Elecsys CMV IgM

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REF		Σ	SYSTEM
07027133190	07027133500	300	**cobas e** 402 **cobas e** 801

English

System information

Short name	ACN (application code number)
CMVIGM	10087

Intended use

Immunoassay for the in vitro qualitative determination of IgM antibodies to cytomegalovirus in human serum and plasma.

Results obtained with this assay are used as an aid in the diagnosis of recent CMV infections.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Summary

The Elecsys CMV IgM assay is intended to be used as an aid to diagnose recent infection with CMV in suspected patients and pregnant women.

Cytomegalovirus (CMV), a member of the herpes virus family, is ubiquitous in all human populations, causing infections which are followed by life-long latency in the host with occasional reactivations.[1,2] The seroprevalence of antibodies in adults ranges from 40-100 % with inverse correlation to socioeconomic status.[1,2,3,4] CMV is transmitted through body fluids, including blood, genital secretions and breast milk. Saliva and urine of infected individuals also represent a prominent source of infection, and children, especially those attending day care facilities, are an important vector for viral spread.[2,3,5,6,7] In immunocompetent individuals primary CMV infection is usually mild or asymptomatic.[2,6] Patients commonly present with a mononucleosis-like syndrome, including fever, sore throat, cervical lymphadenopathy, malaise, headache, muscle ache and joint pains.[2,3,6,8]

During pregnancy, CMV can cause congenital infection which may result in permanent physical and/or neurological sequelae in the child.[6] CMV infection can be primary, i.e. newly acquired, or secondary, i.e. due to reactivation of the latent virus or re-infection with a different viral strain.[3,6] Primary CMV infection is reported in 1-4 % of seronegative women during pregnancy and the risk of transmission to the fetus is estimated to be about 30-40 %.[3,5] Reactivation of CMV infection during pregnancy is reported in 10-30 % of seropositive women and, in this circumstance, the risk of transmission of the virus is about 1-3 %.[3,5,6] Overall, prenatal CMV infection occurs in 0.6-0.7 % of all life births in the developed world.[5,6,9,10] The majority of babies born with congenital CMV infection are asymptomatic at birth.[9,11,12] Of these 5-15 % still develop irreversible impairments, most frequently hearing loss, that can occur several months or even years after birth.[6,9,11,12] For babies symptomatic at birth, prognosis is very poor, as they are likely to develop severe mental impairment and/or hearing loss.[6,9,11,12] Different studies have shown that the risk of symptomatic congenital disease in the fetus or newborn infant is high, when maternal primary infection takes place in early pregnancy before week 20 of gestation, and lower thereafter.[5,6] The congenital CMV infection caused by recurrent maternal infection seldom leads to symptomatic disease at birth.[5,6]

At risk for CMV infection and disease are also immunocompromised patients such as transplant recipients and HIV infected patients where the virus can cause life-threatening diseases.[13,14] The CMV status of transplant donors and recipients is very important, as it will determine prophylactic and pre-emptive treatment strategies against CMV.[15] CMV-negative transplant recipients should receive donations from CMV-negative individuals or leukocyte depleted blood products. During latency, CMV resides in infected cells and the free viral DNA load is usually low. The CMV status can still be determined by testing for CMV IgG antibodies.[16]

Within the appropriate clinical context, the first step in diagnosing acute primary CMV infection is most commonly made by the detection of anti-CMV-specific IgG and IgM antibodies.[6] Samples being reactive for IgM antibodies indicate an acute, recent or reactivated infection.[2,5,6,14] For further analysis of a primary CMV infection the determination of the CMV IgG avidity is used as an aid.[2,5,6,14] A positive IgM result in combination with a low avidity index for IgG is a strong indication of a recent primary CMV infection.[5,6,14]

Seroconversion to CMV IgM and IgG may also indicate a recent CMV infection.[2,3,5,6,14]

Test principle

µ-Capture test principle. Total duration of assay: 18 minutes.

- 1st incubation: 6 µL of sample are automatically prediluted 1:20 with Diluent Universal. Biotinylated monoclonal anti-h-IgM-specific antibodies are added.
- 2nd incubation: CMV-specific recombinant antigen labeled with a ruthenium complex[a)] and streptavidin-coated microparticles are added. Anti-CMV IgM antibodies present in the sample react with the ruthenium-labeled CMV-specific recombinant antigen. The complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The **cobas e** pack (M, R1, R2) is labeled as CMVIGM.

M Streptavidin-coated microparticles, 1 bottle, 14.1 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-h-IgM-Ab~biotin, 1 bottle, 19.7 mL:
Biotinylated monoclonal anti-h-IgM antibody (mouse) > 500 µg/L, MES[b)] buffer 50 mmol/L, pH 6.5; preservative.

R2 CMV-Ag~$Ru(bpy)_3^{2+}$, 1 bottle, 19.7 mL:
CMV-specific antigen (recombinant, E. coli) labeled with ruthenium complex > 50 µg/L; MES buffer 50 mmol/L, pH 5.5; preservative.

b) MES = 2-morpholino-ethane sulfonic acid

CMVIGM Cal1 Negative calibrator 1, 1 bottle of 1.0 mL:
Human serum, negative for anti-CMV IgM; preservative.

CMVIGM Cal2 Positive calibrator 2, 1 bottle of 1.0 mL:
Anti-CMV IgM (human serum) in HEPES[c)] buffer, pH 7.4; bovine albumin; preservative.

c) HEPES = [4-(2-hydroxyethyl)-piperazine]-ethanesulfonic acid

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:

Warning

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H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing mist or vapours.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

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

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 98/79/EC, Annex II, List A). However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[17,18]

The serum containing anti-CMV IgM (CMVIGM Cal2) was sterile filtrated.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The reagents (M, R1, R2) in the kit are ready-for-use and are supplied in **cobas e** packs.

Calibrators:

The calibrators are supplied ready-for-use in bottles compatible with the system.

Unless the entire volume is necessary for calibration on the analyzer, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C or -20 °C (± 5 °C) for later use.

Perform **only one** calibration procedure per aliquot.

All information required for correct operation is available via the **cobas** link.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the **cobas e** pack:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers	16 weeks

Stability of the calibrators:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	8 weeks
after opening at -20 °C (± 5 °C)	16 weeks
on the analyzers at 20-25 °C	use only once

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, Na-heparin, K_2-EDTA, K_3-EDTA, ACD, CPD, CP2D, CPDA and Na-citrate plasma.

Criterion: Mean recovery of serum value: negative samples ± 0.2 COI (cutoff-index); borderline/reactive samples: 80-120 %.

Sampling devices containing liquid anticoagulants have a dilution effect resulting in lower COI values for individual patient specimens.
In order to minimize dilution effects it is essential that respective sampling devices are filled completely according to manufacturer's instructions.

Stable for 7 days at 20-25 °C, 4 weeks at 2-8 °C, 3 months at -20 °C (± 5 °C). The samples may be frozen 5 times.

The sample types listed were tested with a selection of sample collection tubes or systems 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/collection system manufacturer.

Specimens should not be subsequently altered with additives (biocides, anti-oxidants or substances that could possibly change the pH of the sample) in order to avoid erroneous findings.

Pooled samples and other artificial material may have different effects on different assays and thus may lead to discrepant findings.

Centrifuge samples containing precipitates and thawed samples before performing the assay.

Lyophilized samples can be used.

Do not use heat-inactivated samples.

Ensure the samples and calibrators are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples and calibrators on the analyzers should be analyzed/measured within 2 hours.

The performance of the Elecsys CMV IgM assay has not been established with cadaveric samples or body fluids other than serum and plasma.

Materials provided

See "Reagents – working solutions" section for reagents.

- 2 x 6 bottle labels

Materials required (but not provided)

- REF 04784626190, PreciControl CMV IgM, 16 x 1.0 mL
- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- REF 07299001190, Diluent Universal, 36 mL sample diluent
- General laboratory equipment
- **cobas e** analyzer

Additional materials for **cobas e** 402 and **cobas e** 801 analyzers:

- REF 06908799190, ProCell II M, 2 x 2 L system solution
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
- REF 06908853190, PreClean II M, 2 x 2 L wash solution
- REF 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- REF 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- REF 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- REF 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Elecsys CMV IgM

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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.

Resuspension of the microparticles takes place automatically prior to use.

Place the cooled (stored at 2-8 °C) **cobas e** pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas e** pack.

Calibrators:

Place the calibrators in the sample zone.

Read in all the information necessary for calibrating the assay.

Calibration

Traceability: This method has been standardized against a Roche standard. The units have been selected arbitrarily.

Calibration frequency: Calibration must be performed once per reagent lot using CMVIGM Cal1, CMVIGM Cal2 and fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analyzer).

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

Renewed calibration is recommended as follows:

- after 12 weeks when using the same reagent lot
- after 28 days when using the same **cobas e** pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

Quality control

Use Elecsys PreciControl CMV IgM or other suitable controls for routine quality control procedures.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per **cobas e** pack, and following each calibration.

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.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

The analyzer automatically calculates the cutoff based on the measurement of CMVIGM Cal1 and CMVIGM Cal2. The result of a sample is given either as reactive, borderline or non-reactive as well as in the form of a cutoff index (signal sample/cutoff).

Interpretation of the results

Numeric result	Result message	Interpretation/ further steps
COI < 0.7	Non-reactive	Negative for CMV IgM-specific antibodies
COI ≥ 0.7 to < 1.0	Borderline	Sample should be retested. In case the result is still borderline, a second sample should be collected (e.g. within 2-3 weeks) and testing should be repeated.
COI ≥ 1.0	Reactive	Positive for CMV IgM-specific antibodies

The magnitude of the measured result above the cutoff is not indicative of the total amount of antibody present in the sample. The anti-CMV IgM results in a given specimen, as determined by assays from different manufacturers, can vary due to differences in reagents and assay methods.

Limitations - interference

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 342 µmol/L or ≤ 20 mg/dL
Hemoglobin	≤ 0.310 mmol/L or ≤ 500 mg/dL
Intralipid	≤ 1500 mg/dL
Biotin	≤ 410 nmol/L or ≤ 100 ng/mL
Rheumatoid factors[d)]	≤ 2000 IU/mL

d) negative samples only

Criterion: Recovery of positive samples within ± 20 %. Recovery of negative samples ± 0.2 COI.

As with many µ-capture assays, an interference with unspecific IgM is observed. Increasing amounts of unspecific IgM may lead to a decrease in the recovery of positive samples with the Elecsys CMV IgM assay.

A negative CMV IgM test result, also in combination with a positive CMV IgG result, does not completely rule out the possibility of an acute infection with CMV:

- Individuals at the early stage of acute infection may not exhibit detectable amounts of CMV IgM antibodies. In some of these individuals an borderline or low positive result with the Elecsys CMV IgG assay may be found and indicate an early acute infection. A second sample should be tested e.g. within 2-3 weeks. The detection of CMV IgM and/or a significant increase of the Elecsys CMV IgG antibody titer in the second sample supports the diagnosis of acute CMV infection.[19,20]
- The individual immune response following CMV infection varies considerably.

  In some individuals non-reactive results may occur in the late phase of acute infection with the Elecsys CMV IgM assay.

The detection of anti-CMV IgM in a single sample is not sufficient to prove an acute CMV infection. In single cases elevated IgM antibody levels may persist even for years after initial infection. For further clarification additional laboratory tests (e.g. CMV IgG and CMV IgG avidity) or combination of tests should be performed and results should be assessed in conjunction with the patient's medical history and clinical symptoms.

The results in HIV patients, in patients undergoing immunosuppressive therapy, or in patients with other disorders leading to immune suppression, should be interpreted with caution.

Specimens from neonates, cord blood, pretransplant patients or body fluids other than serum and plasma, such as urine, saliva or amniotic fluid have not been tested.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

Pharmaceutical substances

In vitro tests were performed on 18 commonly used pharmaceuticals. No interference with the assay was found.

In addition, the following special drugs were tested. No interference with the assay was found.

Special drugs

Drug	Concentration tested
Ganciclovir	≤ 800 mg/L
Valganciclovir	≤ 900 mg/L

Sera from patients with primary EBV infections can demonstrate positive results in the Elecsys CMV IgM assay. This is not unexpected as both viruses belong to the herpes virus family and this potential interference is known for CMV IgM assays.[20]

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

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

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Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using Elecsys reagents, samples and controls in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

cobas e 402 and **cobas e** 801 analyzers					
		Repeatability		**Intermediate precision**	
Sample	Mean COI	SD COI	CV %	SD COI	CV %
HSP[e)], negative	0.202	0.002	1.2	0.006	2.8
HSP, low positive	1.09	0.018	1.6	0.020	1.8
HSP, high positive	3.46	0.033	1.0	0.049	1.4
PC[f)] CMV IgM 1	0.225	0.002	0.9	0.006	2.6
PC CMV IgM 2	1.85	0.036	1.9	0.041	2.2

e) HSP = human specimen (serum/plasma)

f) PC = PreciControl

Analytical specificity

433 potentially cross reacting samples were tested with the Elecsys CMV IgM assay and a comparison CMV IgM assay comprising the following specimens:

- containing antibodies against HBV, HAV, HCV, HIV*, HTLV, EBV**, HSV***, VZV, Parvo B19***, Rubella****, Treponema pallidum, Toxoplasma gondii
- containing autoantibodies***** (ANA, anti-tissue, RF)

* HIV: 8 discordant samples were found out of 70 samples.
** EBV: 13 discordant samples were found out of 48 samples.
*** HSV, Parvo B19: 1 discordant sample was found in each group.
**** Rubella: 2 discordant samples were found.
***** Autoantibodies: 7 discordant samples were found out of 73 samples.

An overall agreement of 92.3 % (381/413) was found in these specimens with the Elecsys CMV IgM assay and the comparison test. 377 samples were found concordantly negative and 4 samples were found positive. 20 samples were found indeterminate either with the Elecsys CMV IgM assay or the comparison test.

Clinical sensitivity

Sensitivity in primary infections

A total of 365 frozen samples from pregnant women with primary CMV infection including sequential and single samples analyzed by commercially available CMV IgM assays were tested with the Elecsys CMV IgM assay at 4 different sites. For calculation of sensitivity confirmed positive samples had a low avidity index or were clinically characterized. Indeterminate samples were counted as positive. Samples with a high avidity index and all discrepant samples or concordant negative samples with a moderate avidity index were excluded.

Site	N	Sensitivity (%)	
		Elecsys CMV IgM assay	Comparison CMV IgM assay
1[g)]	180	93.0 (106/114)	94.7 (108/114)
2	57	96.5 (55/57)	96.5 (55/57)
3	39[h)]	91.2 (31/34)	79.4 (27/34)
	35[i)]	93.1 (27/29)	100 (29/29)
4[j)]	54	92.3 (48/52)	98.1 (51/52)

g) 66 samples were excluded due to high/moderate avidity.

h) 5 samples were excluded due to moderate avidity and concordant negative results for CMV IgM.

i) 6 samples were excluded due to moderate/high avidity and concordant negative results for CMV IgM.

j) 2 samples were excluded due to moderate avidity and discrepant CMV IgM results.

Specificity in past infection

A total of 158 frozen samples from pregnant women with past CMV infection, analyzed by commercial CMV assays, were tested with the Elecsys CMV IgM assay at 4 different sites. All samples were pre-selected positive for CMV IgG, negative for CMV IgM and a high avidity index showing absence of acute infection.

Relative specificity in past infections

Site	N	Relative specificity (%)	
		Elecsys CMV IgM assay	Comparison CMV IgM assay
1[k)]	48	98	100
2	30	100	100
3[l)]	50	84	86
4	30	100	100

k) 1 sample was found indeterminate with the Elecsys CMV IgM assay and negative with the comparison assay.

l) 8 samples were positive with the Elecsys CMV IgM assay; 7 samples were equivocal with the comparison assay.

Capability to discriminate the persisting IgM after CMV infection

A total of 68 frozen samples from pregnant women analyzed by commercial CMV IgM assays were tested with the Elecsys CMV IgM assay at 3 different sites. All samples were pre-selected positive for CMV IgG and CMV IgM and a high avidity index showing absence of acute infection.

Capability to discriminate the persisting CMV IgM

Site	N	Elecsys CMV IgM assay tested/reactive	Comparison CMV IgM assay tested/reactive
1[m)]	20	20/6	20/20
2[n)]	28	28/4	28/28
3[o)]	20	20/7	20/20

m) 14 samples were discrepant negative with the Elecsys CMV IgM assay.

n) 24 samples were discrepant negative with the Elecsys CMV IgM assay.

o) 12 samples were discrepant negative with the Elecsys CMV IgM assay.

Specificity in pre-selected negative samples

A total of 173 frozen samples from pregnant women in which a CMV infection was excluded and analyzed by commercial CMV IgM assays were tested with the Elecsys CMV IgM assay at 4 different sites.

Site	N	Specificity (%)	
		Elecsys CMV IgM assay	Comparison CMV IgM assay
1	50	100	100
2[p)]	50	98	100
3[q)]	23	100	95.7
4	50	100	100

p) 1 sample was found positive with the Elecsys CMV IgM assay.

q) 1 sample was found equivocal with the comparison assay.

Clinical specificity

A total of 1646 fresh samples from clinical routine (blood donors, site 1) were tested at 3 different sites (pregnancy testing, site 2 and 3) with the Elecsys CMV IgM assay in comparison to competitor assays. The CMV IgG avidity test was used to resolve discrepant results.

Relative specificity after resolution

Site	N	Relative specificity Elecsys CMV IgM assay, %	Lower confidence limit, %
1[r)]	511	98.8 (495/501)	97.4

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Site	N	Relative specificity Elecsys CMV IgM assay, %	Lower confidence limit, %
2[s)]	616	97.1 (574/591)	95.4
3[t)]	519	97.0 (492/507)	95.2

r) 10 samples were excluded due to moderate avidity or missing avidity result.

s) 10 samples were confirmed positive by low avidity index; 15 samples were excluded due to moderate or missing avidity result.

t) 3 samples were confirmed positive by low avidity index; 9 samples were excluded due to moderate or missing avidity result.

Site	N	Relative specificity Comparison CMV IgM test, %	Lower confidence limit, %
1[r)]	511	96.6 (484/501)	94.6
2[s)]	616	93.4 (552/591)	91.1
3[t)]	519	92.9 (471/507)	90.3

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For further information, please refer to the appropriate user guide or operator's manual for the analyzer concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

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.

The Summary of Safety & Performance Report can be found here: https://ec.europa.eu/tools/eudamed

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	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

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