CE IVD

DB Reagent Kit (Chemical Oxidation Method)

Instructions for Use

REF CC1032

PRODUCT NAME

DB 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: 2×80 mL	R2: 2×20 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: 2×30 mL	R1: 4×60 mL	R2: 2×35 mL
R1: 4×60 mL	R2: 4×15 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 direct bilirubin concentration in human serum and plasma. Mainly used clinically as one of the evaluation indicators of bilirubin metabolism disorders.
For professional and laboratory use only.

TEST PRINCIPLE

In the presence of indirect bilirubin inhibitors and surfactants, direct bilirubin is oxidized by chemical oxidants to produce biliverdin. The decrease in absorbance at 450 nm is proportional to the concentration of direct bilirubin.

$$\text{DB} \xrightarrow[\text{Indirect bilirubin inhibitors}]{\text{Chemical oxidizing agent pH3.0}} \text{Biliverdin}$$

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tartaric acid buffer (pH3.0)	10 g/L
	Thiourea	5 g/L
Reagent 2	Phosphate buffer (pH7.0)	0.7 g/L
	Sodium nitrite	0.3 g/L

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

STORAGE AND SHELF LIFE

Reagents should be stored in tightly closed containers at 2°C-8°C, protected from light for a shelf life of 18 months. Once opened, they should be stored at 2°C to 8°C, and the reagents remain valid for 42 days.
Production date and expiration date: see details on 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 serum and heparin-anticoagulated plasma sample. Even slight haemolysis can cause a reduction in value and such samples should be avoided. Lipemic samples should also be avoided. Stable in serum and plasma, protected from light, for 2 days at 15-25°C, for 7 days at 2-8°C and for 6 months at -20°C.

TEST PROCEDURE

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

Primary/secondary wavelength	450 nm/570 nm	**Calibration type**	Linearity
Sample/R1/R2	8/240/60 μL	**Time of mixture of serum + R1**	5 min
Method	Two-point endpoint assay	**Reaction time after addition of R2**	5 min
Calibration method	Two-point calibration	**Direction of reaction**	Downward

Operating procedures:
Dual Reagent Operation

Sample (Standard)	8 μL
Reagent 1 (R1)	240 μL
Mix well, incubate at 37°C for 3-5 min, and read the absorbance A_0.	
Reagent 2 (R2)	60 μL
Mix well, incubate at 37°C for 5 min, and then read the absorbance A_1. $\Delta A = A_1 - A_0$	

3. Calibration procedure: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control procedure: use the serum control 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:

D-BiL concentration (μmol/L)=Concentration of D-BiL Standard Reference Material (SRM) × $\triangle A_{\text{test sample}} / \triangle A_{\text{SRM}}$

REFERENCE RANGE

Reference range: 2-6.84 μmol/L ;
The reference range is for reference only. It is recommended that each laboratory should establish its own reference range.

RESULT INTERPRETATION

Hemolyzed samples interfere with the measurement of the assay and should be avoided as much as possible during the procedure. The sample storage time also influences the assay results.

LIMITATIONS

There is no interference with measurement when hemoglobin is ≤ 200 mg/dL, ascorbic acid ≤ 20 mg/dL, and triglycerides ≤ 1000 mg/dL.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of subvisible particles that do not affect the determination. Reagent 2 is a colorless clear liquid, which may contain a small number of subvisible particles that do not affect the determination.
2. Reagent blank absorbance
   Reagent blank absorbance A_{450nm}≤ 0.100.
3. Accuracy
   By comparison test, the correlation coefficient (r) should not be less than 0.950. In the range of [2, 6] μmol/L, the absolute deviation should not exceed ±1.2 μmol/L; in the range of (6, 342] μmol/L, the relative deviation should not exceed ±20%.
4. Linear range
   4.1 linear correlation coefficient
   The linear correlation coefficient (r) should not be less than 0.990 within the linear range of [2, 342] μmol/L.
   4.2 Linear difference
   The absolute deviation from linearity should not exceed ±2 μmol/L for testing within the linear range of [2, 10] μmol/L;
   The relative deviation from linearity should not exceed ±10% for testing within the linear range of (10, 342] μmol/L.
5. Analytical sensitivity
   When a sample has a concentration of 46.2 μmol/L, its absorbance difference should be ≥ -0.100.
6. Precision
   6.1 Repeatability
   Coefficient of variation (CV) should not be more than 4.0%.
   6.2 Between-run precision
   Between-run precision should not be more 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.
   2.3 Avoid direct sunlight during operation.
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 Clinical Laboratory Procedures (4th Edition). People's Medical Publishing House, 2015: 296-302.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on DB 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	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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