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) activity in human serum or heparin plasma on automated respons®910.

Summary

Cholinesterases (ChE) are a group of enzymes that hydrolyze acetylcholine into choline and acetic acid. They are divided into acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE) [1]. Decreased ChE activity is relevant in preoperative diagnostics, as individuals with low ChE activities are more sensitive to muscle relaxants, leading to e.g. breath insufficiency [1]. Furthermore, decreased values can indicate liver diseases [1,2], or poisoning with insecticides. Other reasons for decreased values are due to drugs and rarely hereditary. The most common reason for elevated ChE values is diabetes mellitus, followed by cardiovascular diseases [2]. However, due to lack of specificity ChE is used as an additional parameter, combined with alanine aminotransferase (ALAT) and gamma-glutamyltransferase (GGT) [2].

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.

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

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

One unit of cholinesterase is the amount of enzyme that will convert 1.0 µmol of butyrylthiocholine in presence of H_2O to thiocholine and butyrate per minute at the enzyme specific conditions.

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

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 15 months until expiry date.

Warnings and Precautions

1. Components contained in Cholinesterase FS are classified according to EC regulation 1272/2008 (CLP) as follows:

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/doctor.

2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) 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.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

7 days	at	15 – 25°C
7 days	at	2 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the molar extinction coefficient. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range from 0.1 kU/L up to 20 kU/L, linearity is given within ± 5%.
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
Limit of quantitation**	0.1 kU/L
Onboard stability	6 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [kU/L]
Ascorbic acid	30 mg/dL	5.15
Bilirubin (conjugated)	60 mg/dL	1.82
	70 mg/dL	4.33
Bilirubin (unconjugated)	30 mg/dL	1.78
	60 mg/dL	4.23
Hemolysis	150 mg/dL	1.88
	500 mg/dL	4.31
Lipemia (triglycerides)	800 mg/dL	1.76
	2000 mg/dL	3.98
For further information on interfering substances, refer to the literature [5].		

Precision			
Repeatability (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	1.03
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 [2]

	kU/L	µkat/L
Women	3.93 – 10.8	65 – 180
Men	4.62 – 11.5	77 – 192

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

Literature

1. Pohanka, M. (2011). CHOLINESTERASES, A TARGET OF PHARMACOLOGY AND TOXICOLOGY. Biomedical papers, 155(3), 219-223
2. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 Jan 03]. Available from: https://www.clinical-laboratory-diagnostics.com/
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 38-9.
5. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2020 [cited 2024 March]. Available from: https://clinfx.wiley.com/ aaccweb/aacc/

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.

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