Elecsys Rubella IgG

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REF		Σ	SYSTEM
07027770190	07027770501	300	**cobas e** 402 **cobas e** 801

English

For use in the USA only

System information

Short name	ACN (application code number)
RUBIGG	10024

Intended use

This assay is for the in vitro quantitative determination of IgG antibodies to rubella virus in human serum and heparin, EDTA and citrate plasma.
This assay may be used as an aid in the assessment of immune status to rubella in individuals including women of childbearing age.

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

Summary

References[1,2,3,4,5,6,7]

Rubella virus is the etiological agent of German measles, a commonly mild rash disease which occurs usually during childhood. It is spread by small droplets via the respiratory route. Postnatal acquired infection is seldom associated with complications.
However, Rubella can be a serious disease when a pregnant woman becomes infected especially during the first trimester of pregnancy. Rubella virus can be transmitted through the placenta and can result in fetal death or may cause severe malformations to the fetus, commonly summarized as congenital Rubella syndrome (CRS). CRS is an important cause of blindness, deafness, congenital heart disease and mental retardation.
Today infant vaccination programs and the vaccination of women in child-bearing age who are susceptible to Rubella infection have considerably reduced the incidence of acute Rubella infection and the incidence of CRS.
The detection of Rubella-specific antibodies is used to determine the immune status of an individual and to aid in the diagnosis of acute Rubella infection. The presence of IgG antibodies to Rubella virus indicates a previous exposure either by vaccination or prior Rubella infection and is indicative of presumptive immunity.
The detection of Rubella-specific IgM antibodies is used as an aid in the diagnosis of acute Rubella infection. Seroconversion of specific Rubella antibodies or a significant rise of the IgG antibody titer from a first to a second sample may support the diagnosis of acute Rubella infection.
Recombinant Rubella-like particles (RLP) have proven to replace authentic Rubella virus as an antigen in diagnostic assays. A recombinant part of the E1 (envelope1) protein of Rubella virus is used to supplement the Elecsys assay.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 6 µL of sample are incubated with biotinylated monoclonal anti-human IgG antibody, RLP (Rubella-like particles) and a ruthenylated monoclonal anti-Rubella antibody fragment. In addition a biotinylated Rubella virus-specific recombinant antigen E1 (E. coli) and E1 labelled with ruthenium complex[a)] react with anti-Rubella IgG from the sample to form a sandwich complex.
- 2nd incubation: Addition of streptavidin-coated microparticles.
- 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 via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the **cobas** link.

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 RUBIGG.

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

R1 Anti-h IgG-Ab~biotin, 1 bottle, 19.7 mL:
Biotinylated monoclonal anti-human IgG antibody (mouse); Rubella-like particles (RLP), phosphate buffer, pH 6.8; preservative.

R2 Anti-Rubella-Ab-fragment~$Ru(bpy)_3^{2+}$, recombinant E1~biotin, recombinant E1~$Ru(bpy)_3^{2+}$, 1 bottle, 19.7 mL:
Ruthenylated monoclonal anti-Rubella antibody fragment; biotinylated recombinant E1; ruthenylated recombinant E1, phosphate buffer, pH 6.8; preservative.

RUBIGG Cal1 Negative calibrator 1, 1 bottle of 1.0 mL:
Human serum, non-reactive for anti-Rubella IgG; preservative.

RUBIGG Cal2 Positive calibrator 2, 1 bottle of 1.0 mL:
Anti-Rubella IgG approximately 400 IU/mL in human serum; preservative.

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.

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

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

Warning

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: 1-800-428-2336

All human material should be considered potentially infectious.

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The negative calibrator (RUBIGG Cal1) has been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

Positive calibrator (RUBIGG Cal2): Materials of human origin were tested for HIV and hepatitis C. The findings were negative.

The testing methods used assays approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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.[8,9]

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 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 **cobas e** analyzers	16 weeks

Stability of the calibrators:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	16 weeks
on the **cobas e** 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, K_2-EDTA, K_3-EDTA and Na-citrate plasma.

Criterion: Slope 0.9-1.1 + intercept within ≤ ± 2 IU/mL + coefficient of correlation ≥ 0.95.

Stable for 7 days at 20-25 °C, 3 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 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.

Specimens should not be altered subsequently with additives (biocides, anti-oxidants or substances possibly changing 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.

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.

Sample stability claims were established by experimental data by the manufacturer only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

Materials provided

See "Reagents – working solutions" section for reagents.

- 2 x 6 bottle labels

Materials required (but not provided)

- REF 04618807160, PreciControl Rubella IgG, 16 x 1.0 mL
- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- General laboratory equipment
- **cobas e** analyzer

Additional materials for the **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 11298500160, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

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 the 1st International Standard for Anti-Rubella Immunoglobulin, human, code RUBI-1-94, from the National Institute for Biological Standards and Control (NIBSC), Hertfordshire, UK, formerly refered to as proposed 3rd WHO Reference Standard Preparation.

The predefined master curve is adapted to the analyzer using RUBIGG Cal1 and RUBIGG Cal2.

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

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

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- as required: e.g. quality control findings with PreciControl Rubella IgG outside the defined limits

Quality control

For quality control, use PreciControl Rubella IgG.

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 analyte concentration of each sample in IU/mL.

Interpretation of the results

Numeric result	Result message	Interpretation/ further steps
< 10 IU/mL	Non-reactive	Negative for anti-Rubella IgG
≥ 10 IU/mL	Reactive	Positive for anti-Rubella IgG.* The presence of IgG antibodies to Rubella virus is an indication of previous exposure either by prior infection or by vaccination.

*The NCCLS subcommittee on Rubella Serology recommended 10 IU/mL as the cutoff level.[7]

Patients suspected of acute Rubella infection should be tested for the presence of Rubella-specific IgM. The diagnosis of acute Rubella infection may be supported by a significant increase of the anti-Rubella IgG titer from a first to a second sample.

Please note

The measured anti-Rubella IgG value of a patient's sample can vary depending on the testing procedure used. The laboratory finding must therefore always contain a statement on the Rubella IgG assay used. Anti-Rubella IgG values determined on patient samples by different testing procedures cannot be directly compared with one another and could be the cause of erroneous medical interpretations.
Therefore, the results reported by the laboratory to the physician should include: "The following results were obtained with the Elecsys Rubella IgG assay. Results from assays of other manufacturers cannot be used interchangeably."

Limitations - interference

A test result < 10 IU/mL does not completely rule out the possibility of an acute Rubella infection. Specimens taken very early in the acute phase of infection may not contain any detectable amounts of anti-Rubella IgG or may have an antibody concentration < 10 IU/mL. The presence of anti-Rubella IgG in a single sample is not sufficient to distinguish between an acute or past infection. The lack of a significant increase of the anti-Rubella IgG titer (e.g. within 3-4 weeks) may not completely exclude acute Rubella infection. When monitoring the anti-Rubella IgG titer it is recommended that serial samples be tested by parallel measurements.

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.

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	≤ 513 µmol/L or ≤ 30 mg/dL
Hemoglobin	≤ 0.621 mmol/L or ≤ 1000 mg/dL
Intralipid	≤ 1500 mg/dL
Albumin	≤ 7 g/dL
IgA	≤ 1.6 g/dL
IgM	≤ 0.4 g/dL

Criterion: For concentrations < 10 IU/mL the deviation is ≤ ± 2 IU/mL. For concentrations ≥ 10 IU/mL the deviation is ≤ ± 20 %.

Increasing amounts of unspecific human IgG may lead to a decrease in the recovery of positive samples with the Elecsys Rubella IgG assay.

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.

Biotin interference

% Bias for samples containing various concentrations of Biotin						
Sample	IU/mLwith no biotin added	Biotin concentration (ng/mL)				
		100	150	200	250	300
Negative	9.74	-2.2	-3.3	-5.7	-8.5	-12
Positive	252	1.0	-2.9	-4.6	-8.1	-10
High Positive	446	-0.8	-3.1	-5.6	-7.1	-9.8

% Bias for samples containing various concentrations of Biotin					
Sample	IU/mL with no biotin added	Biotin concentration (ng/mL)			
		360	720	1080	1440
Negative	9.42	-14	-38	-71	-85
Positive	240	-15	-37	-70	-82
High Positive	475	-14	-36	-69	-83

Specimens with biotin concentrations up to 250 ng/mL demonstrated ≤ 10 % bias in results. Biotin concentrations greater than 250 ng/mL lead to a negative bias for Elecsys Rubella IgG results. Pharmacokinetic studies have shown that serum concentrations of biotin can reach up to 355 ng/mL within the first hour after biotin ingestion for subjects consuming supplements of 20 mg biotin per day[10] and up to 1160 ng/mL for subjects after a single dose of 300 mg biotin.[11]

Pharmaceutical substances

In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found.

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

Special drugs

Drug	Concentration tested
Folic acid	≤ 3 mg/L

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.

Limits and ranges

Measuring range

0.210-500 IU/mL (defined by the Limit of Detection and the maximum of the master curve). Values below the Limit of Detection are reported as < 0.210 IU/mL. Values above the measuring range are reported as

> 500 IU/mL.
Dilution is not recommended for the Elecsys Rubella IgG assay.

Lower limits of measurement
Limit of Blank and Limit of Detection

Limit of Blank = 0.170 IU/mL

Limit of Detection = 0.210 IU/mL

The Limit of Blank and Limit of Detection 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 from n ≥ 60 measurements of low concentration samples over several independent series. 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 %).

Expected values

Epidemiological studies indicate that in most countries 80-90 % of the adult population have detectable antibodies to rubella.[12]
According to the literature, in general, 90 % of the U.S. population has either been vaccinated or exposed to rubella, with rubella IgG values greater than or equal to 10 IU/mL.[13]
In a study of 500 subjects ranging in age from 1 to 82 from a United States reference laboratory, the prevalence of IgG antibodies to Rubella was shown to be 95 %. Prevalence was 94.7 % among women of childbearing age, 100 % among men and 100 % among subjects under age 16.

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 is given below. The precision data was generated on the **cobas e** 801 analyzer. However, since the **cobas e** 801 analyzer is a member of the Elecsys instrument family of analyzers, some of the data below may have been generated on other members of the Elecsys instrument family. 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 801 analyzer[b]					
		Repeatability		**Intermediate precision**	
Sample	Mean IU/mL	SD IU/mL	CV %	SD µIU/mL	CV %
HS[c], negative	1.19	0.064	5.4	0.084	7.0
HS, weakly positive	10.4	0.368	3.5	0.475	4.6
HS, positive	399	11.4	2.9	15.6	3.9
PC[d] Rubella IgG 1	3.01	0.096	3.2	0.155	5.2
PC Rubella IgG 2	57.9	1.27	2.2	2.42	4.2

b) The precision data generated on the **cobas e** 402 analyzer was equivalent to that of the **cobas e** 801 analyzer.

c) HS = human serum

d) PC = PreciControl

Clinical performance

A multi-center study was conducted to characterize the performance of the Elecsys Rubella IgG immunoassay, relative to an FDA-cleared reference method, with individuals from defined populations.

US Clinical Study

500 samples were obtained from a US reference laboratory; representing subjects for whom anti-Rubella testing had been ordered per clinical routine. 11 serum samples were freshly collected and 489 samples were frozen sera which had been banked consecutively from the routine collective. This group consisted predominantly of women of childbearing age; and contained 94 % females and 6 % males, ranging in age from 1 to 82.

The following tables summarize the results for subjects from the clinical routine cohort:

Reference Rubella IgG Assay					
		Positive	Negative	Equivocal	Total
Elecsys Rubella IgG	Positive	466	9	0	475
	Negative	9	16	0	25
	Total	475	25	0	500

Agreement classification	Numerator/ Denominator	Percent agreement (%)	95 % confidence interval
Negative agreement	16/25	64.0	42.5 - 82.0
Positive agreement	466/475	98.1	96.4 - 99.1

Testing of banked samples

345 additional banked samples were tested. 295 samples which had tested negative with a Hemagglutination Inhibition (HI) assay were selected from the banked routine collective of a laboratory in Germany. An additional 50 positive samples were selected from the archived routine collective of a US reference laboratory. All samples were frozen sera. 332 were from females (179 of whom were pregnant) and 14 were from males; ages ranged from 5-61.

The following tables summarize the results for subjects from the supplemental testing cohort:

Reference Rubella IgG Assay					
		Positive	Negative	Equivocal[e]	Total
Elecsys Rubella IgG	Positive	168	3	2	173
	Negative	31	140	1	172
	Total	199	143	3	345

e) The repeatedly equivocal result was counted as a discrepant against the Elecsys.

Agreement classification	Numerator/ Denominator	Percent agreement (%)	95 % confidence interval
Negative agreement	140/145	96.6	92.1 - 98.9
Positive agreement	168/200	84.0	78.2 - 88.8

Samples collected during a rubella outbreak

Samples were collected from 71 pregnant women during a rubella outbreak in Italy. The following tables summarize the results for these subjects:

Reference Rubella IgG Assay					
		Positive	Negative	Equivocal	Total
Elecsys Rubella IgG	Positive	50	0	0	50
	Negative	8	10	3	21
	Total	58	10	3	71

Agreement classification[f]	Numerator/ Denominator	Percent agreement (%)	95 % confidence interval
Negative agreement	10/10	100	69.1 - 100
Positive agreement	50/61	82.0	70.0 - 90.6

f) The equivocal result, which could not be repeated due to insufficient quantity, was counted as a discrepant against the Elecsys.

Pregnant women study

Serum samples were collected from 150 pregnant women in the US and tested on the Elecsys and the reference assay. The Elecsys Rubella IgG showed 100 % agreement (95 % CI: 97.6 % - 100 %), with 150/150 positive tests.

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Vaccination follow-up

Commercially available vaccination follow-up panels comprising 152 samples from 13 subjects were also tested. The final specimen from each panel yielded 100 % agreement (95 % CI: 75.3 % - 100 %) between the methods, with 13/13 positive test results.

Evaluation of low positive samples

84 serum samples that gave low positive results (10-20 IU/mL) on the reference assay were tested with Elecsys Rubella IgG assay. The positive agreement was 80/84 or 95.2 % (95 % CI: 88.3 % - 98.7 %).

Evaluation of CDC reference panel

A panel of 100 serum specimens was obtained through the US Centers for Disease Control and Prevention (CDC) and tested for Rubella IgG on the Elecsys 2010 analyzer. The sera panel consists of 100 specimens, 50 pairs of sera titered by HI. There are 9 negative sera resulting in 18 negative specimens and 41 positive sera resulting in 82 positive specimens. As evaluated by the CDC, the Elecsys 2010 analyzer showed 100 % agreement, with 82/82 positive tests on 82 positive sera and 18/18 negative tests on 18 negative sera.
Note: The results are presented as a means of conveying further information on the performance of this assay with a characterized serum panel. This does not imply an endorsement of the assay by the CDC.

CDC Standard

The low titer (21.0 IU/mL) anti-rubella human reference serum from the CDC was tested neat and diluted 1:2 as described in the CLSI document I/LA6-A. The mean result of the neat standard was 38.8 IU/mL. The mean result of the two-fold diluted standard was 15.4 IU/mL.

Cross-reactivity

The specificity of the Elecsys Rubella IgG assay was evaluated by testing a total of 60 specimens representing a variety of disease states (ANA, CMV, EBV, FTA, HBV, HCV, HIV 1/2, HSV, Mumps, Parvo B19, RH, VZV). The testing results are summarized in the table below.

Cross-reactant	N	IgG Elecsys/ reference Neg/Neg	IgG Elecsys/ reference Pos/Neg	IgG Elecsys/ reference Neg/Pos	IgG Elecsys/ reference Pos/Pos
ANA	3	0	0	0	3
CMV[g)]	4	1	0	0	2
EBV	1	0	0	0	1
FTA	5	1	0	0	4
HBV	6	0	0	2	4
HCV	5	0	0	0	5
HIV 1/2	9	1	0	0	8
HSV	8	0	0	0	8
Mumps	3	0	0	0	3
Parvo B19	4	0	0	0	4
RH	7	0	0	0	7
VZV	5	0	0	0	5
Subtotal	60	3	0	2	54
Total	60	59			

g) One CMV sample was repeatedly equivocal by the reference method and was excluded from the calculations.

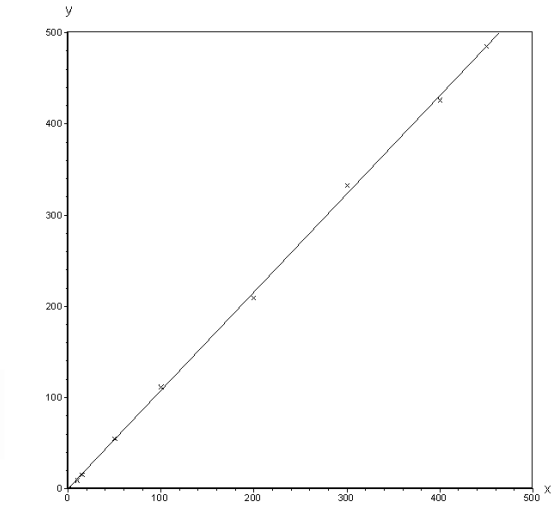
Serum and plasma comparison

The following table summarizes the results for the comparison between serum and three plasma matrices.

Plasma matrix	Number of specimens showing recovery to serum within various ranges		
	< 10 %	10 % - 20 %	> 20 %
Li-heparin	42	8	0
K_3-EDTA	44	5	1
Sodium citrate	26	14	10

Linearity with WHO Standard

Five dilutions of the NIBSC 1st International Standard for anti-Rubella Immunoglobulin, human, formerly referred to as the proposed 3rd WHO Reference Standard Preparation, were tested in triplicate. The mean value for each dilution was used to calculate the linear regression.



x: WHO value (IU/mL)

y: Elecsys Rubella IgG value

Slope = 1.077

Intercept = 0.1129

r = 0.9997

References

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

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 (for USA: see dialog.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

FOR US CUSTOMERS ONLY: LIMITED WARRANTY

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

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