respons®910

Cholinesterase FS*

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

Order Information

Cat. No. 1 1401 99 10 921
4 twin containers for 120 tests each

Method

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

Principle

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.

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

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

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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results.
2. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Serum, heparin or EDTA plasma

Stability [1,2]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration the DiaSys TruCal U calibrator is recommended. This method is traceable to the molar extinction coefficient. For internal quality control DiaSys TruLab N and P controls should be assayed. 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 up to 20 kU/L CHE (in case of higher activities re-measure samples after manual dilution or use rerun function)	
Limit of detection**	0.1 kU/L CHE
On-board stability	6 weeks
Calibration stability	3 weeks

Interfering substance	Interferences < 10%	CHE [kU/L]
Ascorbate	up to 30 mg/dL	5.15
Hemoglobin	up to 150 mg/dL	1.88
	up to 500 mg/dL	4.31
Bilirubin, conjugated	up to 60 mg/dL	1.82
	up to 70 mg/dL	4.33
Bilirubin, unconjugated	up to 30 mg/dL	1.78
	up to 60 mg/dL	4.23
Lipemia (triglycerides)	up to 800 mg/dL	1.76
	up to 2000 mg/dL	3.98
For further information on interfering substances refer to Young DS [3].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [kU/L]	2.86	4.74	8.59
Coefficient of variation [%]	1.95	1.62	2.41
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [kU/L]	3.06	4.67	9.08
Coefficient of variation [%]	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 NCCLS document EP17-A, vol. 24, no. 34

Conversion Factor

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

Reference Range [1]

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. 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.
2. Hallbach J, Klinische Chemie für den Einstieg. 1st ed Stuttgart: Thieme; 2001. p. 143-4.
3. 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.
4. Thomas L, Clinical laboratory diagnostics. 1st ed Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 65-71.

Manufacturer

IVD CE
DiaSys Diagnostic Systems GmbH
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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
Name:	CHE
Shortcut:	
Reagent barcode reference:	028
Host reference:	

Technic	
Type:	Linear Kinetic
First reagent:[µL]	160
Blanc correction	Yes
Second reagent:[µL]	40
Blanc correction	Yes
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 deplation: absorbance limit	0.1
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.1
Concentration technical limits-Upper	20
SERUM	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume [µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	3
Normal dilution (factor)	1
Below normal volume[µL]	5
Below normal dilution (factor)	1
Above normal volume [µL]	3
Above normal dilution (factor)	6

Results	
Decimals	2
Units	kU/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	Male
Age	
SERUM	>=4.62<=11.5
URINE	
PLASMA	>=4.62<=11.5
CSF	
Genre	Female
Age	
SERUM	>=3.93<=10.8
URINE	
PLASMA	>=3.93<=10.8
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*

	Max delta abs.
Cal. 1	0.015
Cal. 2	0.010
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X degree
Degree	1

* Enter calibrator value