respons®910

Cholinesterase FS*

Order Information

Cat. No.	Kit size
1 1401 99 10 921	Σ 480 (4 x 120)

Intended Use

Diagnostic reagent for quantitative in vitro determination of cholinesterase (CHE) in serum or plasma on respons®910.

Summary

Cholinesterases (CHE) are a group of enzymes preferably splitting choline and thiocholine esters. The denomination Serum Cholinesterase and Pseudocholinesterase are also commonly used. The CHE measured in serum and plasma is synthesized in the liver and is determined in diagnosis of liver diseases, nephrotic syndrome and intestinal diseases with loss of protein (exudative enteropathy). Strongly decreased values can indicate intoxication by pesticides. Measurement of CHE is also a part of pre-operative diagnostics as CHE is needed for the inactivation of muscle relaxants often used in surgeries. [1]

Method

Kinetic photometric test, optimized method according to the recommendation of the German Society of Clinical Chemistry (DGKC).

Cholinesterase hydrolyses butyrylthiocholine under release of butyric acid and thiocholine. Thiocholine reduces yellow potassium hexacyanoferrate (III) to colorless potassium hexacyanoferrate (II). The decrease of absorbance is measured at 405 nm.

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

$$2\ \text{Thiocholine} + 2\ [Fe(CN)_6]^{3-} + H_2O \longrightarrow \text{Choline} + 2\ [Fe(CN)_6]^{4-} + H_2O$$

Reagents

Components and Concentrations

R1:	Pyrophosphate	pH 7.6	95 mmol/L
	Potassium hexacyanoferrate (III)		2.5 mmol/L
R2:	Butyrylthiocholine		75 mmol/L

Storage and Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light.

DiaSys respons containers provide protection from light.

Warnings and Precautions

1. ⚠ Reagent 1: Danger. Contains Tetrasodium pyrophosphate-10-hydrate. H318 Causes serious eye damage. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a poison center or doctor/physician.
2. In very rare cases, samples of patients with gammopathy might give falsified results [2].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [1,3]:

1 week	at	15 – 25°C
2 week	at	2 – 8°C
6 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been made traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size		
TruCal U	5 9100 99 83 063	20	x	3 mL
	5 9100 99 83 064	6	x	3 mL
TruLab N	5 9000 99 83 062	20	x	5 mL
	5 9000 99 83 061	6	x	5 mL
TruLab P	5 9050 99 83 062	20	x	5 mL
	5 9050 99 83 061	6	x	5 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 20 kU/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.1 kU/L
Onboard stability	6 weeks
Calibration stability	3 weeks

Interfering substance	**Interferences ≤ 10% up to**	**CHE [kU/L]**
Ascorbic acid	30 mg/dL	5.15
Hemoglobin	150 mg/dL	1.88
	500 mg/dL	4.31
Bilirubin (conjugated)	60 mg/dL	1.82
	70 mg/dL	4.33
Bilirubin (unconjugated)	30 mg/dL	1.78
	60 mg/dL	4.23
Lipemia (triglycerides)	800 mg/dL	1.76
	2000 mg/dL	3.98

For further information on interfering substances refer to Young DS. [4]

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [kU/L]	2.86	4.74	8.59
CV [%]	1.95	1.62	2.41
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [kU/L]	3.06	4.67	9.08
CV [%]	1.42	1.28	1.24

Method comparison (n=134)	
Test x	DiaSys Cholinesterase FS (Hitachi 917)
Test y	DiaSys Cholinesterase FS (respons®910)
Slope	1.032
Intercept	0.038 kU/L
Coefficient of correlation	0.998

** according to CLSI document EP17-A, Vol. 24, No. 34

Conversion Factor
Cholinesterase [kU/L] x 16.67 = Cholinesterase [µkat/L]

Reference Range

As follows [3]:

Women	3.93 – 10.8 kU/L	65.5 – 180 µkat/L
Men	4.62 – 11.5 kU/L	77.0 – 192 µkat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Hallbach J, Klinische Chemie für den Einstieg. 1st ed Stuttgart: Thieme;2001. p. 143-4.
2. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
3. Recommendations of the German Society for Clinical Chemistry. Standardization of methods for the estimation of enzyme activities in biological fluids: Standard method for the determination of Cholinesterase activity. J Clin Chem Clin Biochem 1992;30:163-70.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

IVD CE

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* Fluid Stable

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Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	CHE
Shortcut:	
Reagent barcode reference:	028
Host reference:	028

Technic	
Type:	Linear kinetic
First reagent:[µL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	40
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	06:48
Last reading time [min:sec]	10:00
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance limit	0.1000
Linearity: Maximum deviation [%]	100.0000
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.1000
Concentration technical limits-Upper	20.0000
SERUM	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	3.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	3.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	kU/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	Male
Age	
SERUM	>=4.62<=11.50
URINE	
PLASMA	>=4.62<=11.50
CSF	
Whole blood	
Gender	Female
Age	
SERUM	>=3.93<=10.80
URINE	
PLASMA	>=3.93<=10.80
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.003
Cal. 2	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value