Access
Immunoassay Systems

RUBELLA IgM

REF A32937

Intended Use

The Access Rubella IgM assay is a paramagnetic particle, chemiluminescent immunoassay for the qualitative detection of anti-Rubella virus IgM in human serum using the Access Immunoassay Systems.

Summary and Explanation

Rubella virus is a member of the Togavirus family. In contrast to the majority of togaviruses, rubella virus has no known invertebrate host. Man is the only known natural reservoir for the rubella virus.[1]

The rubella virus is spread through inhalation of virus-containing droplets from the respiratory secretions of infected persons.[2] Following transmission, the rubella virus replicates in the mucosa of the upper respiratory tract and the lymphoid tissue of the nasopharynx. Rubella virus replication in these tissues causes prodromal enlargement of the posterior and occipital lymph nodes, which typically begins 5–10 days before the onset of a rash.[1,3] Rubella virus is spread via the lymphatics and/or through a transient viremia.[3] Following an incubation period of 7–9 days, the virus appears in serum and is shed into the nasopharynx and stool. A maculopapular rash appears at 16–21 days after natural exposure. Viremia is no longer detectable at this stage of disease, which coincides with the appearance of detectable circulating antibodies. Mononuclear cell-borne viremia and virus in nasopharyngeal secretions, however, can be detected for a week or longer following disappearance of the rash.[1,3] Rubella virus infection in children or adults is typically mild. Rubella infection is characterized by a combination of symptoms that may include a maculopapular rash, lymphadenopathy, fever, conjunctivitis, sore throat, and joint pain.[1,3] In the majority of cases, the rash is the first symptom to present, appearing on the face and rapidly spreading to the trunk, arms, and legs. The rash normally disappears in one to three days. In rare cases, arthropathy, thrombocytopenia, and encephalopathy may occur.[1,3]

The level of severity associated with rubella virus infection is primarily governed by age. Postnatal rubella is generally a harmless infection. Disease in children tends to be milder than disease in adults. The fetus, however, is at high risk of developing severe, lasting rubella-induced complications if infection occurs via the placenta during maternal rubella infection in early pregnancy.[2] Such intrauterine infections, particularly during the first four months of pregnancy, can lead to Congenital Rubella Syndrome with consequences that may include deafness, cardiac problems, cataracts or glaucoma, and fetal death. The effects on the fetus vary based on the time of infection. Generally, the younger the fetus, the more severe the disease.[2,3]

An effective rubella vaccine has been available since the late 1960s. Comprehensive vaccination programs utilized in the U.S. and other countries have been successful in reducing the incidence of natural rubella. Alternate vaccination strategies in other countries have not been as successful, however, and some countries continue to be affected by the occurrence of natural rubella infection.[1]

The diagnosis of an acute rubella virus infection is based on several clinical and serological parameters.

- The presence of IgM and/or IgG class antibodies.
- A significant increase in the titer of anti-rubella virus IgG between two samples collected at an interval of at least two weeks.
- The appearance of classical symptoms, especially the well-defined rash.

The main indications for the detection of specific IgM are:

- An aid in the determination of an acute rubella virus infection.
- Follow-up of pregnant women without protective antibodies (IgG to the rubella virus), since rubella virus infections are often clinically unapparent. The serological follow-up may allow the early detection of a seroconversion and the potential infection of the fetus.

Principles of the Procedure

The Access Rubella IgM assay is an immunoenzymatic assay that utilizes the immunocapture principle. A sample is added to a reaction vessel with paramagnetic particles coated with polyclonal antibody to human IgM (sheep). After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. In the second incubation a complex of rubella virus antigen and Rubella specific monoclonal antibody labeled with alkaline phosphatase is added to the reaction vessel. After the incubation and washing step, the chemiluminescent substrate Lumi-Phos* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is proportional to the amount of enzyme conjugate present at the end of the reaction. The presence of specific IgM in the sample is determined by means of a fitted multi-point calibration curve standardized against a clinically defined reference preparation (titration in hemagglutination inhibition test (HAI) after ultracentrifugation).

The curve is expressed in arbitrary units (AU/mL). The valid calibration curve remains stored on the instrument.

Product Information

Access Rubella IgM Reagent Pack

Cat. No. A32937: 100 determinations, 2 packs, 50 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 28 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.

R1a:	Paramagnetic particles coated with a polyclonal anti-human IgM antibody (sheep) suspended in TRIS buffered saline, with surfactant, proteins (bovine), < 0.1% sodium azide, and 0.1% ProClin** 300.
R1b:	Inactivated rubella antigen - monoclonal antibody (mouse) to Rubella virus complex/alkaline phosphatase (bovine) conjugate in TRIS buffered saline with surfactant, proteins (bovine, murine), < 0.1% sodium azide, and 0.3% ProClin 300.
R1c:	TRIS buffered saline with surfactant, < 0.1% sodium azide and 0.1% ProClin 300.
R1d:	Diluent: TRIS buffered saline with surfactant, proteins (bovine, human), < 0.1% sodium azide, and 0.2% ProClin 300.
R1e:	Diluent: TRIS buffered saline with surfactant, proteins (bovine, human), < 0.1% sodium azide, and 0.2% ProClin 300.

Note: Rubella virus antigen has been chemically inactivated (agent: β-propiolactone)

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[4]
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[5]
- Xi. Irritant: 0.3% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Specimen Collection and Preparation

1. Serum is the recommended sample.
2. Observe the following recommendations for handling, processing, and storing blood samples:[6]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation.
   - Centrifuge the samples.
   - Keep tubes stoppered at all times.
   - Store samples tightly stoppered at room temperature (20 to 25°C) for no longer than eight hours.
   - If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C or colder.
3. Use the following guidelines when preparing specimens:
   - In general, allow 1 hour for serum samples to clot completely.
   - All samples stored longer than 8 hours should be centrifuged at 3000 g for 15 minutes prior to testing.
   - Follow blood collection tube manufacturer's recommendations or validated laboratory procedures for centrifugation.
4. Ensure fibrin and cellular matter have been removed prior to analysis. Turbid serum samples containing particulate matter should be transferred from the original tube and re-centrifuged prior to assay. A specimen (original tube) that contains a separating device (gel barrier) is never to be re-centrifuged.[6]
5. Avoid repeated freezing and thawing of samples. Thaw samples no more than four times.
6. Avoid using grossly hemolyzed or cloudy samples.
7. Avoid the use of heat treated samples.

Materials Provided

R1 Access Rubella IgM Reagent Packs

Materials Required But Not Provided

1. Access Rubella IgM Calibrators
   Provided at zero and approximately 5, 15 and 60 AU/mL.
   Cat. No. 34445
2. Access Rubella IgM QC (Quality Control) or other commercially available quality control material.
   Cat. No. 34449
3. Access Substrate
   Cat. No. 81906
4. **Access, Access 2, SYNCHRON LXi:**
   Access Wash Buffer II, Cat. No. A16792
   UniCel DxI:
   UniCel DxI Wash Buffer II, Cat. No. A16793

Procedural Comments

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use twenty (20) µL of sample for each determination in addition to the sample container and system dead volumes. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The first result is obtained in 75 minutes.

Procedure

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

Calibration Details

An active calibration curve is required for all tests. For the Access Rubella IgM assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Quality Control

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[7] Include Access Rubella IgM QC or other commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

Results

Patient test results are determined automatically by the system software using a smoothing spline math model. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Patient test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

Note: Results are expressed in arbitrary units (AU/mL).

The determination of anti-Rubella IgM, using the Access Rubella IgM assay, determines the patient immune status:

- Sera with a titer < 10 AU/mL is non-reactive (not significant) and makes a recent infection by Rubella virus unlikely.
- Sera with titers ≥ 10 and < 15 AU/mL are equivocal.
- Sera with titers ≥ 15 AU/mL are reactive for anti-Rubella IgM.

A possible seroconversion must be confirmed by the quantitative examination of a specific IgG and retesting for IgM and IgG at least 15 days later.

For non-reactive or equivocal samples, if exposure to the virus is suspected, a second sample should be collected at least 15 days after the onset of rash and tested for rubella IgM.

Limitations of the Procedure

1. Samples can be measured within the reportable range of 0–60 AU/mL.
   - If a sample contains more than the stated value of the highest Access Rubella IgM Calibrator (C3), report the result as greater than that value (i.e., > 60 AU/mL).
2. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples.[8,9]

   Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
3. The Access Rubella IgM results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
4. The presence of anti-Rubella IgM does not always indicate a recent infection, because IgM can persist for many months, or even for several years after infection. IgM presence indicates the need for quantitative examination of anti-Rubella IgG.[10]
5. If a collection is made too early during the beginning of a primary infection specific antibodies of IgM class may be absent. To confirm a primary infection, a second collection must be performed 15 days later and the IgM repeated.
6. IgM anti-rubella has not been validated for use on fetal blood.

Expected Values

The prevalence of rubella infection can vary depending on factors including age, gender, vaccination history, geographic location, socio-economic status, race, type of test used, specimen collection and handling procedures, and clinical and epidemiological history of individual patients. It is recommended that each laboratory determine its own prevalence results based upon its diagnostic patient population.[1]

Specific Performance Characteristics

Negative Agreement

A study was conducted at one internal site (France) on non-selected serum samples collected from a geographically diverse population including pregnant women (n = 226), blood donors (n = 2200) and hospital patients (n = 1033). Each specimen was tested using the Access Rubella IgM immunoassay and another commercially available assay.

The negative agreement for the final qualitative interpretation for the Access Rubella IgM assay versus the final qualitative interpretations for the commercially available assay was as follows:

Non-Selected Pregnant Women

The negative agreement of the Access Rubella IgM assay when compared to the commercially available assay was 100% (226/226); 95% Confidence Interval: 98.7% to 100.0%.

Non-selected Blood Donors

The negative agreement of the Access Rubella IgM assay when compared to the commercially available assay was 99.86% (2145/2148); 95% Confidence Interval: 99.6% to 100%.

Non-Selected Hospital Patients

The negative agreement of the Access Rubella IgM assay when compared to the commercially available assay was 99.60% (1005/1009); 95% Confidence Interval: 99.0% to 99.9%.

Positive Agreement

Positive agreement was determined by testing samples that were found positive in a reference assay and tested in the Access Rubella IgM assay. A total of 64 positive serum samples were tested with the Access Rubella IgM assay and a reference assay. The positive agreement on this population was found to be 100% (95% CI: 95.6% to 100.0%).

Imprecision

This assay exhibits total imprecision of less than 15% for reactive samples.

Intra-Assay

The intra-assay precision was determined by testing five different patient samples 30 times in the same run during one day. The results of this study are shown below:

Sample	Mean (AU/mL)	SD (AU/mL)	%CV
1 (neg)	0.1	0.03	N/A†
2	9.3	0.8	8.6
3	15.4	1.6	10.4
4	33.5	1.2	3.6
5	46.5	1.9	4.1

†Due to low dose value (AU/mL), %CV is not applicable.

Inter-Assay

The inter-assay precision was determined by testing five different patient samples in duplicate for 20 days, 2 runs per day. The results of this study are shown below:

Sample	Mean (AU/mL)	SD (AU/mL)	%CV
1 (neg)	0.1	0.07	N/A†
2	10.8	1.1	10.2
3	15.6	1.5	9.6
4	34.0	1.8	5.3
5	46.0	1.9	4.1

†Due to low dose value (AU/mL), %CV is not applicable.

Analytical Specificity/Interferences

Samples containing up to 90 g/L albumin, up to 300 mg/L bilirubin (100 mg/L free and 200 mg/L conjugated), 30 g/L triolein and 5 g/L hemoglobin do not affect the concentration of Rubella IgM assayed.

The following samples, non-reactive on a commercially available assay, were evaluated and found non-reactive in the Access Rubella IgM assay indicating an absence of cross reactivity and/or non-specific reactivity with these specimens.

Pathology	n	Reactive	Non-Reactive
Epstein Barr IgM	10	0	10
HSV IgM	10	0	10
Toxo IgM	10	0	10
Rubella IgG	10	0	10
HIV	11	0	11
CMV IgM	10	0	10
Measles IgM	10	0	10
Myeloma IgM	4	0	4
VZV	10	0	10
HAV	10	0	10
HBV	10	0	10
HCV	10	0	10
Syphilis	10	0	10
Mumps IgM	2	0	2
Rheumatoid Factor	10	0	10
ANA	10	0	10
Flu vaccine	10	0	10
HAMA	10	0	10
Total	167	0	167

Access
Immunoassay Systems

RUBELLA IgM CALIBRATORS

REF 34445

Intended Use

The Access Rubella IgM Calibrators are intended for use with the Access Rubella IgM assay for the detection of anti-Rubella virus IgM in human serum using the Access Immunoassay Systems.

Summary and Explanation

The Access Rubella IgM Calibrators are used to establish calibration (determine the cut-off value) for the Access Rubella IgM assay. By comparing the light intensity generated by a sample to the cut-off value, it is possible to determine the presence or absence of anti-Rubella IgM antibody in the sample.

Traceability

The measurand (analyte) in the Access Rubella IgM Calibrators is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Product Information

Access Rubella IgM Calibrators

Cat. No. 34445: C0–C3, 1.0 mL/vial

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Open vial stability is typically until the expiration date stated on the vial labels when properly handled and stored.
- Signs of possible deterioration are quality control values out of range.
- Refer to calibration card for exact concentrations.

C0:	Negative human defibrinated plasma (0 AU/mL) for anti-Rubella virus IgM containing < 0.1% sodium azide.
C1, C2, C3:	Positive human defibrinated plasma with approximately 5, 15 and 60 AU/mL anti-Rubella virus IgM, and < 0.1% sodium azide.
Calibration Card:	1

Warnings and Precautions

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[4]
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[5]

- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Calibration Details

The Access Rubella IgM Calibrators are provided at four levels – zero and approximately 5, 15 and 60 AU/mL – prepared from human defibrinated plasma, negative and positive for anti-Rubella virus IgM. The Access Rubella IgM Calibrators are titrated in antibody units (AU); standardization is performed against a clinically defined reference preparation.

One calibration for the Access Rubella IgM assay requires approximately 150 µL (4 drops/sample cup) of each of the four levels. Calibrators run in duplicate. Refer to the appropriate system manuals and/or Help system for minimum sample volume required.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

Access
Immunoassay Systems

RUBELLA IgM QC

REF 34449

Intended Use

The Access Rubella IgM QC is intended for monitoring system performance of the Access Rubella IgM assay.

Summary and Explanation

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access Rubella IgM immunoassay. In addition, they are an integral part of good laboratory practices.[7,11,12,13,14,15] One negative and one low level positive quality control are provided to allow performance monitoring in the most relevant areas of the assay range. The assayed values should fall within the acceptable range if the test system is working properly.

Traceability

The measurand (analyte) in the Access Rubella IgM QC is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of QC and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Product Information

Access Rubella IgM QC

Cat. No. 34449: 2.5 mL/vial, 3 vials each level

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- After initial use, vials are stable for 30 days when correctly handled and stored.
- Signs of possible deterioration are quality control values out of range.
- Refer to the QC value card for mean values and standard deviations (SD).

QC 1:	Human defibrinated plasma with < 0.1% sodium azide; negative (non-reactive) for anti-Rubella IgM.
QC 2:	Human defibrinated plasma with < 0.1% sodium azide; positive (reactive) for anti-Rubella IgM.
QC Value Card:	1

Warnings and Precautions

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[4]

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[5]
- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Determine the concentration of anti-Rubella virus IgM in the Access Rubella IgM QC materials using the Access Immunoassay Systems in the same manner as a patient sample. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[7] More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Twenty (20) µL of sample is used for each determination in addition to the sample container and system dead volume. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring quality controls, quality control sample test request entry, and reviewing quality control data.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

Expected Values

For the value assignment of the Access Rubella IgM QC material, a number of samples, representative of the entire lot, are selected and assayed to provide a reliable estimate of the mean value. The mean values and standard deviations are listed on the QC value card. Variations such as in technique, equipment, or reagents may result in values different from those listed. Therefore, each laboratory should establish its own mean values and standard deviations (SD).[15,16]

References

1 Wolinsky JS. Rubella. In: Fields BN, et al, editors. Virology. 2nd ed. New York: Raven Press; 1990. 815-838.

2 Gershon A. Rubella virus (German measles). In: Mandell GL, et al, editors. Principles and practice of infectious disease. 3rd ed. New York: Churchill Livingstone, Inc.; 1990. 1242–1247.

3 Wiedbrauk DL, Johnston SLG. Manual of clinical virology. New York: Raven Press; 1993.

4 HHS Publication, 4th ed., April 1999. Biosafety in Microbiological and Biomedical Laboratories. Available http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

5 DHHS (NIOSH) Publication No. 78–127, August 1976. Current Intelligence Bulletin 13 - Explosive Azide Hazard. Available http://www.cdc.gov/niosh.

6 Approved Guideline – Procedures for the Handling and Processing of Blood Specimens, H18-A3. 2004. Clinical and Laboratory Standards Institute.

7 Cembrowski GS, Carey RN. Laboratory quality management: QC⇌QA. ASCP Press, Chicago, IL, 1989.

8 Kricka L. Interferences in immunoassays – still a threat. Clin Chem 2000; 46: 1037–1038.

9 Bjerner J, et al. Immunometric assay interference: incidence and prevention. Clin Chem 2002; 48: 613–621.

10 Pattison JR, Dane DS, Mace JE. Persistence of specific IgM after natural infection with rubella virus. Lancet 1975; 1: 185–187.

11 Broome HE, Cembrowski GS, Kahn SN, Martin PL, Patrick CA. Implementation and use of a manual multi-rule quality control procedure. Lab Med 1985; 16: 533–537.

12 Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem 1981; 27: 493–501.

13 Koch DD, Oryall JJ, Quam EF, Feldbruegger DH, et al. Selection of medically useful QC procedures for individual tests done in a multitest analytical system. Clin Chem 1990; 36: 230–233.

14 Mugan K, Carlson IH, Westgard JO. Planning QC procedures for immunoassays. J Clin Immunoassay 1994; 17: 216–222.

15 Approved Guideline – Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, C24-A3. June 2006. Clinical and Laboratory Standards Institute.

16 Garret PE. Quality is quantitative: so how do we QC qualitative tests. J Clin Immunoassay 1994; 17 (4): 231.

Manufactured for:
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Brea, CA 92821 U.S.A.

EC REP
Beckman Coulter Ireland Inc.
Mervue Business Park,
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Ireland 353 91 774068

Printed in U.S.A.
Made in France
Revised September 2011

CE 0459