Total Bilirubin Assay Kit (TBil)

Method: Diazo with Dichloraniline (DCA)

Cat .No.	Size	Instrument
GB020G	R1: 4×100 ml R2: 2×50 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS021G	R1: 6×60 ml R2: 2×45 ml	For Hitachi 917 & OlympusAU640/400/600
GH021G	R1: 2×50 ml R2: 1×25 ml	For Hitachi 902
GX021G	R1: 2×80 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9 /LX20/DXC600-800
GT021G	R1: 5×48 ml R2: 2×30 ml	For TOSHIBA

INTENDED USE

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

CLINICAL SIGNIFICANCE

Total bilirubin is comprised of direct bilirubin and indirect bilirubin.The total bilirubin are increased in liver cell jaundice, as if acute jaundice hepatitis, critically ill hepatitis, slow live liver, liver cirrhosis and so on. The total bilirubin and the direct bilirubin are also elevated in the blocking jaundice, like biliary duct stone, biliary duct obstruction and so on. The total bilirubin and the indirect bilirubin are also elevated common in hemolytic jaundice.

ASSAY PRINCIPLE

The bilirubin in acidic conditions reacts with the diazo-dichloraniline and product the color azo compound, the color diazo compound production quantity is proportional to the concentration of the total bilirubin in the sample.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1	
Phosphate buffer solution	40 mmol/L
NaCl	9 g/L
surfactants	
Reagent 2	
2,4-daizodichlorobenzenamine	1 mmol/L
HCl	30 mmol/L
surfactants	

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

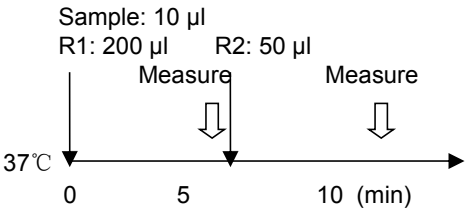
The reagents are stable for 1 month on-board the analyser after opening.

SAMPLE COLLECTION AND PREPARATION

Serum samples. Should be tested within 2 hours after the collection. Serum samples are stable for a 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: 2 Point End， 16-34
Wave Length (main/sub): 546 nm/660 nm



1. Mix 10 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 Randox Calibration Serum Level 3 or Level 2.

QUALITY CONTROL

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.

CONVERSION FACTORS

mg/dl ×17.1=µmol/L

NORMAL VALUE

Adult : up to 17.1 µmol/L (1.0 mg/dl)
Newborn: up to 227 µmol/L (13.3 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 513 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 less than 5%

Intra assay precision		
N=20	Level1	Level 2
Mean	26.8	84.1
SD	0.13	0.89

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CE

Revised 01DEC11 version 0801

CV	0.50%	1.05%
Inter assay precision		
N=5	Level1	Level 2
Mean	30.6	80.1
SD	0.19	0.42
CV	0.63%	0.53%

SENSITIVITY
The minimum detectable level that can be distinguished from zero has been determined as 0.9 μmol/L.

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Hemoglobin: 300 mg/dl
TG: 1000 mg/dl
Ascorbic Acid: 30 mg/dl

CORRELATION
This reagent (Y) was compared with another company DCA method (X) and the following linear regression equation obtained:
Y=0.997X-0.212, R^2=0.999; 319 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. Winsten, S. and Cehely, K. B. (1968) Clin. Chem. 14,107.
2. Tietz, N. (1990) in Clinical Guide To Laboratory Tests.Ed. W. B. Saunders. CP Philadelphia, PA. p90.

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

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