Cholinesterase Assay Kit (CHE)

Method: DGKC

Cat .No.	Size	Instrument
GB080G	R1:2×90 ml R2:1×36 ml	For Hitachi 717 & ShimadzuCL7200/8000
GB0801G	R1:2×40 ml R2:1×16 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS081G	R1:3×60 ml R2:1×36 ml	For Hitachi917 & OlympusAU640/400/600
GS0811G	R1:4×20 ml R2:1×16 ml	For Hitachi917 & OlympusAU640/400/600
GH081G	R1:2×40 ml R2:1×16 ml	For Hitachi902
GT081G	R1:4×45 ml R2:2×18 ml	For TOSHIBA40
GX081G	R1:1×100 ml R2:1×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800

INTENDED USE

For the *in vitro* quantitative determination of cholinesterase (CHE) in serum.

CLINICAL SIGNIFICANCE

The assay kit is for determination of Cholines-terase (CHE). Cholinesterase (CHE) is devided into two groups. One is metabolized in grey matter of central nervous system, sympathetic ganglion, hematid and so on. The other is meta-bolized in plasma, liver, uterus and so on. Cholinesterase (CHE) activity is disposed in patients with acute hepatitis, chronic hepatitis, li-ver sclerosis, CHE activity is the most important indicator of degree of intoxication by organophosphorus pesticide.

ASSAY PRINCIPLE[1]

Butyrylthiocholine is hydrolyzed to give thiochol-ine and butyrate by Cholinesterase. The react-ion between thiocholine and ferricyanide gives ferrocyanide. The rate of decrease in absorban-ce at 405 nm is directly proportional to cholines-terase activity.

SAMPLE COLLECTION AND PREPARATION

Using serum samples.
Serum samples are stable for a week at 2-8°C, or for 1 year at -20°C.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
pyrophosphoric buffer	75 mmol/L, pH 7.6
$Fe(CN)_6^{3-}$	2 mmol/L
Reagent 2 (R2)	
Butyrylthiocholine	15 mmol/L
Stabilizer	

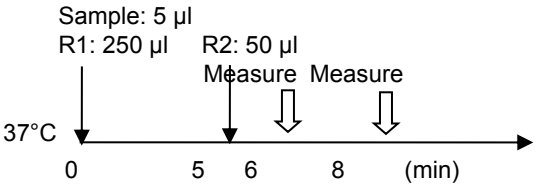
STABILITY AND PREPARATION OF REAGENTS

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

The CHE assay kit reagents are stable for 28 days on board. When the reagents are mixed and used as single reagent, it is stable for 8 hours at room temperature and 2 days at 2-8°C .

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: Rate A, 22-28
Wave Length (main/sub): 405 nm/660 nm



1. Mix 5 µl sample with 250 µl R1 and incubate at 37°C for 5 minutes.
2. Add 50 µl R2 into cuvette, mix and incubate for 1 minute at 37°C.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.
4. Calculate absorbance change per minute (ΔA/min).

CALCULATION

Calculation using calibration

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{calibrator value}$$

Calculation using factor

CHE Activity (KU/l) = ΔA /min × 65.8

CALIBRATION

Recommend that this assay should be calibrate-d 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. Values should fall within a specific 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.
4. Check the quality of the water used for reagents reconstitution.

NORMAL VALUE

Female: 4.0 - 12.6 KU/L
Male: 5.1 - 11.7 KU/L
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 20 KU/L. If the sample above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution factor.

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE Revised 01DEC11 version 1001

PRECISION

The CV of the test should be less than 5%.

Inter assay precision		
N=4	Level1	Level 2
Mean (KU/L)	5.128	4.846
SD	0.0357	0.0231
CV	0.69%	0.48%
Intra assay precision		
N=20	Level1	Level 2
Mean (KU/L)	5.128	4.846
SD	0.0331	0.0243
CV	0.65%	0.50%

SENSITIVITY

The minimum detectable concentration of CHE with an acceptable level of precision was deter-mined as 44 U/L.

INTERFERENCE

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

Hemoglobin: 1000 mg/dl
Introlipid: 3000 mg/dl
Bilirubin: 60 mg/dl
Ascorbic Acid: 60 mg/dl
Glucose: 1000 mg/dl
Heparin sodium: 100 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y=1.004X+18.21, R^2=0.999; 142 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagents contain 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.
3. 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.
4. 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. Knedel, M., and R. Bottger. Klin. Wschr. 1967; 45: 325.

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

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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