Direct bilirubin Assay Kit (DBil)

Method: Diazo with Dichloraniline (DCA)

Cat .No.	Size	Instrument
GB030G	R1: 4×100 ml R2: 2×50 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS031G	R1: 6×60 ml R2: 2×45 ml	For Hitachi 917 & OlympusAU640/400/600
GH031G	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GX031G	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT031G	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA

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

In the blood serum the direct bilirubin reacts with the diazo-dichloraniline and the color azo compound is producted , the color diazo compound production quantity is proportional to the concentration of the direct bilirubin in the sample.

REAGENT COMPOSITION

Contents	Concentration of solutions
Reagent 1 (R1)	
EDTA-Na2	0.70 mmol/L
NaCl	6.6 g/L
Amidosulfuric acid	70 mmol/L
Reagent 2 (R2)	
2,4-daizodichlorobenzenamine	0.09 mmol/L
HCl	130 mmol/L
EDTA-Na_2	0.02 mmol/L

STABILITY AND PREPARATION OF REAGENTS

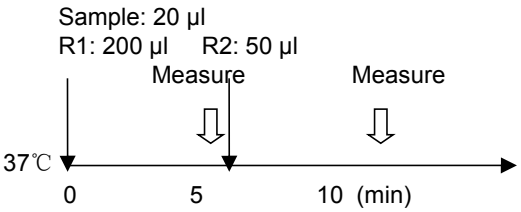
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent is stable for 1 month after opening and on-board the analyzer .

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.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: End Point 16-34
Wave Length (main/sub): 546 nm/660 nm



1. Mix 20 µl sample with 200 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A_1 .
2. Add 50 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃, read final absorbance A_2 .
3. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALCULATION

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

CALIBRATION

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

QUALITY CONTROL

Gcell Control or Randox Assayed Multisera, 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 : up to 4.3 µmol/L (0.25mg/dl)
Each laboratory should establish an expected range with a set of standards.
Unit Conversion
mg/dL×17.1 = µmol/L

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 171 µmol/L. If the sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be CV ≤5%

Intra assay precision		
N=20	Level1	Level 2
Mean	19.04	32.40
SD	0.123	0.278
CV	0.65%	0.86%
Inter assay precision		
N=5	Level1	Level 2
Mean	19.70	30.61
SD	0.151	0.460
CV	0.77%	1.50%

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INTERFERENCE

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

Hemoglobin: 300 mg/dl
Intralipid: 100 mg/dl
Ascorbic Acid: 10 mg/dl

CORRELATION

This reagent (Y) was compared with another company DCA method (X) and the following linear regression equation obtained: Y=1.006X+0.159, R^2=0.998; 246 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. Dual-reagent method, the first step in the reaction can be deducted sample blank (to reduce interference from hemolysis and lipemia)
2. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
3. Reagent 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.
4. 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.
5. 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. Ehrlich P: Sulfondiazolenzol reagen auf Bilirubin.Centr Klin Med 4: 721, 1883.
2. Van den Bergh AAH, Muller PP: Uber eine directe undeine indirekte Diazoreaktion auf Bilirubin. Biochem Z77:90, 1916.
3. Winsten S, Cehelyk B: A rapid diazo technique formeasuring total bilirubin, Clin Chim Acta 25:441, 1969.

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.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
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