

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
20750948 322	Antistreptolysin O (100 tests)	System-ID 07 5094 8 COBAS INTEGRA 400 plus COBAS INTEGRA 800
03555941 190	C.f.a.s. PAC (3 × 1 mL)	System-ID 07 6810 3
10557897 122	Precinorm Protein (3 × 1 mL)	System-ID 07 9105 9
10557897 160	Precinorm Protein (3 × 1 mL, for USA)	System-ID 07 9105 9
11333127 122	Precipath Protein (3 × 1 mL)	System-ID 07 9106 7
11333127 160	Precipath Protein (3 × 1 mL, for USA)	System-ID 07 9106 7
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
20756350 322	NaCl Diluent 9 % (6 × 22 mL)	System-ID 07 5635 0

English

System information

Test ASO2, test ID 0-664 (application for C.f.a.s. PAC)

Intended use

In vitro test for the quantitative immunological determination of human antistreptolysin O in serum on COBAS INTEGRA systems.

Summary^{1,2,3}

Group A streptococci cause different infections: skin diseases or angina tonsillaris that may be followed by glomerulonephritis, acute endocarditis, Sydenham's Chorea, and acute rheumatic fever, when the upper respiratory tract is infected. These infections can later lead to damage of the heart or the kidneys. Early diagnosis, efficient treatment and monitoring of the patient can reduce these risks. Several metabolites of β-hemolyzing streptococci are exogenous toxins for the human body, e.g. NAD-glycohydrolase, streptodornases (ADNases), and hyaluronidase which induce immunological defense reactions. The most clinically important antibody reactions are found against streptolysin O, streptococcal-deoxyribonuclease and streptococcal-hyaluronidase.

Immunological testing for specific antibodies provides useful information about the degree of the streptococcal infection and the course of disease. The determination of the level of antistreptolysin O antibodies (ASO) is the most widely used. Eighty-five percent of patients with acute rheumatic fever show increased ASO levels. ASO levels should be monitored several times at weekly intervals to obtain useful data. The titer development can indicate either a successful antibiotic treatment or the persisting antigen stimulus even if the clinical signs of the infection have already disappeared.

Test principle^{4,5,6,7}

Immunoturbidimetric assay.

Human antistreptolysin O antibodies agglutinate with latex particles coated with streptolysin O antigens. The precipitate is determined turbidimetrically at 552 nm.

Reagents - working solutions

- R1** Glycine buffer with bovine serum albumin; stabilizer
- R2** Latex particles coated with streptolysin O antigens in glycine buffer with bovine serum albumin; stabilizer

R1 is in position A and R2 is in position B.

Precautions and warnings

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

For USA: For prescription use only.

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 12 weeks

COBAS INTEGRA 800 system

On-board in use at 8 °C 12 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

Avoid repeated freezing and thawing.

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:⁸ 2 days at 20-25 °C
8 days at 4-8 °C
6 months at -20 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

NaCl Diluent 9 %, Cat. No. 20756350322, system-ID 07 5635 0 for automatic postdilution. NaCl Diluent 9 % is placed in its predefined rack position and is stable for 4 weeks on-board COBAS INTEGRA 400 plus/800 analyzers.

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

COBAS INTEGRA 400 plus test definition

Measuring mode Absorbance
Abs. calculation mode Kinetic

Reaction mode	R1-R2-S
Reaction direction	Increase
Wavelength A	552 nm
Calc. first/last	34/65
Typical prozone effect	> 2400 IU/mL
Antigen excess check	No
Predilution factor	No
Unit	IU/mL

Pipetting parameters

		Diluent (H ₂ O)
R1	93 µL	
R2	57 µL	7 µL
Sample	2 µL	20 µL
Total volume	179 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-R2-S
Reaction direction	Increase
Wavelength A	552 nm
Calc. first/last	T ₀ /70
Typical prozone effect	> 2400 IU/mL
Antigen excess check	No
Predilution factor	No
Unit	IU/mL

Pipetting parameters

		Diluent (H ₂ O)
R1	93 µL	
R2	57 µL	7 µL
Sample	2 µL	20 µL
Total volume	179 µL	

Calibration

Calibrator	C.f.a.s. PAC
	Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Traceability: This method has been standardized against an internal standard preparation.

Quality control

Reference range	Precinorm Protein or PreciControl ClinChem Multi 1
Pathological range	Precipath Protein 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 concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Limitations - interference

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

Icterus:⁹ No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:⁹ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):⁹ No significant interference up to an L index of 1500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference up to 1200 IU/mL.

Therapeutic drug interference was tested according to the recommendations of the VDGH^{a)}. No interferences were found.

In very rare cases, monoclonal gammopathy (multiple myeloma, Morbus Waldenström) can lead to an excessive overexpression of streptolysin O-specific antibody, which leads to strongly elevated ASO results.

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

a) Verband der Diagnostica und Diagnostica Geräte Hersteller. Refer to section 1 / Introduction of this Method Manual for a list of drugs tested and their concentrations.

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**

20-800 IU/mL

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement

Lower detection limit of the test:

20 IU/mL

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 values²

Adults: up to 200 IU/mL

Children: up to 150 IU/mL

Roche has not evaluated reference ranges in a pediatric population.

In some cases of streptococcal infections, particularly skin infections, there may be no observable increase in the ASO titer. As antistreptolysin O is only detectable in 85 % of all patients with rheumatic fever, the determination of antistreptococcal deoxyribonuclease antibodies and antistreptococcal hyaluronidase antibodies may also be necessary.²

An appropriate evaluation of streptococcal infection is possible only if the test is repeated after one or two weeks.¹⁰ Both clinical and laboratory findings should be correlated in reaching a diagnosis.

ASO levels are age dependent and change with geographic location and with the local frequency of streptococcal infections.^{11,12}

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 (2 aliquots per run, 2 runs per day, 20 days). The following results were obtained:

	Level 1	Level 2
Mean	186 IU/mL	312 IU/mL
CV repeatability	1.1 %	1.3 %
CV intermediate precision	4.1 %	5.3 %

Method comparison

Antistreptolysin O values for human serum samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Antistreptolysin O reagent (x) were compared with those determined using the corresponding reagent on a COBAS INTEGRA 400 analyzer (y). Sample size (n) = 79

COBAS INTEGRA 400 analyzer

Passing/Bablok ¹³	Linear regression
$y = 0.96x + 4.99$ IU/mL	$y = 0.97x + 3.62$ IU/mL
$r = 0.9435$	$r = 0.9970$
SD (md 95) = 8.56	$Sy.x = 3.96$

The sample concentrations were between 21.4 and 338 IU/mL.

Antistreptolysin O values for human serum samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Antistreptolysin O reagent (y) were compared with those determined using the Tina-quant ASLO reagent on a Roche/Hitachi 917 analyzer (x). Sample size (n) = 76

Roche/Hitachi 917 analyzer

Passing/Bablok ¹³	Linear regression
$y = 1.01x - 0.54$ IU/mL	$y = 1.00x - 3.09$ IU/mL
$r = 0.8372$	$r = 0.9625$
SD (md 95) = 32.73	$Sy.x = 13.82$

The sample concentrations were between 21.3 and 343 IU/mL.

References




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- 12 Renneberg J. Age related variations in anti-streptococcal antibody levels. Eur J Clin Microbiol Infect Dis 1989;8:792-795.
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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:

	Contents of kit
	Volume after reconstitution or mixing
	Global Trade Item Number

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