

Rubella IgG

IgG antibodies to Rubella virus

04618793 190

100 tests

cobas®

English

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."

Intended use

Immunoassay for the in vitro quantitative determination of IgG antibodies to Rubella virus in human serum and plasma.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.

Summary^{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 assay.

The quantitative determination of Rubella IgG is used as an aid in the determination of the immune status to Rubella and the diagnosis of acute infection.

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 10 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. 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 reagent barcode.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 Anti-h IgG-Ab-biotin (gray cap), 1 bottle, 10 mL: Biotinylated monoclonal anti-h IgG antibody (mouse), RLP, phosphate buffer pH 6.8; preservative.
- R2 Anti-Rubella-Ab-fragment-Ru(bpy)₃²⁺, recombinant E1-biotin, recombinant E1-Ru(bpy)₃²⁺ (black cap), 1 bottle, 10 mL: Ruthenylated monoclonal anti-Rubella antibody fragment, biotinylated recombinant E1, ruthenylated recombinant E1, phosphate buffer pH 6.8; preservative.
- Cal1 Negative calibrator 1 (white cap), 2 bottles of 1.0 mL each: Human serum, non-reactive for anti-Rubella IgG; preservative.
- Cal2 Positive calibrator 2 (black cap), 2 bottles of 1.0 mL each: Anti-Rubella IgG approx. 400 IU/mL in human serum; preservative.

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.

All human material should be considered potentially infectious.

The negative calibrator (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.

The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

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

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient specimen. In the event of exposure the directives of the responsible health authorities should be followed.^{8,9}

The reagents may not be used after the stated expiration date.

Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).

Reagent handling

The reagents in the kit are ready for use and are supplied in bottles compatible with the system.

Elecsys 2010 analyzer: The calibrators Cal1 and Cal2 should only be left on the analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store at 2-8°C. Ensure that no calibration solution is trapped in the opened snap-cap. Because of possible evaporation effects, not more than 5 calibration procedures per calibrator bottle set should be performed.

MODULAR ANALYTICS E170 analyzer: Unless the entire volume is necessary for calibration on the analyzers, 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 for later use at 2-8°C. Perform **only one** calibration procedure per aliquot.

All information required for correct operation is read in via the respective reagent barcodes.

Storage and stability

Store at 2-8°C.

Store the Elecsys Rubella IgG reagent kit (M, R1, R2) **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use. Stability:

| | |
|------------------------------------|--|
| unopened at 2-8°C: | up to the stated expiration date |
| M, R1, R2 after opening at 2-8°C: | 12 weeks |
| on MODULAR ANALYTICS E170, | 2 weeks or |
| Elecsys 2010: | 12 weeks if stored alternately in the refrigerator and on the analyzers (up to 84 hours) |
| Cal1, Cal2 after opening at 2-8°C: | 8 weeks |
| on Elecsys 2010 at 20-25°C: | up to 5 hours |
| on MODULAR ANALYTICS E170: | use only once |



Rubella IgG

cobas®

IgG antibodies to Rubella virus

Store the calibrators **upright!** Ensure that no calibration solution is trapped in the opened snap-cap.

Specimen collection and preparation

Only the specimens listed below were tested in a sufficient number and found acceptable.

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

Li-heparin, K₃-EDTA, and sodium citrate plasma. Do not use plasma treated with sodium fluoride and potassium oxalate.

Criterion: Mean recovery of positive samples 80-120% of serum value.

Stable for 3 weeks at 2-8°C, 3 days at 25°C, 3 months at -20°C.

The samples may be frozen 6 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.

Centrifuge samples containing precipitates and frozen samples before performing the assay. Lyophilized samples and samples and controls stabilized with azide (up to 1%) can be used. Do not use heat-inactivated samples.

Ensure the patients' samples, calibrators, and controls are at ambient temperature (20-25°C) before measurement.

Because of possible evaporation effects, samples and calibrators on the analyzers should be measured within 2 hours.

Because of possible evaporation effects, samples and calibrators on the analyzers should be measured within 2 hours.

Materials provided

See "Reagents - working solutions" section for reagents.

Materials required (but not provided)

- Cat. No. 04618807, PreciControl Rubella IgG, 8 x 1 mL each of PreciControl Rubella IgG 1 and 2
- Cat. No. 11732277, Diluent Universal, 2 x 18 mL sample diluent or Cat. No. 03183971, Diluent Universal, 2 x 40 mL sample diluent
- Cat. No. 11776576, CalSet Vials, 2 x 56 empty snap-cap bottles
- General laboratory equipment
- Elecsys 2010 or MODULAR ANALYTICS E170 analyzer

Accessories for Elecsys 2010 analyzer:

- Cat. No. 11662988, ProCell, 6 x 380 mL system buffer
- Cat. No. 11662970, CleanCell, 6 x 380 mL measuring cell cleaning solution
- Cat. No. 11930346, Elecsys SysWash, 1 x 500 mL washwater additive
- Cat. No. 11933159, Adapter for SysClean
- Cat. No. 11706802, Elecsys 2010 AssayCup, 60 x 60 reaction vessels
- Cat. No. 11706799, Elecsys 2010 AssayTip, 30 x 120 pipette tips

Accessories for MODULAR ANALYTICS E170 analyzer:

- Cat. No. 12135019, ProCell M, 1 x 2 L system buffer
- Cat. No. 12135027, CleanCell M, 1 x 2 L measuring cell cleaning solution
- Cat. No. 03023141, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- Cat. No. 03005712, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- Cat. No. 03004899, PreClean M, 5 x 600 mL detection cleaning solution
- Cat. No. 12102137, AssayTip/AssayCup Combimagazine M, 48 magazines x 84 reaction vessels or pipette tips, waste bags
- Cat. No. 03023150, WasteLiner, waste bags
- Cat. No. 03027651, SysClean Adapter M

Accessories for all analyzers:

- Cat. No. 11298500, 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 manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically before use.

Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

MODULAR ANALYTICS E170 and Elecsys 2010 analyzers: Bring the cooled reagent to approx. 20°C and place on the reagent disk (20°C) of the

analyzer. Avoid the formation of foam. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Place the calibrators Cal1 and Cal2 in the sample zone of the analyzers.

Only keep open during calibration. All information necessary for calibration is encoded on the barcoded bottle labels and is read in automatically.

After calibration has been performed, store Cal1 and Cal2 at 2-8°C or discard (MODULAR ANALYTICS E170 analyzer).

After calibration has been performed, store Cal1 and Cal2 at 2-8°C or discard (MODULAR ANALYTICS E170 analyzer).

Calibration

Traceability: This method has been standardized against the 1st International Standard for Anti-Rubella Immunglobulin, human, code RUBI-1-94, from the National Institute for Biological Standards and Control (NIBSC), Hertfordshire, UK, formerly referred to as proposed 3rd WHO Reference Standard Preparation.

Every Elecsys Rubella IgG reagent set has a barcoded label containing the specific information for calibration of the particular reagent lot.

The predefined master curve is adapted to the analyzer by the use of Elecsys Rubella IgG Cal1 and Cal2.

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

Renewed calibration is recommended as follows:

- after 1 month (28 days) when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings with Elecsys PreciControl Rubella IgG outside the specified limits
- more frequently when this is required by pertinent regulations

Quality control

For quality control, use Elecsys PreciControl Rubella IgG.

The controls 1 and 2 should be run as single determinations at least once every 24 hours when the test is in use, once per reagent kit, and after every calibration. The control intervals and limits should be adapted to each laboratory's individual requirements. Results must be within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

If necessary, repeat the measurement of the samples concerned.

Calculation

The analyzer automatically calculates the analyte concentration of each sample in IU/mL.

Interpretation of the results

Results obtained with the Elecsys Rubella IgG assay can be interpreted as follows:

Non-reactive: < 10 IU/mL

Reactive: ≥ 10 IU/mL

The NCCLS subcommittee on Rubella Serology recommended 10 IU/mL as the cutoff level.⁶

A result < 10 IU/mL is considered to be non-reactive.

A result ≥ 10 IU/mL is considered to be positive for IgG antibody to Rubella virus.

The presence of IgG antibodies to Rubella virus is an indication of previous exposure to the virus, either by prior infection or by vaccination.

The anti-Rubella IgG result in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay and reagent methods.

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."

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 Rubella IgG antibody titer from a first to a second sample.

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 Rubella IgG antibodies or may have an antibody concentration < 10 IU/mL.

The presence of IgG antibodies in a single sample is not sufficient to distinguish between an acute or past infection.



Rubella IgG

IgG antibodies to Rubella virus

The lack of a significant increase of the Rubella IgG antibody titer (e.g. within 3-4 weeks) may not completely exclude acute Rubella infection.

When monitoring the Rubella-specific IgG antibody 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 assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 3.47 mmol/L or < 5.6 g/dL), lipemia (Intralipid < 1500 mg/dL), and biotin < 205 nmol/L or < 50 ng/mL.

Criterion: Mean recovery of positive samples within ± 20% of initial value.

In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 6210 IU/mL.

There was no high-dose hook effect^b observed with the Elecsys Rubella IgG assay in a panel of n = 33 samples.

In vitro tests were performed on 18 commonly used pharmaceuticals and in addition on folic acid. No interference with the assay was found.

As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes.

In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur.

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

b) High-dose hook effect: A sample with a true concentration clearly above the measuring range, but found within the measuring range.

Measuring range

0.17-500 IU/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 0.17 IU/mL. Values above the measuring range are reported as > 500 IU/mL (or up to 10.000 IU/mL for 20-fold diluted samples).

Dilution

Samples with anti-Rubella concentrations above the measuring range can be diluted with Elecsys Diluent Universal. The recommended dilution is 1:20 (either automatically by the MODULAR ANALYTICS E170 and Elecsys 2010 analyzers or manually). The concentration of the diluted sample must be > 10 IU/mL. After manual dilution, multiply the result by the dilution factor. After dilution by the analyzers, the MODULAR ANALYTICS E170 and Elecsys 2010 software automatically takes the dilution into account when calculating the sample concentration.

Manual dilution can also be performed using human serum negative for IgG antibodies to Rubella.

Note: Antibodies to Rubella are heterogenous. This may lead to non-linear dilution behavior.

Expected values

The Elecsys Rubella IgG assay was used to test 560 samples from clinical routine in France (site 1) and 1000 samples from clinical routine in Germany (site 2). A distribution of these values is given in the following table.

| IU/mL | Site 1, France, n = 560 | | Site 2, Germany, n = 1000 | |
|-----------|-------------------------|------------|---------------------------|------------|
| | N | % of total | N | % of total |
| < 5 | 32 | 5.7 | 19 | 1.9 |
| 5-< 10 | 5 | 0.9 | 2 | 0.2 |
| 10-<20 | 13 | 2.3 | 12 | 1.2 |
| 20-< 50 | 34 | 6.1 | 47 | 4.7 |
| 50-< 100 | 56 | 10.0 | 82 | 8.2 |
| 100-< 300 | 244 | 43.6 | 541 | 54.1 |
| 300-< 500 | 105 | 18.8 | 151 | 15.1 |
| > 500 | 71 | 12.7 | 146 | 14.6 |

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

Reproducibility was determined using Elecsys reagents, human sera, and controls (within-run n = 21, between-run n = 10); total precision on MODULAR ANALYTICS E170 analyzer was determined in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute; formerly NCCLS): 6 times daily for 10 days (n = 60). The following results were obtained:

| Elecsys 2010 Sample | Within-run precision | | | Between-run precision | | |
|-------------------------------|----------------------|-------------|---------|-----------------------|-------------|---------|
| | Mean IU/mL | SD IU/mL | CV % | Mean IU/mL | SD IU/mL | CV % |
| HS ^c , negative | 0.000 | - | - | 0.000 | - | - |
| HS, weakly positive | 72.9 | 1.40 | 1.9 | 68.5 | 2.61 | 3.8 |
| HS, positive | 476 | 12.0 | 2.5 | 458 | 15.4 | 3.4 |
| PC ^d Rubella IgG 1 | 3.57 | 0.075 | 2.1 | 3.62 | 0.232 | 6.4 |
| PC Rubella IgG 2 | 67.0 | 1.07 | 1.6 | 69.0 | 2.49 | 3.6 |

c) HS = human serum

d) PC = PreciControl

| MODULAR ANALYTICS E170 Sample | Within-run precision | | | Total precision | | |
|-------------------------------------|----------------------|-------------|---------|-----------------|-------------|---------|
| | Mean IU/mL | SD IU/mL | CV % | Mean IU/mL | SD IU/mL | CV % |
| HS, negative | 0.000 | - | - | 0.000 | - | - |
| HS, weakly positive | 62.8 | 1.64 | 2.6 | 68.7 | 2.28 | 3.3 |
| HS, positive | 427 | 4.82 | 1.1 | 485 | 15.5 | 3.2 |
| PC Rubella IgG 1 | 3.61 | 0.074 | 2.1 | 3.54 | 0.153 | 4.3 |
| PC Rubella IgG 2 | 72.0 | 0.748 | 1.0 | 67.7 | 2.21 | 3.3 |

Analytical sensitivity

0.17 IU/mL

The detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the negative calibrator (negative calibrator + 2 SD, within-run precision, n = 21).

Clinical sensitivity

Acute Rubella infection

Of 98 samples from 71 patients with primary Rubella infection (including early and late acute phase), 61 samples were found positive with the Elecsys Rubella IgG assay and 37 samples were found negative.

Rubella vaccination

231 samples from 61 individuals vaccinated against Rubella infection were examined with the Elecsys Rubella IgG assay and a comparison test. The average time interval to the first positive bleed was 14.1 days with the Elecsys Rubella IgG assay and 19.7 days with the comparison assay.

Method comparison

A total of 1559 fresh samples obtained from clinical routine (antenatal screening) and 989 pre-selected frozen samples were tested at 4 different sites in comparison to commercially available Rubella IgG assays. Discordant results were re-tested by a third commercial Rubella IgG test.

10 specimens with indeterminate results in one of the assays and 3 samples which could not be retested were excluded from the final calculation of sensitivity and specificity (7 samples at site 1, 4 samples at site 2 and 2 samples at site 3). Relative sensitivity and specificity after resolution

| Study | N | Relative sensitivity (%) | Lower confidence limit (%) | Relative specificity (%) | Lower confidence limit (%) |
|-------|-----|--------------------------|----------------------------|--------------------------|----------------------------|
| 1 | 552 | 100 (514/514) | 99.4 | 97.4 (37/38) | - |
| 2 | 996 | 99.9 (997/978) | 99.5 | 100 (18/18) | - |
| 3 | 198 | 100 (120/120) | 97.5 | 100 (78/78) | 96.2 |
| 4 | 789 | 100 (20/20) | - | 100 (769/769) | 99.6 |

Site 1: Of 17 samples which were initially discordant positive with the Elecsys Rubella IgG assay, 16 samples were also found positive by a third commercial Rubella IgG test.



Rubella IgG

cobas®

IgG antibodies to Rubella virus

Site 2: Of 2 samples which were initially discordant negative with the Elecsys Rubella IgG assay, 1 sample was also found negative by a third commercial Rubella IgG test.

Site 4: Of 20 samples which were initially discordant positive with the Elecsys Rubella IgG assay, 20 samples were also positive by a third commercial Rubella IgG test.

References

1. Pustowitz B, Liebert UG. Predictive Value of Serological Tests in Rubella Virus Infection during Pregnancy. *Intervirology* 1998;41:170-177.
2. Cooper LZ, Alford CA. Rubella, in *Infectious Diseases of the Fetus & Newborn Infant*, 5th Ed 2001, pp 347-88, ed Remington JS & Klein JO, Philadelphia: W.B. Saunders.
3. Banatvala JE, Brown DWG. Rubella. *Lancet* 2004;363:1127-1137.
4. Best JM, Banatvala JE. Rubella Principles and Practice of Clinical Virology, 4th edition, ed by Zuckerman AJ, Banatvala JE and Pattison JR 2000:387-418, John Wiley & Sons, Ltd.
5. Pustowitz B, Grangeot-Keros L, Hobman TC, Hofmann J. Evaluation of recombinant rubella-like particles in a commercial immunoassay for the detection of anti-rubella IgG. *Clin Diagn Virol* 1996;5:13-20.
6. Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline. NCCLS document I/LA6-A (ISBN 1-56238-335-3. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 1997.
7. Skendzel L. Rubella Immunity. Defining the Level of Protective Antibody. *Am J Clin Pathol* 1996;106:170-174.
8. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). *Fed. Register*. July 1, 2001;17:260-273.
9. Council Directive (2000/54/EC). *Official Journal of the European Communities* No. L262 from Oct. 17, 2000.

NOTICE TO PURCHASER: LIMITED LICENSE

The purchase of this product allows the purchaser to use it solely for detection by ECL Technology for human in vitro diagnostic uses. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby. This product may not be used by purchaser to conduct life science research and/or development, patient self-testing, drug discovery and/or development or in any veterinary, food, water or environmental testing or use.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information, and the package inserts of all necessary components.

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.

COBAS, ELECSYS and MODULAR are trademarks of Roche. Other brand or product names are trademarks of their respective holders. INTRALIPID is a trademark of Fresenius Kabi AB. Significant additions or changes are indicated by a change bar in the margin. Changes to reagent barcode test parameters which have already been read in should be edited manually. ©2006 Roche Diagnostics.

CE 0123

Roche Diagnostics GmbH, D-68298 Mannheim
for USA: US Distributor:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336

