



CHE Reagent Kit (Butylthiocholine Kinetic method)

Instructions for Use

REF CC1020

PRODUCT NAME

CHE Reagent Kit (Butylthiocholine Kinetic 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: 4×80 mL	R2: 4×20 mL
R1: 4×100 mL	R2: 2×50 mL	R1: 6×62 mL	R2: 6×15 mL
200 T (R1: 1×27 mL R2: 1×8 mL)			
12×60 T (R1: 12×16.8 mL R2: 12×4.2 mL)			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of cholinesterase activity in human serum and plasma.

Clinically, it is mainly used for the auxiliary diagnosis of liver injury and organophosphorus poisoning. For professional and laboratory use only.

TEST PRINCIPLE

Thiobutyrylcholine generates butyric acid and thiocholine by the action of cholinesterase, and thiocholine then reacts with 5,5 dithio-2-nitrobenzoic acid to form 5-mercapto-2-nitrobenzoic acid, and the cholinesterase activity can be calculated by measuring the rate of increase of 5-mercapto-2-nitrobenzoic acid.

Thiobutyrylcholine $\xrightarrow{\text{CHE}}$ butyric acid + thiocholine
5,5 Dithio-2-nitrobenzoic acid + thiocholine \longrightarrow 5-mercapto-2-nitrobenzoic acid + 2-nitrobenzoic acid-5-mercaptothiocholine

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	5,5 Dithio-2-nitrobenzoic acid	0.2 g/L
	Phosphate buffer (pH 7.7)	8.5 g/L
Reagent 2	Thiobutyrylcholine	1.5 g/L

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

STORAGE AND SHELF LIFE

The unopened reagents are stable for 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 42 days when stored away from direct sunlight at 2-8°C. Refer to the label on the reagent kit for the manufacturing date and the expiry date.

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-400, BS-420, BS-490, BS-600, BS-800, BS-B20, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1200, 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; fully 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; fully automatic biochemistry 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

Serum and heparin anticoagulated plasma should be separated promptly after blood collection to avoid hemolysis, and serum and plasma could be stored for 6 hours at 15-25°C, for 7 days at 2-8°C and 1 year at -20°C.

TEST PROCEDURE

- The dual reagent is ready for use directly.
- Test conditions: (different testing instruments can be requested according to the different parameters on the machine)

Primary/Secondary wavelength	415 nm/505 nm	Calibration type	Linearity
Sample/R1/R2	2/240/60 μ L	Serum + R1 time	1-5 min
Method	Rate assay	Delay time after adding 2	30 s
Calibration method	Two-point calibration	Reaction direction	Upward

- Operational procedures:
Operation using two reagents

Addition	Blank tube	Test tube
Reagent R1	240 μ L	240 μ L
Distilled water	2 μ L	-
Sample	-	2 μ L
Mix and incubate at 37°C for 1-5 min.		
Reagent 2	60 μ L	60 μ L
Mix well, incubate at 37°C for 30 s, continuously monitor the absorbance change of each tube for 30-45s, and calculate $\Delta A/\text{min}$.		

- Calibration procedure:
Randox calibration serum is recommended.
- Quality control procedure:
Use Randox quality control serum, the quality control measurement value should be within the range of the labeled value. If the result deviates from the range, the following steps can be taken to find out the reason:
 - 5.1 Check that the parameter settings and light source are correct.
 - 5.2 Check that the colorimetric cup and pipette needle are clean.
 - 5.3 Check that the water is not contaminated, bacterial growth can lead to incorrect results.
 - 5.4 Check the reaction temperature.
 - 5.5 Check the validity of the kit.
- Calculations
CHE activity (U/L) = $(\Delta A_{\text{Measurement}} / \text{min} - \Delta A_{\text{blank}} / \text{min}) \times 11103$

REFERENCE RANGE

4500-13000 U/L (4.5-13 KU/L)

Determined on the basis of the 95% distribution interval for normal subjects.

The reference ranges cited are for reference only and it is recommended that laboratories establish their own reference ranges.

RESULT INTERPRETATION

Hemolysis interferes with the assay and should be avoided as much as possible during the procedure. The time the sample is left in place also has an effect on the assay.

LIMITATIONS

Hemoglobin ≤ 1000 mg/dL, ascorbic acid ≤ 50 mg/dL, bilirubin ≤ 50 mg/dL and triglycerides ≤ 2000 mg/dL do not interfere with the measurement.

PERFORMANCE CHARACTERISTICS

1. Appearance

Reagent 1 in the kit is a light yellow clarified liquid, there may be a small amount of insoluble particles that do not affect the determination; Reagent 2 is a colorless clarified liquid, there may be a small amount of insoluble particles that do not affect the determination.

2. Reagent blanks

2.1 Reagent blank absorbance

Reagent blank absorbance $A_{415nm} \leq 1.500$.

2.2 Rate of change in absorbance of reagent blanks

Reagent blank absorbance change rate $|\Delta A_{415nm}|/\text{min} \leq 0.020$.

3. Accuracy

Using the comparison test, the correlation coefficient r shall be not less than 0.990, and the absolute deviation shall not exceed ± 600 U/L in the [250, 6000] U/L interval, and the relative deviation shall not exceed $\pm 10\%$ in the (6000, 17000] U/L interval.

4. Linear range

4.1 Linear correlation coefficient

The linear correlation coefficient r between the theoretical and measured concentrations shall be not less than 0.990 in the range [250, 17000] U/L.

4.2 Linearity deviations

The absolute deviation of linearity should not exceed ± 250 U/L in the [250, 1000] U/L interval; the relative deviation of linearity should not exceed $\pm 10\%$ of the range in the (1000, 17000] U/L interval.

5. Analytical sensitivity

The absorbance difference should be ≤ 0.560 at a sample concentration of 4700 U/L.

6. Precision

6.1 Repeatability

Repeatability should be no greater than 4.0%.

6.2 Between-run Precision

Between-run Precision shall be no greater than 6.0%.

PRECAUTIONS

1. General considerations

1.1 This product is intended for *in vitro* diagnostic use only.

1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurement results, clinical symptoms and other examination results.

1.3 Please use this product according to the IFU.

2. Operational considerations

2.1 Please dispose of the specimen as if it were a hazardous substance that could be infected with HIV, HBV, HCV, etc. To avoid or minimize the associated risk of infection, use disposable gloves.

2.2 In case of accidental ingestion into the eyes or mouth, or contact with the skin, rinse well with water and seek medical attention if necessary.

3. Precautions for use

3.1 Store reagents according to the storage method and avoid freezing. The quality of reagents may change after freezing, so do not use them.

3.2 Do not use reagents that have passed their expiration date, as the results may be inaccurate.

3.3 Please avoid adding reagents in the middle of the test.

3.4 Avoid direct sunlight during operation.

3.5 The reagent must not be used if it is cloudy.

4. Waste disposal considerations

Samples, waste fluids, etc. are potentially bioinfectious, and operators should comply with laboratory safety practices and dispose of waste fluids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.

5. Other considerations

5.1 On an automated biochemical analyzer, the linear range is related to the ratio of sample volume to reagent volume used and the time of measurement.

5.2 The amount of reagents and samples may be varied proportionally to the requirements of different instruments.

5.3 Do not divert the reagent bottles for other purposes.

5.4 Calculations using k-values are not as reliable as calibrated measurements using standards.
















5.5 Please do not mix reagents in different batches.

REFERENCE

Shang Hong et al. National clinical testing operation procedures (4th ed.). People's Health Publishing House.2015:291.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CHE Reagent Kit (Butylthiocholine Kinetic 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 instructions for use or consult electronic instructions for use		Do not use if package is damaged and consult instructions for use		Authorized representative
	CE mark		This way up		Do not re-use



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