IGM-2

cobas®

Tina-quant IgM Gen.2

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03507190 190	Tina-quant IgM Gen.2 150 tests	System-ID 07 6788 3	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
11355279 216	Calibrator f.a.s. Proteins (5 x 1 mL)	Code 656	
11355279 160	Calibrator f.a.s. Proteins (5 x 1 mL, for USA)	Code 656	
10557897 122	Precinorm Protein (3 x 1 mL)	Code 302	
10557897 160	Precinorm Protein (3 x 1 mL, for USA)	Code 302	
11333127 122	Precipath Protein (3 x 1 mL)	Code 303	
11333127 160	Precipath Protein (3 x 1 mL, for USA)	Code 303	
10171743 122	Precinorm U (20 x 5 mL)	Code 300	
03121291 122	Precipath PUC (4 x 3 mL)	Code 241	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL, for USA)	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	
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL, for USA)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

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

IGM-2: ACN 465 (Standard application)

IGMP2: ACN 274 (Sensitive application)

For **cobas c** 502 analyzer:

IGM-2: ACN 8465 (Standard application)

IGMP2: ACN 8274 (Sensitive application)

Intended use

In vitro test for the quantitative determination of IgM in human serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5,6,7,8,9,10,11,12]

IgM normally consists of 10 heavy µ-chains and 10 kappa or lambda type light chains which are always identical within a molecule. There is also a J-chain linking all the µ-chains together, so that simply speaking, IgM has a pentameric structure when compared to that of IgG. IgM is the largest immunoglobulin molecule (MW = 970000), but makes up only 6 % of the plasma immunoglobulins.

IgM is the first specific antibody to appear in the serum after infection. It is capable of activating complement, thus helping to kill bacteria. After the infection has subsided, IgM levels sink at a relatively rapid rate compared to IgG. This fact is used to advantage in the differential diagnosis of acute and chronic infections by comparing specific IgM and IgG titers. If IgM is prevalent the infection is acute, whereas if IgG predominates the infection is chronic (e.g. rubella, viral hepatitis). Increased polyclonal IgM levels are found in viral, bacterial, and parasitic infections, liver diseases, rheumatoid arthritis, scleroderma, cystic fibrosis and heroin addiction. Monoclonal IgM is increased in Waldenström's macroglobulinemia. Increased loss of IgM is found in protein-losing enteropathies and in burns. Decreased synthesis of IgM occurs in congenital and acquired immunodeficiency syndromes. Due to the slow onset of IgM synthesis, the IgM concentration in serum from infants is lower than in that from adults.

Use of specific antibodies for quantitation of serum proteins has become a valuable diagnostic tool. Light-scattering properties of antigen/antibody aggregates were first observed by Pope and Healey in 1938, and later confirmed by Gitlin and Edelhoch. Ritchie employed turbidimetric measurements to quantitate specific proteins. Quantitation of immunoglobulins can also be done using nephelometric techniques. Polymeric enhancement with polyethylene glycol (PEG) to improve sensitivity and increase the rate of antigen/antibody complex formation has been described by Lizana and Hellsing.

The Roche IgM assay is based on the principle of immunological agglutination.

In addition to the standard application (test IGM-2), there is a sensitive application (test IGMP2) designed for the quantitative determination of low IgM 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. This may impair the binding to antibody and hence impair accurate quantitation.

Test principle

Immunoturbidimetric assay.

Anti-IgM 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

R2 Anti-human IgM antibody (goat): dependent on titer; TRIS buffer: 20 mmol/L, pH 8.0; NaCl: 150 mmol/L; preservative

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.

For USA: For prescription use only.

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.

IGM-2

Tina-quant IgM Gen.2

Response:

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

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling

Ready for use

Storage and stability

IGM-2

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.

Standard application (IGM-2):

Serum.
Plasma: Li-heparin and K_2-EDTA plasma

Sensitive application (IGMP2):

Serum.
Plasma: Li-heparin 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:[13]	2 months at 15-25 °C
	4 months at 2-8 °C
	6 months at (-15)-(-25) °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 and plasma

Standard application (IGM-2)

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 6-31
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	g/L (µmol/L, mg/dL)
Reagent pipetting	Diluent (H_2O)
R1	120 µL –
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.5 µL	9 µL	180 µL
Decreased	3.6 µL	2 µL	180 µL
Increased	9.4 µL	20 µL	85 µL

cobas c 501/502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-46
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	g/L (µmol/L, mg/dL)
Reagent pipetting	Diluent (H_2O)
R1	120 µL –
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	7.5 µL	9 µL	180 µL
Decreased	3.6 µL	2 µL	180 µL
Increased	9.4 µL	20 µL	85 µL

Sensitive application (IGMP2)

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 6-31
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	g/L (µmol/L, mg/dL)
Reagent pipetting	Diluent (H_2O)
R1	120 µL –
R2	38 µL –

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	–	–
Decreased	8.7 µL	10 µL	95 µL
Increased	10 µL	–	–

cobas c 501/502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 10-46
Wavelength (sub/main)	700/340 nm
Reaction direction	Increase
Units	g/L (µmol/L, mg/dL)
Reagent pipetting	Diluent (H_2O)
R1	120 µL –

R2	38 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2.5 µL	–	–
Decreased	8.7 µL	10 µL	95 µL
Increased	10 µL	–	–

Calibration

Standard application (IGM-2)

Calibrators: S1: H_2O

S2-S6: C.f.a.s. Proteins

Multiply the lot-specific C.f.a.s. Proteins calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:

S2: 0.150 S5: 1.00

S3: 0.300 S6: 4.57

S4: 0.500

Calibration mode: RCM

Calibration frequency: Full calibration
- after reagent lot change
- as required following quality control procedures

Sensitive application (IGMP2)

Calibrators: S1: H_2O

S2-S6: C.f.a.s. Proteins

Multiply the lot-specific C.f.a.s. Proteins calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:

S2: 0.0250 S5: 0.250

S3: 0.0625 S6: 1.00

S4: 0.125

Calibration mode: RCM

Calibration frequency: Full calibration
- after reagent lot change
- as required following quality control procedures

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).[14]

Quality control

For quality control, use control materials as listed in the "Order information" section.

Standard application (IGM-2):	Precinorm Protein, Precipath Protein, Precinorm U, PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2
Sensitive application (IGMP2):	Precinorm Protein, Precipath PUC, PreciControl ClinChem Multi 1

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.

Conversion factors:	mg/dL x 0.01 = g/L	g/L x 1.03 = µmol/L
	g/L x 100 = mg/dL	µmol/L x 0.971 = g/L

Limitations - interference

Standard application (IGM-2):

Criterion: Recovery within ± 10 % of initial value at an IgM concentration of 0.4 g/L (0.41 µmol/L, 40 mg/dL).

Icterus:[15] No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[15] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[15] No significant interference up to an L index of 2000.

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

High dose hook-effect: No false result up to an IgM concentration of 100 g/L (103 µmol/L, 10000 mg/dL) occurs due to an antigen excess within polyclonal specimens.

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

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16,17]

Sensitive application (IGMP2):

Criterion: Recovery within ± 10 % of initial value at an IgM concentration of 0.2 g/L (0.21 µmol/L, 20 mg/dL).

Icterus:[15] No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[15] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[15] No significant interference up to an L index of 1700.

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

High dose hook-effect: No false result up to an IgM concentration of 30 g/L (31 µmol/L, 3000 mg/dL) occurs due to an antigen excess within polyclonal specimens.

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

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16,17]

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.[18]

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-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

Standard application (IGM-2):

0.25-6.50 g/L (0.26-6.70 µmol/L, 25.0-650 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:9 dilution. Results from

samples diluted using the rerun function are automatically multiplied by a factor of 9.

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 5. The results are automatically divided by this factor.

Sensitive application (IGMP2):

0.04-1.50 g/L (0.04-1.55 µmol/L, 4.0-155 mg/dL)

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 4. The results are automatically divided by this factor.

Lower limits of measurement

Lower detection limit of the test

Standard application (IGM-2):

0.05 g/L (0.05 µmol/L, 5.00 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 the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Sensitive application (IGMP2):

0.01 g/L (0.01 µmol/L, 1.00 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 the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Expected values

Reference values according to CRM 470 Protein Standardization:[19,20]

Adults	0.4-2.3 g/L	0.4-2.4 µmol/L	40-230 mg/dL
Children and juveniles			
0-1 year	0.00-1.45 g/L	0.00-1.49 µmol/L	0-145 mg/dL
1-3 years	0.19-1.46 g/L	0.19-1.50 µmol/L	19-146 mg/dL
4-6 years	0.24-2.10 g/L	0.25-2.16 µmol/L	24-210 mg/dL
7-9 years	0.31-2.08 g/L	0.32-2.14 µmol/L	31-208 mg/dL
10-11 years	0.31-1.79 g/L	0.32-1.84 µmol/L	31-179 mg/dL
12-13 years	0.35-2.39 g/L	0.36-2.46 µmol/L	35-239 mg/dL
14-15 years	0.15-1.88 g/L	0.15-1.94 µmol/L	15-188 mg/dL
16-19 years	0.23-2.59 g/L	0.24-2.67 µmol/L	23-259 mg/dL

Roche has not evaluated reference ranges in a pediatric population.

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:

Standard application (IGM-2):

Repeatability	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	0.75 (0.773, 75.0)	0.01 (0.010, 1.00)	1.6
Precipath Protein	1.36 (1.40, 136)	0.02 (0.02, 2)	1.3
Human serum 1	0.71 (0.731, 71.0)	0.01 (0.010, 1.00)	1.6
Human serum 2	0.97 (0.999, 97.0)	0.01 (0.010, 1.00)	0.9

Intermediate precision	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	0.745 (0.767, 74.5)	0.03 (0.031, 3.00)	3.8
Precipath Protein	1.34 (1.38, 134)	0.03 (0.03, 3)	2.0
Human serum 3	0.822 (0.847, 82.2)	0.02 (0.021, 2.00)	2.8
Human serum 4	1.31 (1.35, 131)	0.03 (0.03, 3)	1.9

Sensitive application (IGMP2):

Repeatability	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	0.75 (0.773, 75.0)	0.007 (0.007, 0.700)	0.9
Precipath PUC	0.20 (0.206, 20.0)	0.002 (0.002, 0.2)	0.9
Human serum 1	0.23 (0.237, 23.0)	0.005 (0.005, 0.5)	2.3
Human serum 2	0.75 (0.773, 75.0)	0.006 (0.006, 0.6)	0.8

Intermediate precision	*Mean*	*SD*	*CV*
	g/L (µmol/L, mg/dL)	*g/L (µmol/L, mg/dL)*	*%*
Precinorm Protein	0.74 (0.762, 74.0)	0.011 (0.011, 1.10)	1.5
Precipath PUC	0.20 (0.206, 20.0)	0.003 (0.003, 0.3)	1.8
Human serum 3	0.25 (0.258, 25.0)	0.004 (0.004, 0.4)	1.7
Human serum 4	0.86 (0.886, 86.0)	0.009 (0.009, 0.9)	1.1

Method comparison

IgM values for human serum and plasma 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).

Standard application (IGM-2):

Sample size (n) = 82

Passing/Bablok[21]	Linear regression
y = 1.003x + 0.007 g/L	y = 1.002x + 0.009 g/L
τ = 0.975	r = 0.999

The sample concentrations were between 0.275 and 4.94 g/L (0.283 and 5.09 µmol/L, 27.5 and 494 mg/dL).

Sensitive application (IGMP2):

Sample size (n) = 273

Passing/Bablok[21]	Linear regression
y = 1.000x - 0.003 g/L	y = 1.011x - 0.010 g/L
τ = 0.965	r = 0.998

The sample concentrations were between 0.049 and 1.44 g/L (0.050 and 1.48 µmol/L, 5 and 144 mg/dL).

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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

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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CE

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