from bright light as bilirubin is photolabile.[11]

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[12]

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04V51 Alinity c Total Bilirubin Reagent Kit

Materials Required but not Provided

- Alinity c Total Bilirubin (Bili Total) assay file
- 08P6101 Alinity c Bilirubin Calibrator Kit
- Commercially available controls containing bilirubin
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, **refer to the Alinity ci-series Operations Manual, Section 9.**

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section

4 to ensure sufficient specimen is present.

- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 2.6 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. **For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.**
- Refer to the Alinity c Bilirubin Calibrator Kit package insert and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, **refer to the Alinity ci-series Operations Manual, Section 5.**
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, **Section 9. Perform maintenance more frequently when required by laboratory procedures.**

Sample Dilution Procedures

Samples with a total bilirubin value exceeding 25.0 mg/dL (427.5 µmol/L) are flagged with the code "> 25.0 mg/dL" ("> 427.5 µmol/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The system performs a **1:5 or a 1:10** dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 0.1 mg/dL (1.71 µmol/L), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

Calibration is stable for approximately **14 days (336 hours)**, but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the laboratory quality control requirements procedure. If control results fall outside acceptable ranges,

recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by the laboratory quality control procedure, sample results may be suspect. Follow the laboratory quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[15]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Total Bilirubin assay utilizes the Linear data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (µmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Total Bilirubin assay is **0.1 to 25.0** mg/dL (1.71 to 427.5 µmol/L).

LIMITATIONS OF THE PROCEDURE

For patients undergoing evaluations involving the administration of indocyanine green (ICG), it is recommended that samples are drawn after ICG has been eliminated. See the Interference section for additional information.[16, 17]

In samples where the concentration of bilirubin is low, or where conjugated bilirubin is the predominant form, the Direct Bilirubin assay may report results that are greater than results obtained using the Total Bilirubin assay. Under these circumstances, report the Total Bilirubin results for both the Total Bilirubin and Direct Bilirubin assays.

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

Manufacturer provided reference ranges will be adopted, effort made to verify in house.

Reference Range

Serum/Plasma

	Range (mg/dL)	**Range (µmol/L)**
Adult[18]	0.2 to 1.2	3.4 to 20.5
A confirmation study was conducted with the Total Bilirubin assay (List Number 6L45) on the ARCHITECT c System using 26 serum and plasma samples from adult volunteers. Data were analyzed as described in CLSI protocol NCCLS C28-A3c.[19] From this study, 96% of results were within the range of 0.2 to 1.2 mg/dL, confirming the adult reference interval.		
	Range (mg/dL)	**Range (µmol/L)**
Premature (serum)[20]		
< 24 hours	< 8.0	< 136.8
< 48 hours	< 12.0	< 205.2
3 to 5 days	< 15.0	< 256.5
7 days	< 15.0	< 256.5
Full-term Newborn (serum)[20]		
< 24 hours	< 6.0	< 102.6
< 48 hours	< 10.0	< 171.0
3 to 5 days	< 12.0	< 205.2

	Range (mg/dL)	Range (µmol/L)
7 days	< 10.0	< 171.0

For additional information on neonatal bilirubin values, refer to the American Academy of Pediatrics recommendation in *Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation*.[21]

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2.[22] Testing was conducted using 1 lot of the Alinity c Total Bilirubin Reagent Kit, 1 lot of the Alinity c Bilirubin Calibrator Kit, 1 lot of commercially available controls, and 1 instrument. Three controls and 1 serum panel were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (mg/dL)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	0.7	0.01	1.3	0.01	1.3
Control Level 2	120	2.8	0.02	0.9	0.03	0.9
Control Level 3	120	5.9	0.05	0.8	0.07	1.3
Panel	120	15.4	0.07	0.4	0.14	0.9

[a] Includes within-run, between-run, and between-day variability.

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	**n**	**Mean (µmol/L)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	120	12.0	0.16	1.3	0.16	1.3
Control Level 2	120	47.8	0.41	0.9	0.43	0.9

Sample	n	Mean (µmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 3	120	101.5	0.81	0.8	1.27	1.2
Panel	120	262.9	1.13	0.4	2.35	0.9

[a] Includes within-run, between-run, and between-day variability.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.*23* Testing was conducted using 3 lots of the Alinity c Total Bilirubin Reagent Kit on each of 2 instruments over a minimum of 3 days. The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below. These representative data support the lower limit of the measuring interval.

	mg/dL	µmol/L
LoB[a]	0.02	0.34
LoD[b]	0.04	0.68
LoQ[c,d]	**≤ 0.1**	≤ 1.71

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

[d] This value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity c analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.*24*

This assay is linear across the measuring interval of **0.1 to 25.0** mg/dL (1.71 to 427.5 µmol/L).

Interference

This study was performed on the ARCHITECT c System.

Potentially Interfering Substances

A study was performed based on guidance from CLSI EP07-A2.*25*

Interference effects were assessed by Dose Response and Paired Difference methods at 2 testing intervals. A bias outside the limits of ± 10% or ± 0.3 mg/dL is considered significant interference.

Potentially Interfering Substance	Interferent Level Default Units	Total Bilirubin		
		Target Level (mg/dL)	Observed (mg/dL)	Observed (%)*
Hemoglobin	1000 mg/dL	1.07	1.13	105
	2000 mg/dL	1.07	1.09	101
	1000 mg/dL	14.08	14.11	100
	2000 mg/dL	14.08	14.07	100
Intralipid	750 mg/dL	1.27	1.57	123
	1000 mg/dL	1.27	1.78	140
	750 mg/dL	16.50	16.62	101
	1000 mg/dL	16.50	16.61	101
Indican (Indoxyl Sulfate)	0.175 mmol/L	1.32	1.59	120
	0.200 mmol/L	1.32	1.65	125
	0.750 mmol/L	16.01	16.83	105
	1.000 mmol/L	16.01	16.96	106
Indocyanine Green	18.8 mg/L	1.53	1.77	115
	25.0 mg/L	1.53	1.85	121
	75.0 mg/L	14.27	15.18	106
	100.0 mg/L	14.27	15.46	108

* Percentages have been rounded to whole numbers.

Potentially Interfering Substance	Interferent Level Alternate Units	Total Bilirubin		
		Target Level (µmol/L)	Observed (µmol/L)	Observed (%)*
Hemoglobin	10 g/L	18.30	19.32	105
	20 g/L	18.30	18.64	101
	10 g/L	240.77	241.28	100
	20 g/L	240.77	240.60	100
Intralipid	7.5 g/L	21.72	26.85	123
	10 g/L	21.72	30.44	140
	7.5 g/L	282.15	284.20	101

Potentially Interfering Substance	Interferent Level Alternate Units	Total Bilirubin		
		Target Level (µmol/L)	Observed (µmol/L)	Observed (%)*
	10 g/L	282.15	284.03	101
Indican (Indoxyl Sulfate)	0.175 mmol/L	22.57	27.19	120
	0.200 mmol/L	22.57	28.22	125
	0.750 mmol/L	273.77	287.79	105
	1.000 mmol/L	273.77	290.02	106
Indocyanine Green	24.2 µmol/L	26.16	30.27	115
	32.3 µmol/L	26.16	31.64	121
	96.8 µmol/L	244.02	259.58	106
	129.0 µmol/L	244.02	264.37	108

* Percentages have been rounded to whole numbers.

Interferences from medication or endogenous substances may affect results.[26]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[27] using the Passing-Bablok regression method.

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Total Bilirubin vs ARCHITECT Total Bilirubin (LN 6L45)	Serum	mg/dL	116	1.00	0.00	1.00	0.2 to 21.4
		µmol/L	116	1.00	0.00	1.00	3.4 to 365.1
	Neonatal Serum	mg/dL	51	1.00	0.00	1.01	0.2 to 20.4
		µmol/L	51	1.00	-0.04	1.01	3.4 to 348.0

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