


REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
08057885190*	08057885500	Tina-quant IgA Gen.2 (300 tests)	System-ID 2072 001	cobas c 303, cobas c 503, cobas c 703
08057885214*	08057885500	Tina-quant IgA Gen.2 (300 tests)	System-ID 2072 001	cobas c 303, cobas c 503, cobas c 703

Materials required (but not provided):

11355279216	Calibrator f.a.s. Proteins (5 x 1 mL)	Code 20656	
03121291122	Precipath PUC (4 x 3 mL)	Code 20241	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

* Some kits shown may not be available in all countries.

English

System information

IGA2: ACN 20720 (Standard application)

IGA2-P: ACN 20721 (Sensitive application)

Intended use

In vitro test for the quantitative determination of IgA in human serum and plasma on **cobas c** systems.

Summary

Immunoglobulin A (IgA) measurements performed with this assay in human serum and plasma are used as an aid in diagnosis of clinical conditions associated with increased IgA levels, such as infections and inflammatory diseases, and with decreased IgA levels, such as IgA deficiencies.

Immunoglobulins (Ig) or antibodies are glycoproteins produced by plasma cells to protect the human body against invading organisms and agents. Human immunoglobulin molecules consist of 1 or more basic units built of 2 identical heavy (H) chains and 2 identical light (L) chains. Each of the 4 chains has 1 variable and 1 (L chain) or 3 to 4 (H chain) constant domains. Diversity in the variable domains is generated by somatic recombination and mutation of the immunoglobulin genes. Individual plasma cells or clonally expanded cells are committed to synthesis of a single variable domain sequence for H and L chains. The variable domains contain the antigen binding regions and the constant domains of the heavy chains contain sites for complement activation and receptor binding. Cleavage of immunoglobulins with pepsin or papain can yield antigen binding fragments (Fab) and constant region fragments (Fc). The Fab portion recognizes antigens in solution (e.g. toxins) and antigens associated with microorganisms (e.g. bacteria, viruses). The Fc portion interacts with cells of the immune system and complement factors. Antigen binding initiates the direct neutralization of toxins, the sensitization of immunocompetent cells, the reduction of viral infectivity, or the development of an inflammatory reaction. Variations in the Fc region result in the classes and subclasses into which immunoglobulins are grouped: IgM, IgG (4 subclasses), IgA (2 subclasses), IgD, and IgE, respectively. As a normal result of infections all immunoglobulin classes increase in serum.¹

Immunoglobulin A (IgA) has a molecular weight of 160 kDa and usually accounts for about 10 to 15 % of the total circulating immunoglobulins. IgA exists in monomeric, dimeric and polymeric forms. In CSF and blood the monomeric form is predominant. In bodily secretions, such as saliva, sweat, mucosa, milk and colostrum, IgA exists predominantly in dimeric form. IgA is an important component of mucosal immunity; in colostrum and milk it may aid in protection of neonates from intestinal infection, while the exact role of IgA in serum is not clear.¹ Due to the slow onset of IgA synthesis, the IgA concentration in serum of infants is lower than in adults.^{1,2,3}

Increases of polyclonal immunoglobulins (including IgA) are the normal response to infections. IgA is increased in skin, gut, respiratory, and renal infections.¹ IgA increases may additionally be associated with chronic inflammatory conditions, including cirrhosis, rheumatoid arthritis, systemic lupus erythematosus and Wiscott-Aldrich syndrome.^{1,4,5,6,7,8,9} Monoclonal

IgA increases in diseases where neoplastic proliferation of secretory B cells is present, such as multiple myeloma.¹

Decreased levels of IgA can be due to reduced synthesis, increased loss, hypercatabolism or a combination of causes. IgA deficiencies occur in congenital and acquired immunodeficiency syndromes, inherited deficiencies, hematologic malignancies.^{1,10,11}

This assay is based on the principle of immunological agglutination. In addition to the standard application (test IGA-2), there is a sensitive application (test IGAP2) designed for the quantitative determination of low IgA concentrations, e.g. in pediatric samples.

It is known that the so-called paraproteins secreted in monoclonal gammopathies (monoclonal immunoglobulinemia) may differ from the respective immunoglobulins of polyclonal origin by amino acid composition and size.¹ This may impair the binding to antibody and hence impair accurate quantitation.

Test principle

Immunoturbidimetric assay

Anti-IgA antibodies react with antigen in the sample to form an antigen/antibody complex. Following agglutination, this is measured turbidimetrically. Addition of PEG allows the reaction to progress rapidly to the end point, increases sensitivity, and reduces the risk of samples containing excess antigen producing false negative results.

Reagents - working solutions

R1 TRIS buffer: 20 mmol/L, pH 8.0; NaCl: 200 mmol/L; polyethylene glycol: 3.6 %; preservative; stabilizers

R3 Anti-human IgA antibody (goat): dependent on titer; TRIS buffer: 20 mmol/L, pH 8.0; NaCl: 150 mmol/L; preservative

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for laboratory 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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Danger

H318 Causes serious eye damage.

Prevention:

P280 Wear eye protection/ face protection.

Response:

P305 + P351 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
 + P338
 + P310 Continue rinsing. Immediately call a POISON CENTER/ doctor.

Hazardous components:

- Polyoxyethylene alkyl ether

Product safety labeling follows EU GHS guidance.
 Contact phone: all countries: +49-621-7590

Reagent handling

Ready for use

Storage and stabilityShelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 26 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.

Standard application (IGA2)Serum
Plasma: Li-heparin and K₂-EDTA plasma**Sensitive application (IGA2-P)**Serum
Plasma: Li-heparin and K₂-EDTA 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.

Partially filled K₂-EDTA plasma tubes can cause incorrect results.

Centrifuge samples containing precipitates before performing the assay.

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

Stability:¹²
 8 months at 15-25 °C
 8 months at 2-8 °C
 8 months at -20 °C (± 5 °C)

Freeze only once.

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 and plasma**Standard application (IGA2)****Test definition**

Reporting time 10 min
 Wavelength (sub/main) 700/340 nm
 Reagent pipetting Diluent (H₂O)
 R1 77 µL –
 R3 24 µL –

	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	3.2 µL	5 µL	100 µL
Decreased	2 µL	1.1 µL	115 µL
Increased	4.6 µL	25 µL	50 µL

Sensitive application (IGA2-P)**Test definition**

Reporting time 10 min
 Wavelength (sub/main) 700/340 nm
 Reagent pipetting Diluent (H₂O)
 R1 77 µL –
 R3 24 µL –

	Sample	Sample dilution	
		Sample	Diluent (NaCl)
Normal	6.4 µL	9 µL	75 µL
Decreased	6.4 µL	4.8 µL	130 µL
Increased	6.4 µL	22 µL	60 µL

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration**Standard application (IGA2)**Calibrators S1: H₂O
S2-S6: C.f.a.s. Proteins

Calibration mode Non-linear

Calibration frequency Automatic full calibration

- after reagent lot change

Full calibration

- as required following quality control procedures

Sensitive application (IGA2-P)Calibrators S1: H₂O
S2-S6: C.f.a.s. Proteins

Calibration mode Non-linear

Calibration frequency Full calibration

- after reagent lot change

- as required following quality control procedures

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

Traceability: This method has been standardized against the reference preparation of the IRMM (Institute for Reference Materials and Measurements) BCR470/CRM470 (RPPHS - Reference Preparation for Proteins in Human Serum).¹³

Quality control

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

Standard application (IGA2): PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2

Sensitive application (IGA2-P): Precipath PUC, PreciControl ClinChem Multi 1

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 26 weeks. 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 c systems automatically calculate the analyte concentration of each sample in the unit g/L ($\mu\text{mol/L}$, mg/dL, mg/L).

Conversion factors:

- $\text{g/L} \times 6.25 = \mu\text{mol/L}$
- $\text{g/L} \times 100 = \text{mg/dL}$
- $\text{g/L} \times 1000 = \text{mg/L}$

Limitations - interference

Standard application (IGA2):

Criterion: Recovery within ± 0.07 g/L of initial values of samples ≤ 0.7 g/L and within $\pm 10\%$ for samples > 0.7 g/L.

Icterus:¹⁴ No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 $\mu\text{mol/L}$ or 60 mg/dL).

Hemolysis:¹⁴ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 $\mu\text{mol/L}$ or 1000 mg/dL).

Lipemia (Intralipid):¹⁴ No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 1200 IU/mL.

High dose hook-effect: No false result up to an IgA concentration of 100 g/L occurs due to an antigen excess within polyclonal specimens.

There is no cross-reaction between IgA and IgG or IgM under the assay conditions.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{15,16}

Sensitive application (IGA2-P):

Criterion: Recovery within ± 0.04 g/L of initial values of samples ≤ 0.4 g/L and within $\pm 10\%$ for samples > 0.4 g/L.

Icterus:¹⁴ No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 $\mu\text{mol/L}$ or 60 mg/dL).

Hemolysis:¹⁴ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 $\mu\text{mol/L}$ or 1000 mg/dL).

Lipemia (Intralipid):¹⁴ No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 500 IU/mL.

High dose hook-effect: No false result up to an IgA concentration of 20 g/L occurs due to an antigen excess within polyclonal specimens.

There is no cross-reaction between IgA and IgG or IgM under the assay conditions.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{15,16}

As with other turbidimetric or nephelometric procedures, this test may not provide accurate results in patients with monoclonal gammopathy, due to

individual sample characteristics which can be assessed by electrophoresis.¹⁷

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 c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Limits and ranges

Measuring range

Standard application (IGA2):

0.50-8.00 g/L (3.13-50 $\mu\text{mol/L}$)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:8 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 8.

Determine samples having lower concentrations via the rerun function. For samples with lower concentrations, the rerun function increases the sample volume by a factor of 10. The results are automatically divided by this factor.

Sensitive application (IGA2-P):

0.1-4.00 g/L (0.63-25 $\mu\text{mol/L}$)

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 increases the sample volume by a factor of 2.5. The results are automatically divided by this factor.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Standard application (IGA2)

Limit of Blank = 0.05 g/L (0.31 $\mu\text{mol/L}$)

Limit of Detection = 0.05 g/L (0.31 $\mu\text{mol/L}$)

Limit of Quantitation = 0.50 g/L (3.13 $\mu\text{mol/L}$)

Sensitive application (IGA2-P)

Limit of Blank = 0.04 g/L (0.25 $\mu\text{mol/L}$)

Limit of Detection = 0.04 g/L (0.25 $\mu\text{mol/L}$)

Limit of Quantitation = 0.1 g/L (0.63 $\mu\text{mol/L}$)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from $n \geq 60$ measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 20 %. It has been determined using low concentration IgA samples.

Expected values

Reference values according to CRM 470 Protein Standardization:^{18,19}

Adults 0.7-4 g/L

Children and juveniles

0 - < 1 year female	< 0.14 g/L
0 - < 1 year male	< 0.14 g/L
1 - < 3 years female	< 0.80 g/L
1 - < 3 years male	< 0.80 g/L
3 - < 6 years female	0.11-1.42 g/L
3 - < 6 years male	0.11-1.42 g/L
6 - < 14 years female	0.34-2.20 g/L
6 - < 14 years male	0.34-2.22 g/L
14 - < 19 years female	0.40-2.93 g/L
14 - < 19 years male	0.40-2.93 g/L

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. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Standard application (IGA2)

Repeatability	Mean g/L	SD g/L	CV %
PCCC1 ^{a)}	1.49	0.00838	0.6
PCCC2 ^{b)}	2.12	0.0114	0.5
Human serum 1	0.671	0.00643	1.0
Human serum 2	1.10	0.00748	0.7
Human serum 3	2.06	0.0108	0.5
Human serum 4	4.14	0.0212	0.5
Human serum 5	7.32	0.0416	0.6

Intermediate precision	Mean g/L	SD g/L	CV %
PCCC1 ^{a)}	1.49	0.0149	1.0
PCCC2 ^{b)}	2.12	0.0162	0.8
Human serum 1	0.672	0.00794	1.2
Human serum 2	1.10	0.0103	0.9
Human serum 3	2.06	0.0271	1.3
Human serum 4	4.16	0.0270	0.6
Human serum 5	7.25	0.0510	0.7

Sensitive application (IGA2-P)

Repeatability	Mean g/L	SD g/L	CV %
PCCC1 ^{a)}	1.49	0.00809	0.5
Precipath PUC	0.234	0.00177	0.8
Human serum 1	0.135	0.00152	1.1
Human serum 2	0.451	0.00277	0.6
Human serum 3	1.05	0.00627	0.6
Human serum 4	2.09	0.0117	0.6

Human serum 5	3.71	0.0199	0.5
<i>Intermediate precision</i>	<i>Mean g/L</i>	<i>SD g/L</i>	<i>CV %</i>
PCCC1 ^{a)}	1.49	0.0174	1.2
Precipath PUC	0.234	0.00707	3.0
Human serum 1	0.135	0.00235	1.7
Human serum 2	0.451	0.00394	0.9
Human serum 3	1.05	0.00810	0.8
Human serum 4	2.09	0.0148	0.7
Human serum 5	3.70	0.0240	0.7

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

Method comparison

IgA values for human serum and plasma samples obtained on a **cobas c** 503 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Standard application (IGA2):

Sample size (n) = 69

Passing/Bablok²⁰

y = 0.974x + 0.0366 g/L

τ = 0.940

Linear regression

y = 0.985x + 0.0211 g/L

r = 0.992

The sample concentrations were between 0.620 and 7.99 g/L.

Sensitive application (IGA2-P):

Sample size (n) = 73

Passing/Bablok²⁰

y = 0.989x + 0.00586 g/L

τ = 0.979

Linear regression

y = 0.995x - 0.0117 g/L

r = 0.999

The sample concentrations were between 0.169 and 3.80 g/L.

IgA values for human serum and plasma samples obtained on a **cobas c** 303 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Standard application (IGA2):

Sample size (n) = 72

Passing/Bablok²⁰

y = 0.997x - 0.0188 g/L

τ = 0.978

Linear regression

y = 0.997x - 0.0134 g/L

r = 1.000

The sample concentrations were between 0.610 and 7.74 g/L.

Sensitive application (IGA2-P):

Sample size (n) = 73

Passing/Bablok²⁰

y = 1.01x - 0.0272 g/L

τ = 0.986

Linear regression

y = 1.01x - 0.0282 g/L

r = 0.999

The sample concentrations were between 0.150 and 3.95 g/L.

IgA values for human serum and plasma samples obtained on a **cobas c** 703 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Standard application (IGA2):

Sample size (n) = 85

Passing/Bablok²⁰

Linear regression

$$y = 1.004x - 0.0377 \text{ g/L} \quad y = 1.007x - 0.0402 \text{ g/L}$$

$$\tau = 0.990 \quad r = 1.000$$

The sample concentrations were between 0.562 and 7.51 g/L.

Sensitive application (IGA2-P):

Sample size (n) = 98

Passing/Bablok²⁰ Linear regression

$$y = 1.046x - 0.0410 \text{ g/L} \quad y = 1.037x - 0.0208 \text{ g/L}$$

$$\tau = 0.978 \quad r = 0.998$$

The sample concentrations were between 0.109 and 3.98 g/L.

References

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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.

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:

CONTENT

Contents of kit



Volume for reconstitution

GTIN

Global Trade Item Number

Rx only

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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CE 0123



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