

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
20764655 322	Prealbumin (100 tests)	System-ID 07 6465 5 COBAS INTEGRA 400 plus
Materials required (but not provided):		
03555941 190	C.f.a.s. PAC (3 x 1 mL)	System-ID 07 6810 3
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	System-ID 07 7469 3
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	System-ID 07 7469 3
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	System-ID 07 7470 7
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	System-ID 07 7470 7
20756350 322	NaCl Diluent 9 % (6 x 22 mL)	System-ID 07 5635 0

English**System information**

Test PREA3, test ID 0-665

Intended use

In vitro test for the quantitative immunological determination of human prealbumin in serum and plasma on COBAS INTEGRA systems

Summary^{1,2,3}

Prealbumin or thyroxine-binding prealbumin is also known as transthyretin. It is a protein with a molecular weight of approximately 50 kDa. Prealbumin transports about one third of the serum thyroxine. It has a short half-life and demonstrates a marked dependency on adequate protein and energy intake for synthesis. Therefore, prealbumin is mainly used to assess the nutritional status as well as the hepatic synthesis in acute liver disease. Decreased values of prealbumin are also found during an acute phase response and estrogen administration. Increased prealbumin levels are found during glucocorticosteroid intake and malignancies such as Hodgkin's disease.

Various methods have been described for the measurement of prealbumin. The most commonly used are turbidimetry, nephelometry, and radial immunodiffusion.

Test principle

Immunoturbidimetric assay

Human prealbumin forms a precipitate with a specific antiserum which is determined turbidimetrically at 340 nm.

Reagents - working solutions

- R1** Accelerator
Polyethylene glycol (PEG) 50 g/L, in phosphate buffer; preservative
- SR** Anti-prealbumin T antiserum (rabbit) specific for human prealbumin
> 0.25 g/L in phosphate buffer; preservative

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

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

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

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C See expiration date on **cobas c** pack label

On-board in use at 10-15 °C 8 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

Plasma: Li-heparin and K₂-EDTA plasma

The use of Li-heparin plasma may lead to approximately 5 % lower values.

The use of K₂-EDTA plasma may lead to approximately 6 % lower values.

Samples and controls are automatically prediluted 1:21 (1+20) with NaCl solution by the instrument.

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.

See the limitations and interferences section for details about possible sample interferences.

Stability: ⁴	3 days at 20-25 °C
	6 months at 4-8 °C
	1 year at -20 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

NaCl Diluent 9 %, Cat. No. 20756350 322, system-ID 07 5635 0 for automatic sample and standard serial dilutions. NaCl Diluent 9 % is placed in its predefined rack position and is stable for 4 weeks on-board COBAS INTEGRA 400 plus analyzer.

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**Test definition**

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	D-R1-S-SR
Reaction direction	Increase
Wavelength A	340 nm
Calc. first/last	33/55
Typical prozone effect	> 14.0 g/L (> 255 µmol/L or > 1400 mg/dL)
Antigen excess check	No
Predilution factor	21
Unit	g/L

Pipetting parameters

		Diluent (H ₂ O)
R1	90 µL	
Sample	25 µL	5 µL
SR	10 µL	5 µL
Total volume	135 µL	

Calibration

Calibrator	C.f.a.s. PAC
Calibrator dilution ratio	1:5.5, 1:7.5, 1:9.5, 1:18, 1:40, 1:120, performed automatically by the instrument
Calibration mode	Logit/log 5
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Enter the assigned lot-specific prealbumin value of the undiluted calibrator indicated in the package insert for C.f.a.s. PAC.

Traceability: This method has been standardized against the certified reference material in human serum of the IRMM (Institute for Reference Materials and Measurements) ERM-DA470k/IFCC.

Quality control

Reference range	PreciControl ClinChem Multi 1
Pathological range	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 400 plus analyzer automatically calculates the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help.

Conversion factors: ⁵	$\text{g/L} \times 18.2 = \mu\text{mol/L}$
	$\text{g/L} \times 100 = \text{mg/dL}$
	$\text{mg/dL} \times 0.182 = \mu\text{mol/L}$

Limitations - interference

Criterion: Recovery within $\pm 10\%$ of initial value

Icterus:⁶ No significant interference.

Hemolysis:⁶ No significant interference.

Lipemia (Intralipid):⁶ Lipemia interferes.

Rheumatoid factors: No significant interference up to a rheumatoid factors level of 200 IU/mL.

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

Exception: Intralipid causes artificially high prealbumin results.

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**

0.06-1.35 g/L (1.09-24.6 µmol/L or 6.00-135 mg/dL) (typical measuring range)

The upper and lower limits of the measuring range depend on the actual calibrator value.

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

Determine samples having lower concentrations via the rerun function. For samples with lower concentrations, the rerun function reduces the sample predilution factor to 10.5. The results are automatically multiplied by the reduced predilution factor.

Lower limits of measurement

Lower detection limit of the test:
0.03 g/L (0.55 µmol/L or 3 mg/dL)

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 = 30).

Expected values^{10,11}

Adults: 0.2-0.4 g/L (3.64-7.28 µmol/L or 20.0-40.0 mg/dL)

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

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 and intermediate precision (1 aliquot per run, 2 runs per day, 20 days). The following results were obtained:

	Level 1	Level 2
Mean	0.10 g/L (1.82 µmol/L or 10.0 mg/dL)	0.28 g/L (5.10 µmol/L or 28.0 mg/dL)
CV repeatability	4.7 %	2.3 %
CV intermediate precision	4.9 %	3.4 %

Method comparison

Prealbumin values for human serum samples obtained on a COBAS INTEGRA 400 analyzer using the COBAS INTEGRA Prealbumin reagent (x) were compared with those determined using the same reagent on a COBAS INTEGRA 800 analyzer (y) and using the Tina-quant Prealbumin reagent on a Roche/Hitachi 917 analyzer (y).

COBAS INTEGRA 800 analyzer	Sample size (n) = 77
Passing/Bablok ¹²	Linear regression
$y = 1.03x - 0.006 \text{ g/L}$	$y = 1.03x - 0.002 \text{ g/L}$
$\tau = 0.9491$	$r = 0.9947$
SD (md 95) = 0.018	$Sy.x = 0.008$

The sample concentrations were between 0.06 and 0.56 g/L (1.09 and 10.2 µmol/L or 6.00 and 56.0 mg/dL).

Roche/Hitachi 917 analyzer	Sample size (n) = 69
Passing/Bablok ¹²	Linear regression

Prealbumin - Application for C.f.a.s. PAC

$$y = 0.94x - 0.005 \text{ g/L}$$

$$\tau = 0.8858$$

$$\text{SD (md 95)} = 0.025$$

$$y = 0.90x + 0.003 \text{ g/L}$$

$$r = 0.9862$$

$$\text{Sy.x} = 0.011$$

The sample concentrations were between 0.07 and 0.54 g/L (1.27 and 9.83 $\mu\text{mol/L}$ or 7.00 and 54.0 mg/dL).

References

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- 5 Young DS, Huth EJ. SI Units For Clinical Measurement. American College of Physicians 1998.
- 6 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.
- 7 Breuer J. Report on the Symposium "Drug Effects in Clinical Chemistry Methods". Eur J Clin Chem Clin Biochem 1996;34:385-386.
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- 9 Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007;45(9):1240-1243.
- 10 Schumann G, Dati F. Vorläufige Referenzbereiche für 14 Proteine im Serum (für Erwachsene) nach Standardisierung immunchemischer Methoden unter Bezug auf das internationale Referenzmaterial CRM 470. Lab Med 1995;19:401-403.
- 11 Consensus values of the Deutsche Gesellschaft für Laboratoriumsmedizin, the Deutsche Gesellschaft für Klinische Chemie and the Verband der Diagnostica-Industrie e.V. (VDGH). DG Klinische Chemie Mitteilungen 1995;26:119-122.
- 12 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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT

Contents of kit



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

+800 5505 6606

