respons®920

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®920.

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. 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.
5. 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**	0.2 kU/L
Onboard stability	8 weeks
Calibration stability	8 weeks

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin	60 mg/dL
Hemoglobin	1000 mg/dL
Lipemia (triglycerides)	2000 mg/dL
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]	4.07	5.64	11.4
CV [%]	0.83	1.58	1.43
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [kU/L]	3.76	5.05	9.58
CV [%]	0.89	1.09	0.78

Method comparison (n=120)	
Test x	DiaSys Cholinesterase FS (Hitachi 917)
Test y	DiaSys Cholinesterase FS (respons®920)
Slope	1.01
Intercept	0.010 kU/L
Coefficient of correlation	0.999

** lowest measurable activity which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

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

respons®920

Cholinesterase FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CHE				Auto Rerun		☐
Report Name	:	Cholinesterase				Online Calibration		☐
Unit	:	kU/L	Decimal Places	:	3	Cuvette Wash		☐
Wavelength-Primary	:	405	Secondary	:	0	Total Reagents	:	2
Assay Type	:	RATE-A	Curve Type	:	Linear	Reagent R1	:	CHE R1
M1 Start	:	0	M1 End	:	0	Reagent R2	:	CHE R2
M2 Start	:	22	M2 End	:	33			
Sample Replicates	:	1	Standard Replicates	:	3	**Consumables/Calibrators:**		
Control Replicates	:	1	Control Interval	:	0	Blank /Level 0		0
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.25	Calibrator 1		*
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	0.20	Technical Maximum	:	20.0			
Y = aX + b a=	:	1.0000	b=	:	0.0000			

* Enter calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	CHE				
Sample Type	:	Serum				

Sample Volumes

Normal	:	3.00 µL	Dilution Ratio	:	1 X
Increase	:	5.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	1 X
Standard Volume	:	3.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	160 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CHE		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (kU/L)	Upper Limit (kU/L)
Normal	:	4.62	11.50
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other