TOTAL BILIRUBIN

This package insert contains information to run the Total Bilirubin assay on the ARCHITECT *c* Systems™ and the AEROSET System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States:	**1-877-4ABBOTT**
Canada:	**1-800-387-8378 (English speaking customers)**
	1-800-465-2675 (French speaking customers)
International:	**Call your local Abbott representative**

Symbols in Product Labeling

CAL 1-2	Calibrators 1 and 2	REF	Catalog number/List number
CONC	Concentration	SN	Serial number
EC REP	Authorized Representative in the European Community		Consult instructions for use
INGRED	Ingredients		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limitation
LOT	Batch code/Lot number		Use by/Expiration date
R1	Reagent 1		Do not shake/agitate
R2	Reagent 2		Protect from light

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NAME

TOTAL BILIRUBIN

INTENDED USE

The Total Bilirubin assay is used for the quantitative analysis of total bilirubin in human serum or plasma of adults and neonates.

SUMMARY AND EXPLANATION OF 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 diglucuronides) 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 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

REAGENTS

Reagent Kit

REF 6L45 Total Bilirubin is supplied as a liquid, ready-to-use, two-reagent kit which contains:

REF 6L45-20

- R1 10 x 53 mL
- R2 10 x 17 mL

Estimated tests per kit: 2,750*

REF 6L45-40

- R1 8 x 93 mL
- R2 8 x 28 mL

Estimated tests per kit: 3,840*

* Calculations are based on the minimum reagent fill volume per kit.

REAGENTS (Continued)

Reagent Kit (Continued)

Reactive Ingredients		Concentration
R1	Surfactants	4.51%
	HCl	8.204 g/L
R2	2, 4-dichloroaniline	0.81 g/L
	HCl	5.563 g/L
	Sodium Nitrite	0.345 g/L
	Surfactant	2.00%

REAGENT HANDLING AND STORAGE

Reagent Handling

NOTE: Do not invert reagent cartridges prior to use. Reagents are susceptible to the formation of foam and bubbles.

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles or foam to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C and protected from light. Store Total Bilirubin reagents in the box.

Reagent stability is 21 days if the reagent is uncapped and onboard.

Indications of Deterioration

Deterioration should be suspected if there are visible signs of leakage, extreme turbidity, microbial growth, or if quality control results are outside of the acceptable range defined by your laboratory.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. R1 and R2 contain hydrochloric acid and are classified per applicable European Community (EC) Directives as: Corrosive (C). The following are the appropriate Risk (R) and Safety (S) phrases:

R34	Causes burns.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35	This material and its container must be disposed of in a safe way.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. **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.[7] Biosafety Level 2[8] or other appropriate biosafety practices[9,10] should be used for materials that contain or are suspected of containing infectious agents.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum and plasma are acceptable specimens.

- **Serum:** Use serum collected by standard venipuncture or capillary collection techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Separate serum from red blood cells or gel as soon after collection as possible.

  Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- **Plasma:** Use plasma collected by standard venipuncture or capillary collection techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier), sodium heparin, and EDTA. The use of tubes containing sodium fluoride/potassium oxalate is not recommended due to the potential for hemolysis with this anticoagulant. Ensure centrifugation is adequate to remove platelets. Separate plasma from red blood cells or gel as soon after collection as possible.

Refer to the specimen collection tube manufacturer's instructions for processing and handling requirements.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and *Section 5* of the instrument-specific operations manual.

Specimen Storage

Serum and plasma: Specimens should be protected from bright light as bilirubin is photolabile.[11] Bilirubin is stable in serum and plasma as follows:

Temperature	Maximum Storage	Bibliographic Reference
20 to 25°C	1 day	12
2 to 8°C	7 days	12, 13
-20°C	6 months	14
-80°C	6 months	14

Limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C and/or -80°C for specimen storage. The temperature ranges may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

REF 6L45-20 or 6L45-40 Total Bilirubin Reagent Kit

Materials Required but not Provided

- REF 1E66 Bilirubin Calibrator, CAL 1-2 3 x 5 mL
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT *c* Systems and AEROSET System have automatic dilution features; refer to *Section 2* of the instrument-specific operations manual for additional information.

Serum and plasma: Specimens with total bilirubin values exceeding 25.0 mg/dL (427.5 µmol/L) are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

PROCEDURE (Continued)

Specimen Dilution Procedures (Continued)

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a 1:5 or a 1:10 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the instrument-specific operations manual.

CALIBRATION

Calibration is stable for approximately 14 days (336 hours) and is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Bilirubin Calibrator package insert.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

- **ARCHITECT System Operations Manual**—*Appendix C*
- **AEROSET System Operations Manual**—*Appendix A*

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

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

For the AEROSET System ONLY

REF 6L45 Total Bilirubin must be configured on a separate line from the following reagents:

- REF 6L35 MULTIGENT® Amikacin
- REF 6L31 MULTIGENT Quinidine
- REF 6E44 MULTIGENT Vancomycin

EXPECTED VALUES

Reference Range

	Range (mg/dL)	Range (µmol/L)
Adult (serum and plasma)[15]	0.2 to 1.2	3.4 to 20.5

A study was conducted with a similar methodology (Total Bilirubin REF 8G62-20) using 135 serum samples from volunteers ranging in age from 25 to 66 years. Data were analyzed as described in Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A.[16] From this study, 95% of all results were within 0.2 to 1.2 mg/dL with results ranging from 0.2 to 1.8 mg/dL.

A confirmation study was conducted with REF 6L45 Total Bilirubin using 25 serum and plasma samples from adult volunteers. Data were analyzed as described in CLSI protocol NCCLS C28-A2.[17] From this study, all results were within the range of 0.2 to 0.9 mg/dL, confirming the adult reference interval of 0.2 to 1.2 mg/dL.

	Range (mg/dL)	Range (µmol/L)
Premature (serum)[18]		
< 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)[18]		
< 24 hours	< 6.0	< 102.6
< 48 hours	< 10.0	< 171.0
3 to 5 days	< 12.0	< 205.2
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*.[19]

To convert results from mg/dL to µmol/L, multiply mg/dL by 17.1.

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

Linearity for Total Bilirubin is 0.1 to 25.0 mg/dL (1.71 to 427.5 µmol/L). Linearity was verified using a modified CLSI protocol NCCLS EP6-A.[20]

Limit of Detection (LOD)

The LOD for Total Bilirubin is 0.05 mg/dL (0.86 µmol/L). LOD is the lowest amount of analyte in a sample that can be detected with 95% probability.

Limit of Quantitation (LOQ)

The LOQ for Total Bilirubin is ≤ 0.1 mg/dL (≤ 1.71 µmol/L). The LOQ is the analyte concentration at which the CV = 20%.

Interfering Substances[21]

Potential interference in the Total Bilirubin assay from 1,000 mg/dL hemoglobin, 500 mg/dL Intralipid, or 0.125 mmol/L Indican (indoxyl sulfate) is ≤ 10% or ± 0.3 mg/dL, whichever is greater.

Interference effects were assessed by Dose Response method, at the medical decision levels of the analyte.

Interfering Substance	Interferent Concentration		N	Target (mg/dL)	Observed* (mg/dL)	(%)
Hemoglobin	1,000 mg/dL	(10 g/L)	7	1.1	0.9	86
	2,000 mg/dL	(20 g/L)	7	1.1	0.9	80
	1,000 mg/dL	(10 g/L)	7	16.4	15.7	96
	2,000 mg/dL	(20 g/L)	7	16.4	15.5	95
Intralipid	1,000 mg/dL	(10 g/L)	7	1.0	1.2	115
	2,000 mg/dL	(20 g/L)	7	1.0	1.4	136
	1,000 mg/dL	(10 g/L)	7	16.6	16.6	100
	2,000 mg/dL	(20 g/L)	7	16.6	16.8	101

* Percentages have been rounded to whole numbers.

SPECIFIC PERFORMANCE CHARACTERISTICS (Continued)

Interfering Substances[21] (Continued)

Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to solutions of human serum albumin. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to solutions of human serum albumin.

Taki et al. reported indoxyl sulfate concentrations up to 8.62 mg/dL (0.40 mmol/L), with an average of 3.52 mg/dL (0.17 mmol/L), in 224 hemodialysis (HD) patients.[22] Indoxyl sulfate falsely increases bilirubin results when assayed by this methodology; however, the use of an earlier read time has been shown to reduce Indican interference.[23] Testing at Abbott Laboratories (Main Read Time 20-22) demonstrated that addition of 0.18 mmol/L 3-indoxyl sulfate potassium salt, at a targeted total bilirubin of 1.2 mg/dL, increased the total bilirubin concentration by 0.3 mg/dL.

Precision

The imprecision of the Total Bilirubin assay is ≤ 5% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A2[24] are summarized below.

Control		Level 1	Level 2	Level 3	Level 4
N		80	80	80	80
Mean (mg/dL)		0.81	4.07	6.03	16.09
Within Run	SD	0.01	0.02	0.03	0.12
	%CV	1.0	0.5	0.6	0.7
Between Run	SD	0.01	0.04	0.04	0.03
	%CV	0.7	0.9	0.6	0.2
Between Day	SD	0.01	0.08	0.10	0.17
	%CV	1.2	1.9	1.6	1.1
Total	SD	0.01	0.09	0.11	0.21
	%CV	1.7	2.1	1.8	1.3

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A2.[25]

Results from the Total Bilirubin assay on an ARCHITECT *c* System and the AEROSET System were compared with those from a commercially available liquid 2,5-dichloro-phenyldiazonium tetrafluoroborate methodology.

Results from the Total Bilirubin assay on an ARCHITECT *c* System were compared with those from the Total Bilirubin assay on the AEROSET System.

Adult

Serum and Plasma	ARCHITECT vs. Comparative Method	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	137	137	137
Y - Intercept	0.20	0.22	-0.02
Correlation Coefficient	0.999	0.999	1.000
Slope	0.95	0.96	0.99
Range (mg/dL)	0.2 to 24.4	0.2 to 24.4	0.3 to 22.8

Neonatal

Serum*	ARCHITECT vs. Comparative Method	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	52	52	52
Y - Intercept	0.06	0.22	-0.13
Correlation Coefficient	0.992	0.993	0.996
Slope	0.98	0.96	1.02
Range (mg/dL)	4.7 to 15.9	4.7 to 15.9	4.8 to 15.8

* Neonatal serum samples were from patients ≤ 5 days old.

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TRADEMARKS

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ARCHITECT®

Total Bilirubin Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **BiliT** Type: **Photometric** Version: †
Number: **1094**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **End up**

	Primary		Secondary	Read times
Wavelength:	**548**	/	**604**	Main: 20 – 22

Last required read: 22
Absorbance range: ___ – ___ Color correction: ___ – ___
Sample blank type: **Self** Blank: **14 – 16**

O Reaction definition ● Reagent / Sample O Validity checks

Reagent: **BILIT** Reagent volume: R1 **160** R2 **40**
Diluent: **Saline** Water volume: ___ ___
Diluent dispense mode: **Type 0** Dispense mode: **Type 0** **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**4.0**	___	___	___	=	**1:1.00**	●
1:5 :	**20.0**	**4.0**	**80**	___	=	**1:5.00**	O
1:10 :	**10.0**	**4.0**	**90**	___	=	**1:10.00**	O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **End Subtraction**

	A	B
Read time:	**14 – 16**	**7 – 9**
Calculation limits:	**-0.1000 – 0.0070**	

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **BiliT** Calibration method: **Linear**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **Bil**
Replicates: **3** [Range 1 – 3]

	Calibrator level:	Concentration:
Blank:	**Water**	**0.0**
Cal 1:	**Bil1**	‡
Cal 2:	**Bil2**	‡

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: **Bil**

	Calibrator level	Sample	Diluted sample	Diluent	Water
Blank:	**Water**	**4.0**	___	___	___
Cal 1:	**Bil1**	**4.0**	___	___	___
Cal 2:	**Bil2**	**4.0**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **336** (hours)
Calibration type:
Adjust type: **None**

O Calibrators O Volumes O Intervals ● Validity checks

Blank absorbance range: _____ – _____
Span: **Blank** – **Blank**
Span absorbance range: _____ – _____
Expected cal factor: **0.00**
Expected cal factor tolerance %: **0**

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **BiliT**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**BILD0**	**Detergent A**	**345**	**1**
R2	**BILD0**	**0.5% Acid Wash**	**345**	**1**
Cuvette	**Trig**	**10% Detergent B*****	**345**	

***** Select "**Detergent B**" for software prior to version 2.2.

Total Bilirubin Serum/Plasma—Conventional Units

Configure assay parameters — Results — Conventional Units

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **BiliT** Result units: **mg/dL**
Assay defaults:
Low-Linearity: **0.1**
High-Linearity: **25.0**
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Either	**0 – 130 (Y)**	**0.2 – 1.2**	

Configure result units — Conventional Units

Assay: **BiliT**
Version: †
Result units: **mg/dL**
Decimal places: **1** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

Total Bilirubin Serum/Plasma—SI Units

Configure assay parameters — Results — SI Units

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **BiliT** Result units: **µmol/L**
Assay defaults:
Low-Linearity: **1.8**††
High-Linearity: **427.5**
Gender and age specific ranges:*

GENDER	AGE (UNITS)	NORMAL**	EXTREME
Either	**0 – 130 (Y)**	**3.4 – 20.5**	

Configure result units — SI Units

Assay: **BiliT**
Version: †
Result units: **µmol/L**
Decimal places: **1** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

* User defined.
** Adult reference range.
† Due to differences in instrument systems and unit configurations, version numbers may vary.
‡ Refer to concentration specified on calibrator labeling or value sheet.
†† The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET®

Total Bilirubin Serum/Plasma—Conventional Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
BiliT	94	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	0.2	1.2	0.0	0.0*	*
		0.1	L-Linear Range-H		25.0	

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	548 / 604	20 – 22 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
BiliT (94)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	4.0	0.0	0	0		Rgt Name/Pos
Dil 1	20.0	4.0	80	0	Diluent:	DILUENT D–18*
Dil 2	10.0	4.0	90	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	BILIT51‡‡ – ___*	160	0	0
Reagent 2	BILIT42‡‡ – ___*	40	0	0

Reaction Check	Read Time – A/B	Range	Minimum
END SUB	14 – 16 / 7 – 9	-0.1 – 0.007	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	1	mg/dL

Assay Configuration: Calibration Page

Calib Mode	Interval (H)
Linear	336

Blank/Calib Replicates	Extrapolation %	Span	Span Abs Range
3 / 3	0	BLK – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	4.0	0.0	0	0	0.0 – 0.0
C1	Bil 1	4.0	0.0	0	0	**Cal Deviation**
C2	Bil 2	4.0	0.0	0	0	0.0
						FAC Limit (%)
						10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
BILD051	AlkW	345
BILD012	AcidW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Total Bilirubin Serum/Plasma—SI Units

Assay Configuration: Outline Page

Assay Name	Assay #	Line
BiliT	94	B-Line

Quantitative Ranges

Min Text	Min	Panic-L	L-Reference-H**	Panic-H	Max	Max Text
*	0.0*	0.0	3.4	20.5	0.0	0.0*	*
		1.8††	L-Linear Range-H		427.5	

Reference Ranges*

Age	Male	Female
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0
0 Year	0.0 – 0.0	0.0 – 0.0

Qualitative Ranges N/A

Assay Configuration: Base Page

Reaction Mode	Wavelength-Prim/Sec	Read time-Main/Flex	AbsMaxVar
END UP	548 / 604	20 – 22 / 0 – 0	0.0
Sample Blank Test	**Blank Read Time**	**Abs Window**	**Abs Limits**
BiliT (94)	14 – 16	0 – 0	0.0 – 0.0

	S.Vol	DS.Vol	D.Vol	W.Vol		
Standard	4.0	0.0	0	0		Rgt Name/Pos
Dil 1	20.0	4.0	80	0	Diluent:	DILUENT D–18*
Dil 2	10.0	4.0	90	0	Type#	0

	Rgt Name/Pos	R.Vol	W.Vol	Type#
Reagent 1	BILIT51‡‡ – ___*	160	0	0
Reagent 2	BILIT42‡‡ – ___*	40	0	0

Reaction Check	Read Time – A/B	Range	Minimum
END SUB	14 – 16 / 7 – 9	-0.1 – 0.007	0.0

Factor/Intercept	Decimal Places	Units
1.0 / 0.0	1	µmol/L

Assay Configuration: Calibration Page

Calib Mode	Interval (H)
Linear	336

Blank/Calib Replicates	Extrapolation %	Span	Span Abs Range
3 / 3	0	BLK – 1	0.0 – 0.0

	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range
BLK	Water	4.0	0.0	0	0	0.0 – 0.0
C1	Bil 1	4.0	0.0	0	0	**Cal Deviation**
C2	Bil 2	4.0	0.0	0	0	0.0
						FAC Limit (%)
						10

Assay Configuration: SmartWash Page

Rgt Probe

Reagent	Wash	Vol
BILD051	AlkW	345
BILD012	AcidW	345

Cuvette

Assay Name	Wash	Vol
—	—	—

Sample Probe

Wash
—

Refer to **Assay Configuration** in *Section 2* of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** Adult reference range.

†† The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

‡‡ Rgt Name listed is for 6L45-20. For 6L45-40, change Reagent 1 name to BILIT61; change Reagent 2 name to BILIT52.