

# BILIRUBIN DIRECT VANADATE Multi-Purpose Liquid Reagent

### KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL2035BR	4 x 50ml	Reagent 1	10 - 25°C
	2 x 25ml	Reagent 2	

### INTENDED USE:

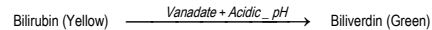
In Vitro Diagnostic reagent pack for the quantitative determination of Direct Bilirubin in serum on automated and semi-automated analysers.

### SUMMARY AND EXPLANATION:

Direct Bilirubin consists of 2 isomers, mono and di glucuronide. Conjugation with glucuronic acid takes place inside the hepatocytes. The conjugated Bilirubin is subsequently excreted in the bile. Direct Bilirubin is measured in the investigations of pre-hepatic, post-hepatic and hepatic jaundice. Increased levels are evident with hepatocellular diseases such as hepatitis and cholestasis or decreased drainage such as carcinoma, stricture or stones affecting extra hepatic obstruction.

### PRINCIPLE OF THE TEST:

In an acidic solution, Direct Bilirubin present in a sample reacts with the detergent of Reagent 1 and the Vanadate of Reagent 2 to be oxidised to Biliverdin. The absorbance of the yellow Bilirubin decreases. The Direct Bilirubin concentration in the sample is directly proportional to the decreases in absorbance after addition of reagent 2.



### 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 colourless liquid.

Any significant changes 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:

Material Safety Data Sheet is available upon request.

#### Label Elements:



#### WARNING

H317 May cause an allergic skin reaction.

#### Precautionary Statements:

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.

P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.

#### Handling precautions:

- Take the necessary precautions required for handling all laboratory reagents.
- 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.

### INSTRUMENTS:

Instrument applications are available upon request.

### COMPONENT COMPOSITION:

Component	Ingredients	Initial Concentrations
Reagent 1	Citrate Buffer pH 2.8	100 mmol/l
Reagent 2	Phosphate Buffer pH 7.0	4.6 mmol/l
	Vanadate	4.0 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.

Stability on board the Instrument: 28 days.

The reagents can be stored short term up to 4 weeks at 2-8°C. Long term storage should be between 10 and 25°C.

### TYPE OF SPECIMEN:

Use serum free of haemolysis.

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. Serum should be assayed fresh.

Storage: It is essential to store specimens in the dark, at 2-8°C.

### TEST PROCEDURE:

Materials required but not supplied:

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

#### Assay procedure:

Wavelength:  $\lambda$ : 450 nm  
 Temperature: 37°C (25°C or 30°C)  
 Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1000 $\mu$ l	1000 $\mu$ l	1000 $\mu$ l
Sample	----	----	40 $\mu$ l
Calibrator	----	40 $\mu$ l	----
Gently mix and incubate at 37°C Measure the Optical Density (OD1) after 2 minutes.			
Reagent 2	250 $\mu$ l	250 $\mu$ l	250 $\mu$ l
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.
- 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 Q.C. Laboratory Programme.

### EXPECTED VALUES:

	$\mu$ mol/l	mg/dl
Serum	0-6	0-0.4

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

### 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  $\mu$ mol/l = 17.1 x Qty in mg/dl.

### 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 350  $\mu$ mol/L.

For samples with a higher activity, dilute 1:1 with Saline solution 0.9% NaCl (9 g/l) and re-assay. Multiply result by 2.

#### Interfering Substances

Results of study are as follows:

Lipemia: Less than 5% up to 5g/L  
 Haemolysis: Use serum free of haemolysis

#### Sensitivity

The lowest detectable level of Direct Bilirubin Vanadate was estimated at 0.28  $\mu$ mol/L.

#### Precision

Within Run N=10	Mean ( $\mu$ mol/L)	SD	%CV	Between Run N=20	Mean ( $\mu$ mol/L)	SD	%CV
Level 1	16.4	0.4	2.4	Level 1	16.6	0.26	1.6
Level 2	24.9	0.3	1.2	Level 2	25.8	0.56	2.2

#### Method Composition

Using 34 samples, a composition between Direct Bilirubin Vanadate test (y) and another commercially available test (x) gave the following results.


















Y=0.972x +0.4217	R <sup>2</sup> = 0.9937	Sample Range: 0 to 111.9 $\mu$ mol/L
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### BIBLIOGRAPHY:

- Burris CA, Ashwood ER, Tietz Fund. Of Clin. Chem. 5<sup>th</sup> ed. 30-54, 601-606 and 966.

### SYMBOLS:

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

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Antibody
	Calibrator		Substrate
	Buffer		Aqueous Standard
	CE Mark - Device complies with the Directives 98/79/EC		Storage temperature
	Expiry Date (Last day of the month)		Reconstitute with
	Biological risk		Manufactured By
			Consult Instruction for Use

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