IGM-2

cobas®

Tina-quant IgM Gen.2

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08057923190	08057923500	Tina-quant IgM Gen.2 (300 tests)	System-ID 2075 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	
10557897122	Precinorm Protein (3 x 1 mL)	Code 20302	
11333127122	Precipath Protein (3 x 1 mL)	Code 20303	
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	

English

System information

IGM2: ACN 20750 (Standard application)

IGM2-P: ACN 20751 (Sensitive application)

Intended use

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

Summary

Immunoglobulin M (IgM) measurements performed with this assay in human serum and plasma are used as an aid in diagnosis of clinical conditions associated with increased IgM levels, such as infection and inflammation, and with decreased IgM levels, such as IgM 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 M (IgM) is a high molecular weight (970 kDa) immunoglobulin and usually accounts for 5 to 10 % of the total circulating immunoglobulins. As a membrane receptor molecule it is monomeric, but most of the serum IgM is a pentamer containing 5 monomers linked via disulfide bonds. IgM is the first specific antibody to appear in the serum after infection.[1] Due to the slow onset of IgM synthesis, the IgM concentration in serum of infants is lower than in adults.[1]

In serum, increased polyclonal IgM levels are found in viral, bacterial, and parasitic infections,[1] in liver diseases (e.g. primary biliary cirrhosis),[2] in rare immunological disorders, such as hyper IgM (HIGM) syndromes, but also in autoimmune diseases.[3,4,5] Elevated monoclonal IgM levels are also found in B-cell lymphoproliferative disorders (LPD).[6,7] Decreased levels of IgM can be due to reduced synthesis, increased loss, hypercatabolism or a combination of causes. IgM deficiencies occur in congenital and acquired immunodeficiency syndromes, inherited deficiencies, hematologic malignancies.[8]

This 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 in serum/plasma, e.g. in pediatric samples.

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

R3 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 R3 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.

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 + 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/ doctor.

IGM-2

Tina-quant IgM Gen.2

cobas®

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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 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 (IGM2):

Serum
Plasma: Li-heparin and K_2-EDTA plasma

Sensitive application (IGM2-P):

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.

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

Stability:[9]	2 months at 15-25 °C
	4 months at 2-8 °C
	6 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 (IGM2)

Test definition

Reporting time	10 min		
Wavelength (sub/main)	700/340 nm		
Reagent pipetting		Diluent (H_2O)	
R1	77 µL	–	
R3	24 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	4.8 µL	5 µL	100 µL
Decreased	2.3 µL	1.5 µL	135 µL
Increased	6.0 µL	20 µL	84 µL

Sensitive application (IGM2-P)

Test definition

Reporting time	10 min		
Wavelength (sub/main)	700/340 nm		
Reagent pipetting		Diluent (H_2O)	
R1	82 µL	–	
R3	26 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	1.7 µL	–	–
Decreased	1.7 µL	25 µL	50 µL
Increased	6.8 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 (IGM2)

Calibrators	S1: H_2O
	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 (IGM2-P)

Calibrators	S1: H_2O
	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

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).[10]

Quality control

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

Standard application (IGM-2):	Precinorm Protein, Precipath Protein, 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. 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 (µmol/L, mg/dL).

Conversion factors:	g/L × 1.03 = µmol/L
	g/L × 100 = mg/dL

Limitations - interference

Standard application (IGM2):

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

Icterus:[11] No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[11] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[11] 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 occurs up to an IgM concentration of 100 g/L.

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.[12,13]

Sensitive application (IGM2-P):

Criterion: Recovery within ± 0.02 g/L of initial values of samples ≤ 0.2 g/L and within ± 10 % for samples > 0.2 g/L.

Icterus:[11] No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[11] No significant interference up to an H index of 600 (approximate hemoglobin concentration: 373 µmol/L or 600 mg/dL).

Lipemia (Intralipid):[11] No significant interference up to an L index of 600.

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

High dose hook-effect: No false result occurs up to an IgM concentration of 30 g/L.

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.[12,13]

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.[14]

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 (IGM2):

0.25-6.50 g/L (0.26-6.70 µmol/L)

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 (IGM2-P):

0.04-1.50 g/L (0.04-1.55 µmol/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 4. The results are automatically divided by this factor.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Standard application (IGM2)

Limit of Blank	= 0.05 g/L (0.05 µmol/L)
Limit of Detection	= 0.05 g/L (0.05 µmol/L)
Limit of Quantitation	= 0.25 g/L (0.26 µmol/L)

Sensitive application (IGM2-P)

Limit of Blank	= 0.01 g/L (0.01 µmol/L)
Limit of Detection	= 0.01 g/L (0.01 µmol/L)
Limit of Quantitation	= 0.04 g/L (0.04 µmol/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 ≥ 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 IgM samples.

Expected values

Reference values according to CRM 470 Protein Standardization:[15,16]

g/L

Adults	0.4-2.3 g/L
Children and juveniles	
0-14 days female	0.03-0.32 g/L
0-14 days male	0.03-0.32 g/L
15 days - < 13 weeks female	0.10-0.67 g/L
15 days - < 13 weeks male	0.10-0.67 g/L
13 weeks - < 1 year female	0.14-0.82 g/L
13 weeks - < 1 year male	0.14-0.82 g/L
1 - < 19 years female	0.45-1.78 g/L
1 - < 19 years male	0.36-1.44 g/L

µmol/L*

Adults	0.4-2.4 µmol/L
Children and juveniles	
0-14 days female	0.03-0.33 µmol/L
0-14 days male	0.03-0.33 µmol/L

15 days - < 13 weeks female	0.10-0.69 µmol/L
15 days - < 13 weeks male	0.10-0.69 µmol/L
13 weeks - < 1 year female	0.14-0.84 µmol/L
13 weeks - < 1 year male	0.14-0.84 µmol/L
1 - < 19 years female	0.46-1.83 µmol/L
1 - < 19 years male	0.37-1.48 µmol/L

* calculated by unit conversion factor

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 (IGM2)

Repeatability	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	0.661	0.0124	1.9
PCCC2[b)]	0.869	0.0106	1.2
Human serum 1	0.347	0.0150	4.3
Human serum 2	0.475	0.0110	2.3
Human serum 3	2.37	0.0134	0.6
Human serum 4	3.28	0.0170	0.5
Human serum 5	5.42	0.0247	0.5

Intermediate precision	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	0.661	0.0226	3.4
PCCC2[b)]	0.869	0.0188	2.2
Human serum 1	0.347	0.0199	5.7
Human serum 2	0.475	0.0168	3.5
Human serum 3	2.31	0.0196	0.8
Human serum 4	3.18	0.0250	0.8
Human serum 5	5.58	0.0312	0.6

Sensitive application (IGM2-P)

Repeatability	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	0.653	0.00291	0.4
Precipath PUC	0.276	0.00176	0.6
Human serum 1	0.0497	0.00142	2.9
Human serum 2	0.175	0.00153	0.9
Human serum 3	0.451	0.00267	0.6
Human serum 4	0.760	0.00389	0.5
Human serum 5	1.31	0.00636	0.5

Intermediate precision	*Mean g/L*	*SD g/L*	*CV %*
PCCC1[a)]	0.646	0.00652	1.0
Precipath PUC	0.276	0.00332	1.2
Human serum 1	0.0515	0.00265	5.1
Human serum 2	0.175	0.00283	1.6
Human serum 3	0.451	0.00410	0.9
Human serum 4	0.762	0.00498	0.7
Human serum 5	1.30	0.00902	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

IgM 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 (IGM2):

Sample size (n) = 73

Passing/Bablok[17]	Linear regression
y = 0.972x + 0.0150 g/L	y = 0.983x + 0.00177 g/L
τ = 0.985	r = 0.999

The sample concentrations were between 0.260 and 6.06 g/L.

Sensitive application (IGM2-P):

Sample size (n) = 72

Passing/Bablok[17]	Linear regression
y = 0.988x + 0.00622 g/L	y = 1.011x + 0.00339 g/L
τ = 0.946	r = 0.990

The sample concentrations were between 0.0480 and 1.50 g/L.

IgM 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 (IGM2):

Sample size (n) = 72

Passing/Bablok[17]	Linear regression
y = 0.992x – 0.000433 g/L	y = 0.995x – 0.00326 g/L
τ = 0.984	r = 1.000

The sample concentrations were between 0.346 and 6.42 g/L.

Sensitive application (IGM2-P):

Sample size (n) = 70

Passing/Bablok[17]	Linear regression
y = 0.982x + 0.0134 g/L	y = 0.973x + 0.0179 g/L
τ = 0.984	r = 0.999

The sample concentrations were between 0.0860 and 1.50 g/L.

IgM 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 (IGM2):

Sample size (n) = 73

Passing/Bablok[17]	Linear regression
y = 1.010x - 0.0198 g/L	y = 0.999x - 0.00150 g/L
τ = 0.986	r = 1.000

The sample concentrations were between 0.423 and 6.22 g/L.

IGM-2

Tina-quant IgM Gen.2

Sensitive application (IGM2-P):

Sample size (n) = 72

Passing/Bablok[17]	Linear regression
y = 0.977x + 0.0158 g/L	y = 0.966x + 0.0212 g/L
τ = 0.994	r = 1.000

The sample concentrations were between 0.0604 and 1.49 g/L.

References

1 Dietzen DJ, Willrich MAV. Amino acids, peptides, and proteins. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, editors. Tietz Textbook of Laboratory Medicine, Saunders Elsevier, Philadelphia, 7th edition, 2023, chapter 31, p. 348-349.e42.

2 Rosenberg WMC, Badrick T, Lo S, et al. Liver disease. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, editors. Tietz Textbook of Laboratory Medicine, Saunders Elsevier, Philadelphia, 7th edition, 2023, chapter 51, p. 701-763.e21

3 Davies EG, Thrasher AJ. Update on the hyper immunoglobulin M syndromes. Br J Haematol 2010 Apr;149(2):167-180.

4 Duarte-Rey C, Bogdanos DP, Leung PS, et al. IgM predominance in autoimmune disease: genetics and gender. Autoimmun Rev 2012 May;11(6-7):A404-412.

5 de la Morena MT. Clinical Phenotypes of Hyper-IgM Syndromes. J Allergy Clin Immunol Pract 2016 Nov-Dec;4(6):1023-1036.

6 Gertz MA. Waldenström macroglobulinemia: 2017 update on diagnosis, risk stratification, and management. Am J Hematol 2017 Feb;92(2):209-217.

7 Cox MC, Di Napoli A, Scarpino S, et al. Clinicopathologic characterization of diffuse-large-B-cell lymphoma with an associated serum monoclonal IgM component. PLoS One 2014 Apr 4;9(4):e93903.

8 Michniacki TF, Madkaikar M, Walkovich K, et al. Primary immunodeficiencies and secondary immunodeficiencies. In: Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, editors. Tietz Textbook of Laboratory Medicine, Saunders Elsevier, Philadelphia, 7th edition, 2023, chapter 100, p. 1358-1389.e12.

9 Use of Anticoagulants in Diagnostic Laboratory Investigations. WHO Publication WHO/DIL/LAB/99.1 Rev. 2: Jan 2002.

10 Baudner S, Bienvenu J, Blirup-Jensen S, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins CRM470. Report EUR 15243 EN 1993;1-186.

11 Glick MR, Ryder KW, Jackson SA. Graphical Comparisons of Interferences in Clinical Chemistry Instrumentation. Clin Chem 1986;32:470-475.

12 Breuer J. Report on the Symposium "Drug effects in Clinical Chemistry Methods". Eur J Clin Chem Clin Biochem 1996;34:385-386.

13 Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem 2001;38:376-385.

14 Attaelmannan M, Levinson SS. Understanding and identifying monoclonal gammopathies. Clin Chem 2000;46(8 Pt 2):1230-1238.

15 Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996;34:517-520.

16 Estey MP, Cohen AH, Colantonio DA, et al. CLSI-based transference of the CALIPER database of pediatric reference intervals from Abbott to Beckman, Ortho, Roche and Siemens Clinical Chemistry Assays: Direct validation using reference samples from the CALIPER cohort. Clin Biochem 2013;46:1197-1219.

17 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:

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.

CE 0123

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.roche.com
+800 5505 6606