



TB Reagent Kit (Chemical Oxidation Method)

Instructions for Use

REF CC1074

PRODUCT NAME

TB Reagent Kit (Chemical Oxidation Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2×30 mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 4×35 mL	R2: 2×20 mL
R1: 4×40 mL	R2: 2×20 mL	R1: 4×50 mL	R2: 2×25 mL
R1: 4×50 mL	R2: 3×20 mL	R1: 4×60 mL	R2: 4×15 mL
R1: 4×60 mL	R2: 2×35 mL	R1: 4×60 mL	R2: 2×30 mL
R1: 4×100 mL	R2: 2×50 mL	R1: 4×120 mL	R2: 2×60 mL
R1: 6×62 mL	R2: 6×19 mL		
2×300 T (R1: 2×80 mL+R2: 2×20 mL)			
12×52 T (R1: 12×17.2 mL+R2: 12×4.3 mL)			

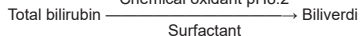
INTENDED USE

Used for the *in vitro* quantitative determination of Total Bilirubin in human serum and plasma. Mainly used clinically for the auxiliary diagnosis of bilirubin metabolism disorder. For professional and laboratory use.

TEST PRINCIPLE

Total bilirubin is oxidized by chemical oxidants in the presence of surfactants to form biliverdin, and the decrease in absorbance at 450 nm measured is proportional to the concentration of total bilirubin.

Chemical oxidant pH8.2



MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tris (hydroxymethyl) aminomethane hydrochloride buffer (pH8.2)	100 mmol/L
	Triton X-100	10 mL/L
Reagent 2	Sodium nitrite	1.3 g/L
	Phosphate buffer(pH7.0)	50 mmol/L

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The reagent should be stored at 2°C - 8°C in the dark and unopened state, and the validity period is 18 months. After opening, the reagent should be stored at 2°C - 8°C and valid for 42 days.

Production date and expiry date to see the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from

Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc. models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

Use morning fresh serum and heparin anticoagulant plasma; keep the sample out of light. The test results for serum and plasma will not change within 1 day of storage at 15-25°C, 7 days of storage at 4-8°C and 1 year of storage at -20°C.

TEST PROCEDURE

1. Reagent preparation: Use directly.
2. Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelengths	450 nm/546 nm	Calibration type	Linearity
Sample/R1/R2	8/240/60 μL	Time of mixture of serum + R1	1-5 min
Method	Two-point end point assay	Reaction time after addition of R2	5 min
Calibration method	Two-point calibration	Direction of reaction	Downward

(Absorbance (A) read by the instrument= $A_{\text{Primary wavelength}} - A_{\text{Secondary wavelength}}$)
Operating procedures:

Substances added	Blank tubes	Test tubes
Reagent 1	240 μL	240 μL
Sample	-	8 μL
Distilled water	8 μL	-
Mix well, incubate at 37°C for 3-5 min, and read the absorbance (A_0);		
Reagent 2	60 μL	60 μL
Mix well, incubate at 37°C for 5 min, and read the absorbance (A_1); then calculate the change in absorbance (ΔA) according to the formula $\Delta A = A_0 - A_1$		

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: Select quality control serum from Randox, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
 - 4.1 Check whether the parameter settings and light source are correct.
 - 4.2 Check whether the cuvettes and sampling probes are clean.
 - 4.3 Check whether water is contaminated, and bacterial growth will cause incorrect results.
 - 4.4 Check reaction temperature.
 - 4.5 Check the expiration date of the kit.

5. Result calculation:

$$\text{Concentration of T-BIL } (\mu\text{mol/L}) = \text{Concentration of T-BIL Standard Reference Material (SRM)} \times \frac{\Delta A_{\text{test sample}}}{\Delta A_{\text{standard}}}$$

REFERENCE RANGE

Male (aged 20-79) ≤ 26.0 μmol/L, Female, (aged 20-79) ≤ 21.0 μmol/L.

The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Since hemolysis interferes with determination, it should be avoided as much as possible during operation.

LIMITATIONS

There is no interference with measurement when hemoglobin ≤ 300 mg/dL, ascorbic acid ≤ 30 mg/dL, and

triglycerides \leq 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
R1 and R2 are colorless and clear solution. There are possibly some undissolved small particulates that does not interfere the test result.
2. Reagent blank absorbance
Reagent blank absorbance $A_{450nm} \leq 0.100$.
3. Accuracy
The relative deviation should be within $\pm 20.0\%$.
4. Linear range
4.1 Linear correlation coefficient (r) should be ≥ 0.990 in the range of [2.5, 684] $\mu\text{mol/L}$.
4.2 Linear deviation:
When test a sample with concentration of [2.5, 10] $\mu\text{mol/L}$, the deviation should be within $\pm 2 \mu\text{mol/L}$.
When test a sample with concentration of [10, 684] $\mu\text{mol/L}$, the deviation should be within $\pm 10\%$.
5. Analytical sensitivity
When a sample has a concentration of 79.9 $\mu\text{mol/L}$, its absorbance difference should be ≥ 0.170 .
6. Precision
Repeatability: The repeatability should not be greater than 4.0%.
Between-run precision: Between-run precision should not be greater than 5.0%.

PRECAUTIONS
















1. General precautions
 - 1.1 This product is for *in vitro* diagnosis only.
 - 1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
 - 1.3 Please use this product according to the IFU.
2. Precautions for operation
 - 2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
 - 2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
3. Precautions for use
 - 3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
 - 3.2 Please do not use expired reagents whose test results may be inaccurate.
 - 3.3 Please avoid adding reagents halfway during a test.
 - 3.4 Please avoid direct sunlight during operation.
 - 3.5 The reagents cannot be used if they are cloudy.
4. Precautions for waste disposal
Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
 - 5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
 - 5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
 - 5.3 Please do not use the reagent bottles for other purposes.
 - 5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
 - 5.5 Please do not mix reagents in different batches.

REFERENCE


Shang Hong, *et al.* National Standard Operating Procedure for Clinical Testing (4th Edition). People's Medical Publishing House, 2015: 296-302.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TB Reagent Kit (Chemical Oxidation Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date		Catalogue number
	Date of manufacture		Batch code		Temperature limit
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight		Biological risks
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Do not use if package is damaged and consult <i>instructions for use</i>		Authorized representative
	CE mark		This way up		Do not re-use

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