ASLOT

cobas®

Tina-quant Antistreptolysin O

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04489403 190	Tina-quant Antistreptolysin O, 150 tests	System-ID 07 6865 0	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
03555941 190	C.f.a.s. PAC (3 x 1 mL)	Code 589	
10557897 122	Precinorm Protein (3 x 1 mL)	Code 302	
11333127 122	Precipath Protein (3 x 1 mL)	Code 303	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

ASLOT: ACN 037

For **cobas c** 502 analyzer:

ASLOT: ACN 8037

Intended use

In vitro test for the quantitative immunological determination of antistreptolysin O in human serum and plasma on Roche/Hitachi **cobas c** 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. 85 % 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.

Reagents - working solutions

R1 TRIS buffer: 170 mmol/L, pH 8.2

R2 Borate buffer: 10 mmol/L, pH 8.2; latex particles coated with streptolysin O: 2 mL/L

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

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Mix **cobas c** pack well before placing on the analyzer.

Carefully invert reagent container several times prior to use to ensure that the reagent components are mixed.

Storage and stability

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Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Diluent NaCl 9 %

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	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.
Plasma: Li-heparin and K_2-EDTA plasma

The use of plasma can lead to a decrease in antistreptolysin O activity of approximately 7 %. For samples with an activity below 100 IU/mL the recovery in plasma can be either decreased or increased in comparison to serum.

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)

- See "Order information" section
- General laboratory equipment

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.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum

cobas c 311 **test definition**

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Tina-quant Antistreptolysin O

Assay type	2-Point End		
Reaction time / Assay points	10 / 10-19		
Wavelength (sub/main)	–/700 nm		
Reaction direction	Increase		
Unit	IU/mL		
Reagent pipetting		Diluent (H_2O)	
R1	124 µL	–	
R2	124 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	168 µL
Increased	2 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 16-28		
Wavelength (sub/main)	–/700 nm		
Reaction direction	Increase		
Unit	IU/mL		
Reagent pipetting		Diluent (H_2O)	
R1	124 µL	–	
R2	124 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	168 µL
Increased	2 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End		
Reaction time / Assay points	10 / 16-28		
Wavelength (sub/main)	–/700 nm		
Reaction direction	Increase		
Unit	IU/mL		
Reagent pipetting		Diluent (H_2O)	
R1	124 µL	–	
R2	124 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	4 µL	15 µL	168 µL
Increased	4 µL	–	–

Calibration

Calibrators	S1: H_2O
	S2: C.f.a.s. PAC
Calibration mode	Linear
Calibration frequency	2-point calibration • after reagent lot change • as required following quality control procedures

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

Quality control

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

Roche/Hitachi **cobas c** systems automatically calculate the analyte concentration of each sample.

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at an antistreptolysin O activity of 200 IU/mL.

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 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors up to 180 IU/mL do not interfere.

High dose hook-effect: No false result occurs up to an antistreptolysin O concentration of 4000 IU/mL.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[10,11]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[12]

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 Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/Multiclean/SCCS or the NaOHD/SMS/SmpCln1+2/SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is not required.

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

Limits and ranges

Measuring range

20-600 IU/mL

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:6.1 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 6.1.

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 the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

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Expected values[2]

Adults	up to 200 IU/mL
Children	up to 150 IU/mL

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 anti-streptococcal deoxyribonuclease antibodies and anti-streptococcal 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.[13] 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.[14,15]

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 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 (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

Repeatability	*Mean*	*SD*	*CV*
	IU/mL	*IU/mL*	*%*
Precinorm Protein	145	2	1.6
Precipath Protein	263	3	1.1
Human serum 1	115	1	1.1
Human serum 2	246	2	0.8
Intermediate precision	*Mean*	*SD*	*CV*
	IU/mL	*IU/mL*	*%*
Precinorm Protein	151	4	2.6
Precipath Protein	277	6	2.2
Human serum 3	123	3	2.5
Human serum 4	256	4	1.7

Method comparison

Antistreptolysin O values for human serum samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Sample size (n) = 88

Passing/Bablok[16]	Linear regression
y = 0.987x - 0.268 IU/mL	y = 0.978x + 1.44 IU/mL
τ = 0.981	r = 0.999

The sample concentrations were between 28.8 and 594 IU/mL.

References

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15 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.

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

CE

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Roche