

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
04498577 190	Cholinesterase Gen.2 (200 tests)	System-ID 07 6842 1 COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6
10759350 360	Calibrator f.a.s. (12 × 3 mL, for USA)	System-ID 07 3718 6
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	System-ID 07 7999 7
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6
12149443 160	Precipath U plus (10 × 3 mL, for USA)	System-ID 07 8000 6
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	System-ID 07 7469 3
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	System-ID 07 7470 7

English

System information

Test CHE2, test ID 0-021

Intended use

In vitro test for the quantitative determination of the catalytic activity of cholinesterase (EC 3.1.1.8; acylcholine acylhydrolase) in serum and plasma

Summary^{1,2,3}

Cholinesterase (pseudocholinesterase or cholinesterase II) is found in the liver, pancreas, heart, serum and in the white matter of the brain. This enzyme must not be confused with acetylcholinesterase from erythrocytes (EC 3.1.1.7), which is also referred to as cholinesterase I.

The biological function of cholinesterase is unknown. Serum cholinesterase serves as an indicator of possible insecticide poisoning. It is measured as an index of liver function. In pre-operative screening, cholinesterase is used to detect patients with atypical forms of the enzyme and hence avoid prolonged apnea caused by slow elimination of muscle relaxants.

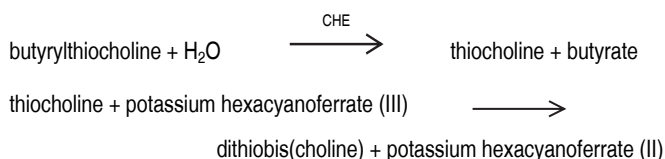
Depressed cholinesterase levels are found in cases of intoxication with organophosphorus compounds and in hepatitis, cirrhosis, myocardial infarction, acute infections and atypical phenotypes of the enzyme.

This assay is based on the method published by Schmidt E et al. in 1992.³

Test principle

Method with butyrylthiocholine.³

Cholinesterase catalyzes the hydrolysis of butyrylthiocholine to thiocholine and butyrate. Thiocholine instantaneously reduces the yellow hexacyanoferrate (III) to the almost colorless hexacyanoferrate (II). This decrease in color can be measured at wavelengths between 405 and 415 nm.



Reagents - working solutions

- R1** Pyrophosphate buffer: 92 mmol/L, pH 7.7; potassium hexacyanoferrate : 2.4 mmol/L
- SR** GOOD's buffer: 10 mmol/L, pH 4.0; butyrylthiocholine: 46 mmol/L; stabilizers

R1 is in position B and SR is in position C.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C	See expiration date on cobas c pack label
COBAS INTEGRA 400 plus system	
On-board in use at 10-15 °C	4 weeks
COBAS INTEGRA 800 system	
On-board in use at 8 °C	4 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable:

Serum: Collect serum using standard sampling tubes.

Plasma: Li-heparin, K₂-EDTA or K₃-EDTA plasma.

Do not use citrate and fluoride plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Stability: ^{2,4,5}	6 hours at 15-25 °C
	7 days at 2-8 °C
	1 year at -20 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Application for serum and plasma**COBAS INTEGRA 400 plus test definition**

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-S-SR
Reaction direction	Decrease
Wavelength A/B	409/659 nm
Calc. first/last	43/52
Unit	U/L

Pipetting parameters

		Diluent (H ₂ O)
R1	120 µL	
Sample	2 µL	5 µL
SR	24 µL	
Total volume	151 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-S-SR
Reaction direction	Decrease
Wavelength A/B	409/659 nm
Calc. first/last	60/75
Unit	U/L

Pipetting parameters

		Diluent (H ₂ O)
R1	120 µL	
Sample	2 µL	5 µL
SR	24 µL	
Total volume	151 µL	

Calibration

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot

Traceability: This test is standardized against a reference method using a manual application of the butyrylthiocholine/hexacyanoferrate (III) method on a photometer and the published molar absorptivity of hexacyanoferrate (III).³

Quality control

Reference range	Precinorm U, Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U, Precipath U plus or PreciControl ClinChem Multi 2
Control interval	24 hours recommended

Control sequence

User defined

Control after calibration

Recommended

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

COBAS INTEGRA analyzers automatically calculate the analyte activity of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factor: U/L × 0.0167 = µkat/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Icterus:⁶ No significant interference.

Hemolysis:⁶ No significant interference up to an H index of 350 (approximate hemoglobin concentration: 217 µmol/L or 350 mg/dL).

Lipemia (Intralipid):⁶ No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{7,8}

Anticoagulants: Citrate and fluoride inhibit the reaction and must not be used.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.⁹

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges**Measuring range**

200-14000 U/L (3.34-234 µkat/L)

Determine samples having higher activities via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Lower detection limit of the test:

200 U/L (3.34 µkat/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 21).

Expected values^{10,*}

Women aged 40 years or more, children, men:

5320-12920 U/L (89-215 µkat/L)

Women aged 16-39 years, not pregnant, not using hormonal contraceptives:

4260-11250 U/L (71-187 µkat/L)

Women aged 18-41 years, pregnant or taking contraceptives:

3650-9120 U/L (61-152 µkat/L)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

*Calculated with a temperature conversion factor of 1.52 (25 → 37 °C).¹¹

Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (1 aliquot per run, 1 run per day, 21 days). The following results were obtained:

Sample	Repeatability			Intermediate precision		
	Mean		CV	Mean		CV
	U/L	μkat/L	%	U/L	μkat/L	%
Human serum	6374	106	0.5	6675	111	1.4
Precinorm U	6263	105	0.6	6213	104	1.1
Precipath U	6015	100	0.6	5964	100	0.9

Method comparison

CHE values for human serum samples obtained on a COBAS INTEGRA 800 analyzer using the Roche CHE2 reagent (y) were compared with those determined using the Roche CHE reagent on the same analyzer (x).

Sample size (n) = 51

Passing/Bablok¹²

$y = 0.970x + 128$ (U/L)

$r = 0.967$

SD (md95) = 125

Linear regression

$y = 0.965x + 153$ (U/L)

$r = 0.999$

$Sy.x = 37.1$

The sample activities were between 1192 U/L and 14411 U/L (19.9-241 μkat/L).

References

- Moss DW, Henderson AR, Kachmar JF. Enzymes. In: Tietz NW, ed. Fundamentals of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders 1987;346-421.
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- Schmidt E, Gerhardt W, Henkel E, et al. Proposal of Standard Methods for the Determination of Enzyme Catalytic Concentrations in Serum and Plasma at 37 °C. Eur J Clin Chem Clin Biochem 1992;30:163-170.
- Use of Anticoagulants in Diagnostic Laboratory Investigations. WHO Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
- Huizenga JR, van der Belt K, Gips CH. The Effect of Storage at Different Temperatures on Cholinesterase Activity in Human Serum. J Clin Chem Clin Biochem 1985;24:283-385.
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- Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin Lab 1994;40:33-42.
- Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem 1988 Nov;26(11):783-790.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT



Contents of kit

Volume after reconstitution or mixing

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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