ARCHITECT

DIRECT BILIRUBIN

This package insert contains information to run the Direct Bilirubin assay on the ARCHITECT *c* Systems.

Revised March 2022.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

Key to Symbols

ISO 15223 Symbols		Other Symbols	
	Consult instructions for use	DISTRIBUTED IN THE USA BY	Distributed in the USA by
	Manufacturer	FOR USE WITH	Identifies products to be used together
	Sufficient for	INFORMATION FOR USA ONLY	Information needed for United States of America only
	Temperature limitation	MANUFACTURED FOR	Manufactured for
	Use by/Expiration date	PRODUCT OF CANADA	Product of Canada
IVD	*In Vitro* Diagnostic Medical Device	R1	Reagent 1
LOT	Lot Number	R2	Reagent 2
REF	List Number	Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).
SN	Serial number		

Abbott

NAME

DIRECT BILIRUBIN

INTENDED USE

The Direct Bilirubin assay is used for the quantitative analysis of direct bilirubin in human serum or plasma.

SUMMARY AND EXPLANATION OF TEST

Red blood cells at the end of their circulating life are broken down in the reticuloendothelial system, mainly the spleen. The resulting heme, once the iron is removed, is then converted to bilirubin. This process accounts for about 80% of the 500 µmol (300 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) to form conjugated bilirubin by the enzyme uridyl diphosphate glucuronyl transferase. 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.

Direct bilirubin is the sum of the conjugated fractions. Direct bilirubin is elevated in conditions causing hepatic obstruction, hepatitis, cirrhosis, several inherited enzyme deficiencies, and inherited defects in canalicular excretion.

PRINCIPLES OF PROCEDURE

Bilirubin determination is generally based on the reaction of bilirubin with a diazotized sulfanilic acid, described by Ehrlich.[1] In this method, direct (conjugated fractions) bilirubin couples with a diazonium salt in the presence of sulfamic acid to form the colored compound azobilirubin. The increase in absorbance at 548 nm due to azobilirubin is proportional to the direct bilirubin concentration.

Methodology: Diazo Reaction

REAGENTS

Reagent Kit

REF 8G63-22 Direct Bilirubin is supplied as a liquid, ready-to-use, two-reagent kit which contains:

- R1 10 x 39 mL
- R2 10 x 13 mL

Estimated tests per kit: 2000

Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients		Concentration
R1	Sulfamic acid	9.7 g/L
R2	2, 4-dichloroaniline	< 0.1 g/L
	Sodium nitrite	< 0.1 g/L
	HCl	33.54 g/L

REAGENT HANDLING AND STORAGE

Reagent Handling

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 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. The reagents should be clear.

Reagent stability is 28 days if the reagent is uncapped and onboard.

Indications of Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, extreme turbidity, microbial growth, if calibration does not meet the appropriate package insert and/or **ARCHITECT System Operations Manual** criteria, or if controls do not meet the appropriate criteria.

WARNINGS AND PRECAUTIONS

Precautions for Users

- IVD
- For *In Vitro* Diagnostic Use.
- Rx ONLY
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- **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.[2] Biosafety Level 2[3] or other appropriate biosafety practices[4,5] should be used for materials that contain or are suspected of containing infectious agents.
- The following warnings and precautions apply to: R1

DANGER:	Contains sulfamic acid.
H314	Causes severe skin burns and eye damage.
Prevention	
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.
Disposal	
P501	Dispose of contents/container in accordance with local regulations.

- The following warnings and precautions apply to: R2

DANGER:	Contains hydrochloric acid.
H314	Causes severe skin burns and eye damage.
H332	Harmful if inhaled.
H290	May be corrosive to metals.
Prevention	
P260	Do not breathe mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/ eye protection.
P234	Keep only in original container.
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.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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 contact your local representative.
- For a detailed discussion of safety precautions during system operation, refer to the **ARCHITECT System Operations Manual,** Section 8.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Use serum or plasma specimens without visible hemolysis or lipemia. Refer to the SPECIFIC PERFORMANCE CHARACTERISTICS section of this package insert.

Abbott Laboratories has not verified the assay performance characteristics with neonatal specimens.

NOTE: Abbott Laboratories recommends the use of sample interference indices in the semi-quantitative mode to assist in the determination of sample integrity for all specimens. Refer to the Sample Interference Indices (HIL) application sheets.

- **Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum from blood cells.

  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 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 of hemolysis formation with this anticoagulant. Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.

For total sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert and *Section 5* of the **ARCHITECT System Operations Manual.**

Specimen Storage

Serum and Plasma: Specimens should be protected from bright light as bilirubin is photolabile.[6] Direct bilirubin is stable in serum and plasma as follows:

Temperature	Maximum Storage	Bibliographic Reference
20 to 25˚C	2 days	7
2 to 8˚C	7 days	7, 8
-20˚C	3 months	9
-80˚C	3 months	9

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. These 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 8G63-22 Direct Bilirubin Reagent Kit

Materials Required but not Provided

- REF 1E66-05 Bilirubin Calibrator
- 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 **ARCHITECT System Operations Manual**.

Specimen Dilution Procedures

The ARCHITECT *c* Systems have an automatic dilution feature; refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

Serum and Plasma: Specimens with direct bilirubin value exceeding 15.0 mg/dL (256.5 µmol/L) are flagged and may be diluted by following the Manual Dilution Procedure.

PROCEDURE (Continued)

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor. To set up the automatic dilution feature, refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

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 **ARCHITECT System 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 **ARCHITECT System 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 the 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 *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. 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.

Some specimens may give a direct bilirubin result slightly greater than the total bilirubin result. During internal testing at Abbott Laboratories, specimens with total bilirubin concentrations of 0.2 mg/dL (3.4 µmol/L) or less occasionally gave a direct bilirubin result that slightly exceeded their respective total bilirubin result. This may be observed when nearly all reacting bilirubin is direct bilirubin.

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 Interfering Substances section for additional information.[10,11]

Abbott Laboratories has not verified the assay performance characteristics with neonatal specimens.

EXPECTED VALUES

Reference Range

Serum[12]

	Range (mg/dL)	Range (µmol/L)
Adult	0.0 to 0.5	0.0 to 8.6

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

A study was conducted using 135 serum samples from volunteers ranging in age from 25 to 66 years. Data were analyzed as described by Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS C28-A.[13] From this study, 95% of all specimens fell within 0.0 to 0.5 mg/dL, with samples ranging from 0.1 to 0.6 mg/dL.

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 Direct Bilirubin is 0.1 to 15.0 mg/dL (1.7 to 256.5 µmol/L), with recovery within 10% or within the 95% confidence level of the predicted value. Linearity was verified using a modified CLSI protocol NCCLS EP6-P.[14] A study performed on an ARCHITECT *c* System produced linear results for Direct Bilirubin up to 16.9 mg/dL (289.0 µmol/L).

Limit of Detection (LOD)

The LOD is the Limit of Absence (LOA*) + 1.645 SD, where SD = the pooled, within-run standard deviation of a low concentration sample. A study performed on an ARCHITECT *c* System produced an LOD for Direct Bilirubin of 0.04 mg/dL (0.69 µmol/L).

* LOA = mean concentration of analyte-free sample + 1.645 SD, where SD = pooled SD of analyte-free sample.

Limit of Quantitation (LOQ)

The LOQ for Direct Bilirubin is ≤ 0.10 mg/dL (1.71 µmol/L). The LOQ is the analyte concentration at which the CV = 20%. Performance studies produced an LOQ of 0.05 mg/dL (0.86 µmol/L).

Interfering Substances

Potential interference in the Direct Bilirubin assay from 62 mg/dL (0.62 g/L) hemoglobin, 125 mg/dL (1.25 g/L) Intralipid, 0.50 mmol/L Indican (indoxyl sulfate), or 6.3 mg/L (8.1 µmol/L) indocyanine green is ≤ 10% or ± 0.1 mg/dL, whichever is greater, at the medical decision level of the analyte.

Interference studies were conducted using a modified CLSI protocol NCCLS EP7-P.[15] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent	Concentration	N	Target (mg/dL)	Difference from Target (mg/dL)
Hemoglobin	31 mg/dL	(0.31 g/L)	5	0.4	-0.1
	62 mg/dL	(0.62 g/L)	5	0.4	-0.1
	125 mg/dL	(1.25 g/L)	5	0.4	-0.2
	250 mg/dL	(2.50 g/L)	5	0.4	-0.2
	500 mg/dL	(5.00 g/L)	5	0.4	-0.2
Human triglyceride	519 mg/dL	(5.86 mmol/L)	5	0.4	-0.1
	1,034 mg/dL	(11.68 mmol/L)	5	0.4	+0.3
Intralipid	125 mg/dL	(1.25 g/L)	5	0.4	-0.1
	250 mg/dL	(2.50 g/L)	5	0.4	+0.1
	500 mg/dL	(5.00 g/L)	5	0.4	+0.4
Indocyanine Green	6.3 mg/L	(8.1 µmol/L)	3	0.3	+0.1
	12.5 mg/L	(16.1 µmol/L)	3	0.3	+0.3
	18.8 mg/L	(24.2 µmol/L)	3	5.1	+0.4
	25.0 mg/L	(32.3 µmol/L)	3	5.1	+0.5

Interfering Substances (Continued)

Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Human triglyceride solutions at the above concentrations were prepared by mixing an elevated triglyceride human serum pool with a normal triglyceride human serum pool. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

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.[16] Indoxyl sulfate does not cause significant interference with this direct bilirubin method. Testing at Abbott Laboratories demonstrated that addition of 12.57 mg/dL (0.50 mmol/L) 3-indoxyl sulfate potassium salt to specimens increased the direct bilirubin concentration by a maximum of 0.1 mg/dL.
Indocyanine green solutions at the concentrations listed in the table were prepared by the individual addition of indocyanine green to two pools of plasma, one with a high concentration of bilirubin and one with a low concentration of bilirubin.

Interferences from medications or endogenous substances may affect results.[17]

Precision

The imprecision of the Direct Bilirubin assay is ≤ 5% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A[18] are summarized below.

Control		Level 1	Level 2	Level 3	Level 4
N		80	80	80	80
Mean (mg/dL)		0.41	2.11	3.50	8.59
Within Run	SD	0.01	0.01	0.02	0.05
	%CV	2.1	0.6	0.6	0.5
Between Run	SD	0.00	0.04	0.06	0.14
	%CV	0.0	1.7	1.6	1.6
Between Day	SD	0.01	0.04	0.07	0.16
	%CV	3.6	1.8	2.0	1.9
Total	SD	0.02	0.05	0.09	0.22
	%CV	4.1	2.6	2.7	2.6

Method Comparison

Correlation studies were performed using a modified CLSI protocol NCCLS EP9-A.[19]

Serum results from the Direct Bilirubin assay on an AEROSET System were compared with those from a commercially available methodology based on Jendrassik-Gróf procedure; factored application.

Serum results from the Direct Bilirubin assay on an ARCHITECT *c* System were compared with those from a commercially available methodology based on Jendrassik-Gróf procedure; factored application.

	AEROSET vs. Comparative Method	ARCHITECT vs. Comparative Method
N	129	107
Y - Intercept	0.21	0.21
Correlation Coefficient	0.995	0.996
Slope	1.08	1.08
Range (mg/dL)	0.1 to 9.9	0.1 to 9.9

Serum results from the Direct Bilirubin assay on an AEROSET System were compared with the manual Jendrassik-Gróf method.

Serum results from the Direct Bilirubin assay on an ARCHITECT *c* System were compared with the Direct Bilirubin assay (REF 8G63-22) on an AEROSET System.

	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	49	107
Y - Intercept	0.31	-0.01
Correlation Coefficient	0.998	0.999
Slope	0.983	1.01
Range (mg/dL)	-0.1 to 15.6	0.1 to 11.1

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Abbott

ARCHITECT

Direct Bilirubin Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **BilD** Type: **Photometric** Version: †
Number: **1065**
Run controls for onboard reagents by: **Lot**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **End up**
Primary Secondary Read times
Wavelength: **548** / **660** Main: **31 – 33**
Last required read: **33**
Absorbance range: ___ – ___ Color correction: ___ – ___
Sample blank type: **Self** Blank: **14 – 16**

O Reaction definition ● Reagent / Sample O Validity checks

						R1	R2
Reagent:	**BILD0**			Reagent volume:		**160**	**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 :	**5.0**	___	___	___	=	**1:1.00**	●
_____ :	___	___	___	___	=		O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **BilD** 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**	**5.0**	___	___	___
Cal 1: **Bil1**	**5.0**	___	___	___
Cal 2: **Bil2**	**5.0**	___	___	___

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: **BilD**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**BILD0**	**Detergent A**	**345**	**1**
R2	**BILD0**	**Detergent A**	**345**	**1**

Direct Bilirubin Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **BilD** Assay number: **1065**
Dilution default range: Result units: **mg/dL**
Low-Linearity: **0.1**‡‡
High-Linearity: **15.0**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**0.0 – 0.5**	

Configure result units

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

Direct Bilirubin Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **BilD** Assay number: **1065**
Dilution default range: Result units: **µmol/L**
Low-Linearity: **1.8**‡‡
High-Linearity: **256.5**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**0.0 – 8.6**	

Configure result units

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

† Due to differences in instrument systems and unit configurations, version numbers may vary.
§ Refer to the concentration specified on calibrator labeling or value sheet. These values are defined on the Configure calibrator set screen.
‡‡ The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.