Direct Bilirubin Assay Kit (DBil)

Method: Vanadate Oxidation

Cat .No.	Size	Instrument
GB9030G	R1: 4×90 ml R2: 2×45 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS9031G	R1: 6×60 ml R2: 2×45 ml	For Hitachi917 & OlympusAU640/400/600
GH0931G	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GT9031G	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA
Gx9031G	R1: 2×50 ml R2: 1×25 ml	For SYNCHRON CX4-5-7-9/LX20

INTENDED USE

For the *in vitro* quantitative determination of direct bilirubin in serum.

CLINICAL SIGNIFICANCE

Each types hepatitis, liver cirrhosis, the blocking jaundice obviously direct bilirubin increase, is more sensitive than the transaminase. It is especially suits in the chronic hepatitis prognosis appraisal and the early liver cirrhosis diagnosis. When serious anemia in the blood serum or the blood plasma direct bilirubin decreases.

ASSAY PRINCIPLE

When a sample is mixed with the reagent containing the detergent and the vanadate, at around pH 3, the direct bilirubin in the sample is oxidized to biliverdin. This causes the absorbance of yellow, specific to bilirubin, to decrease. Therefore, the total bilirubin concentration in the sample can be obtained by measuring the absorbances before and after the vanadate oxidation.

bilirubin $\xrightarrow{\text{vanadic acid}}$ biliverdin

SAMPLE COLLECTION AND PREPARATION

Serum samples. Should be tested within 2 hours after collection.

Serum samples are stable for 12 hours at 2-8 ℃, or for 3 months at -20℃. Be taken to avoid hemolysis and dark save.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tartaric acid buffer solution	0.1 mol/L
Surfactants	
Reagent 2 (R2)	
Phosphate buffer solution	0.01 mol/L
Sodium metavanadate	4 mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃.

The reagent is stable for 1 month after opening and on-board the analyzer.

ASSAY PROCEDURE

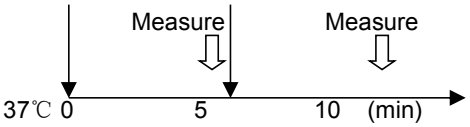
Test Procedure for Analyzers (HITACHI 917)

Assay Mode: 2 Point End , 16-34

Wave Length (main/sub): 450 nm/546 nm

Sample: 8 µl

R1: 224 µl R2: 56 µl



1. Mix 8 µl sample with 224 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 at 450 nm.
2. Add 56 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, Read final absorbance A_2.
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

MATERIALS REQUIRED BUT NOT PROVIDED

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

Randox Assayed Multi-sera Level 2 (Cat .No. HN1530) and Level 3 (Cat .No. HE1532).

CALCULATION

$$\text{Concentration}=\frac{A_{sample}-A_{blank}}{A_{calibrator}-A_{blank}}\times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control.

Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Serum : 1.7-6.8 µmol/L (0-0.4 mg/dl)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

UNIT CONVERSION

mg/dl × 17.1 = µmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 340 µmol/L. If the sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

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CE Revised 01DEC11 version 0801

PRECISION

The CV of the test should be less than 5%.

Intra assay precision		
N=20	Level 1	Level 2
Mean	14.84	32.11
SD	0.11	0.27
CV	0.75%	0.84%
Inter assay precision		
N=5	Level 1	Level 2
Mean	14.59	31.90
SD	0.23	0.60
CV	1.59%	1.88%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 1.14 μmol/L.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Introlipid : 500 mg/dl
Heparin Na: 60 U/ml
Hemoglobin : 200 mg/dl
Ascorbic Acid: 50 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.9447X+0.1175, and a correlation coefficient of 0.9989; 74 patient samples were analyzed .

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The regents contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Lott JA, Doumas BT. Direct and total bilirubin tests: contemporary problems. Clin Chem, 1993,39(4):641-647.
2. Shetty K, Rybicki L, Carey WD. The Child Pugh classification as a prognostic indicator for survival in primary sclerosing cholangitis. Hepatol, 1996,25(5):1049-1053.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
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Tel：+86 10 61667168

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