TOTAL BILIRUBIN DPD
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL2015BR	5 x 100 ml	TOTAL BILIRUBIN DPD - 1	2 - 8°C
	1 x 100 ml	TOTAL BILIRUBIN DPD - 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Total Bilirubin in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [1]

Serum bilirubin is present in 4 different isomers. Unconjugated α, monoconjugated β, diconjugated γ and covalently albumin bound δ. Bilirubin is produced from the degradation of red blood cells. It is extracted and biotransformed in the liver and excreted in the bile and urine. Bilirubin measurements are performed primarily for the diagnosis of liver diseases and the detection of haemolytic anaemia.

PRINCIPLE OF THE TEST: [2]

Indirect bilirubin is liberated by the detergent, and then total bilirubin is coupled with a diazonium compound to give the corresponding azo-bilirubin.

Bilirubin + diazonium ion $\xrightarrow{pH<2}$ azobilirubin

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear, colourless liquid.
Reagent 2: Clear, pale beige liquid
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Label Elements:

DANGER

H314 – Causes severe skin burns and eye damage.

Precautionary Statements:
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor/physician.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.
- **R2 is light sensitive, store in the dark.**

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Hydrochloric Acid (HCl)	150 mmol/l
	DETERGENT	---
Reagent 2	Hydrochloric Acid (HCl)	17 mmol/l
	Accelerator	50 mmol/l
	2,5-dichlorophenyl diazonium salt (DPD)	1.5 mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.#
Reagent 2 is light sensitive and must be stored in the dark

TYPE OF SPECIMEN: [1]

Use serum, free of haemolysis, or EDTA/heparinised plasma as specimen.
A morning specimen from a fasting patient is preferred.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification. Plasma/Serum should be separated from cells within 2 hours after collection.
Stability: It is essential to store specimens in the dark, at 2-8°C. Stability is maintained in these conditions for three days.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932		

Assay procedure:
Wavelength: λ: 570 nm
Temperature: 37°C (25°C or 30°C)
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	20 µl
Calibrator	----	20 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 2 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 5 minutes.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the laboratory QC Program.

CALCULATION:

$$\text{Concentration of Bilirubin} = \frac{\text{Sample}_{OD2} - \text{Sample}_{OD1}}{\text{Calibrator}_{OD2} - \text{Calibrator}_{OD1}} \times \text{Concentration of Calibrator}$$

(Conversion Factor: Qty in µmol/l = 17.1 x Qty in mg/dl.)

EXPECTED VALUES: [1]

	µmol/l	*mg/dl*
Serum	0 -21	0 – 1.2

Each laboratory should establish its own reference range. Total Bilirubin results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear up to 628µmol/l (37 mg/dl).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Interfering substances:
Results of study are as follows:

Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 2.5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.4µmol/l.

Precision:

Within Run N = 20	Mean *(µmol/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(µmol/l)*	*SD*	*% CV*
Level 1	15.4	0.68	4.44	Level 1	13.7	0.54	3.91
Level 2	83.4	1.86	2.23	Level 2	84.3	3.00	3.57

Method Comparison:
Using 50 samples, a comparison, between this Total Bilirubin test (y) and another commercially available test (x), gave the following results:

y = 1.048x – 0.901	r = 0.997	Sample range: 1.0 to 248.0 µmol/l

BIBLIOGRAPHY:

1. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 601-606 and 966.
2. Weigh E, Bach H, Kreig US. Med. Klin. 1975, 70, 664.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	CAL	Calibrator
CE	CE Mark - Device complies with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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