Bioway Chemistry Reagent Series

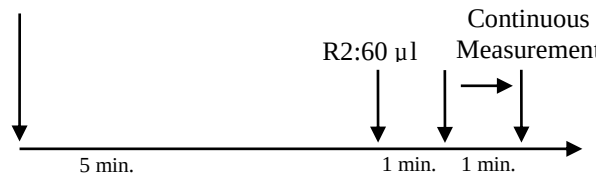
The Serum Cholinesterase Reagent Kit

Detection of Cholinesterase in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R017K11 ***The Serum CHE Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram



*Refer to Figure 1 and the package insert for detail

Table 1: Instrument Parameters*

F factor	11103	Slope of reaction	Increase
Testing wavelength	Dλ : 410 nm Sλ : 505 nm	Sample volume	2 µl
Test method	Rate Method	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	60 µl

INTENDED USE

Bioway Chemistry Reagent Series **CHE Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of cholinesterase in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

There are two different kinds of cholinesterase exist in human bodies. One is acetylcholinesterase or so called true cholinesterase and usually be detected in erythrocytes and cholinergic nerve terminals. The other is butyrylcholine or pseudocholinesterase, which is found in plasma, liver, smooth muscle and fat cells. Serum cholinesterase activity is the result of the metabolic reaction of 13 isoenzymes. It can be a sensitive indicator of chronic and infectious hepatic pathologies. The level of serum cholinesterase is decreased in the patients who are poisoned by organophosphate pesticides, which are CHE inhibitors.

TEST PRINCIPLES

The Kit utilizes enzymatic and kinetic reactions to measure the CHE activity (U/L) in human serum or plasma.

$$\text{Butyrylthiocholine} + H_2O \xrightarrow{\text{CHE}} \text{Butyrate} + \text{Thiocholine}$$

$$\text{Thiocholine} + \text{DTNB} \longrightarrow \text{5-thio-2-nitrobenzoic acid}$$

After thiocholine is produced by the cholinesterase catalyzed hydrolysis reaction of butyrilthiocholine, it reacts with DTNB and turns to free yellow-colored 5-thio-2-nitrobenzoic acid. The process is quantified by measuring the absorabances at 410 nm in a kinetic fashion.

The rate of increase in absorbance at 410 nm is directly proportional to the CHE activity in the sample.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, pH7.6 DTNB	50 mmol/L 0.25 mmol/L
R2	Butyrylthiocholine Sodium azide	6 mmol/L 1 ml/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. CHE control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Be sure to do a self-blank control to erase the effects of lipemia and jaundice interferences.
6. Reagents contain sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be frozen at -20℃ and avoid repeated freeze-thaw cycle.

TEST PROCEDURE (see Figure 1)

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 2 µl of sample and 240 µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 60µl of R2; mix well and incubate at 37℃ for 1 minute.
3. Take continuous optical density measurement for 1 minute.
4. Calculate average Δ A /min

RESULT

The CHE activity in U/L can be obtained by the following calculation:

$$\text{CHE (U/L)} = (\Delta A_{test}/\text{min} - \Delta A_{blank}/\text{min}) \times \text{factor (F)}$$

The calculation factor for UV spectrophotometer is 11103 when the optical path is 10 mm. Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

5000~12000U/L (37℃)
It is recommended for each laboratory to establish its own expected values

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with CHE exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 - 20000 U/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤5%

REFERENCES

1. Rehiman S. *et al.*, J Nepal Med Assoc 47(170): 47-52 (2008).

Not Intended for Sale in the United States.

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