BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access Rubella IgG QC
Rubella Antibody, IgG

REF 34439

FOR PROFESSIONAL USE ONLY

Rx Only

PRINCIPLE

CAUTION

For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

INTENDED USE

The Access Rubella IgG QC is intended for monitoring system performance of the Access Rubella IgG 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 IgG immunoassay. The use of quality control materials is indicated for detecting and potentially resolving critical testing errors due to test kits, personnel and instrumentation and is an integral part of good laboratory practices.[1,2,3,4,5,6,7] When performing assays with Access reagents for IgG antibodies to the rubella virus, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly. One negative and one low positive control level are provided to allow performance monitoring in the most relevant areas of the assay range.

TRACEABILITY

The measurand (analyte) in the Access Rubella IgG QC is traceable to WHO Second International Standard Preparation for Anti-Rubella Serum (2nd ISP). 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.

REAGENTS

PRODUCT INFORMATION

Access Rubella IgG QC

Ref. No. 34439: 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.

- Open vial stability is typically until the expiration date stated on the vial label when properly stored and handled.
- Signs of possible deterioration are 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; contains no detectable level of anti-rubella IgG as assayed using the Access Rubella IgG assay.
QC 2:	Human defibrinated plasma with < 0.1% sodium azide; contains a low level of anti-rubella IgG (target mean of 22-43 IU/mL) as assayed using the Access Rubella IgG assay.
QC Value Card:	1

WARNING 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.[8]
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

TESTING PROCEDURE(S)

PROCEDURE

Determine the concentration of IgG antibodies to the rubella virus in the Access Rubella IgG QC materials using the Access Immunoassay System 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.[1] 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. Refer to the appropriate system manuals and/or Help system for information on quality control theory, configuring controls, quality control sample test request entry, and reviewing quality control data.

REPORTING RESULTS

EXPECTED RESULTS

The expected means and standard deviations for the Access Rubella IgG QC controls (QC1 and QC2) are provided on the QC value card contained in the kit for initial Access Rubella IgG assay quality control system configuration. Each laboratory should establish its own acceptability criteria by selecting the QC rules to be applied to the control results. Individual control results should fall within the initial acceptable range, however, each laboratory should update the mean and SD after sufficient data has been collected.[6,7]

PROCEDURAL NOTES

LIMITATIONS

1. Controls must be run within the 24 hour period prior to running patient samples. Include any additional controls if required for the laboratory's quality control program as guided by the appropriate regulatory agencies.
2. Use controls in accordance with the appropriate accrediting organizations' requirements (for appropriate definitions of QC in the U.S.A., refer to CLSI documents C24-A3, I/LA18-A2, and I/LA6-A). Users should refer to the appropriate system manuals and/or Help system for instructions on the use of the Quality Control functions and for selection of QC rules.
3. In the U.S.A., it is suggested that a 1–3s QC rule be used for a low level reactive control.
4. 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.
5. If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

ADDITIONAL INFORMATION

REVISION HISTORY

Revision D

IFU updated to change copyright, add revision history and add patent statement.

Revision E

Updated "Reagents" section.

Updated "Additional Information" section.

Revision F

Updated "Principle" section.

Updated "Reagents" section.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

REFERENCES

1. Cembrowski GS, Carey RN. Laboratory quality management: QC ⇌ QA. ASCP Press, Chicago, IL, 1989.
2. 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.
3. 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.
4. 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.
5. Mugan K, Carlson IH, Westgard JO. Planning QC procedures for immunoassays. J Clin Immunoassay 1994; 17:216-222.
6. Approved Guideline - Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, C24-A3. June 2006. Clinical and Laboratory Standards Institute.
7. Garrett PE. Quality is quantitative: so how do we QC qualitative tests? J Clin Immunoassay 1994; Vol 17, No. 4: 231.
8. HHS Publication, 5th ed., December 2009. Biosafety in Microbiological and Biomedical Laboratories.

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