



QUIDEL

MicroVue™ Complement CIC-C1q CONTROLS

Control specimens for use in the CIC-C1q EIA Kit for measurement of Circulating Immune Complexes

For *in vitro* diagnostic use

Rx ONLY

A symbols glossary can be found at quidel.com/glossary

CONTENTS

One vial each of Low (Normal) and High (Abnormal) Control with volumes sufficient for single use. Each Control consists of human serum with heat-aggregated gamma globulins (HAGG).



INTENDED USE

The CIC-C1q Controls are intended for use as controls in the MicroVue CIC EIA. This assay is for the detection and quantitation of circulating immune complexes in human serum or plasma.

SUMMARY AND EXPLANATION

Elevated circulating immune complexes (CIC) have been detected in serum or plasma obtained from patients with a variety of diseases, for example, from patients with autoimmune disorders, leukemia, various cancers, bacterial or viral infections. CIC determinations can be important in the diagnosis or prognosis of certain diseases (e.g., SLE¹ and rheumatoid arthritis²). Several immunological techniques such as the Raji Cell assay, C1q deviation test, conglutinin test, fluid phase C1q binding procedures, rheumatoid factor assay, PEG precipitin test, and solid-phase C1q assays have been described to detect or quantitate CIC.^{3,4} The MicroVue CIC EIA uses human C1q in the solid phase to capture CIC.

REAGENTS AND MATERIALS PROVIDED

The MicroVue CIC-C1q Controls Kit contains the following:

- | | | | |
|----------|---|-------------------|---------------|
| L | CIC-C1q Low Control | Part A2774 | 0.1 mL |
| | Contains low levels of HAGG in human serum, 20 mM EDTA, 0.01% Thimerosal. | | |
| H | CIC-C1q High Control | Part A2775 | 0.1 mL |
| | Contains low levels of HAGG in human serum, 20 mM EDTA, 0.01% Thimerosal. | | |

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer (60 minute range)
- MicroVue CIC-C1q Enzyme Immunoassay Kit

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Follow Universal Precautions when handling contents of this kit and any patient samples.
- Use the supplied reagents as an integral unit prior to the expiration date indicated on the package label.
- Store controls as indicated.

- Thimerosal is used as a preservative. Incidental contact with or ingestion of buffers or reagents containing thimerosal can lead to increased hypersensitivity reactions including irritation to the skin, eyes, or mouth. Seek medical attention if symptoms are experienced. Exposure to thimerosal may have potential mutagenic effects. Avoid contact with strong acids and bases.
- Avoid microbial or cross-contamination of the Controls.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory regulations.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.⁵
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE

Controls are shipped on dry ice and must be stored at -20°C or below. The Controls should be used on the day of thawing; they should be kept cold until ready to use.

PROCEDURE

One set of Controls, i.e., one Low and High Control, should be tested at least once on each CIC microassay plate. More frequent testing per plate is optional. Each Control should be diluted 1:50 in the Complement Specimen Diluent provided with the MicroVue CIC-C1q EIA kit. Determination of the CIC concentration in the Controls is accomplished using the protocol defined in the package insert of the MicroVue CIC-C1q EIA kit. If desired, the presence of CIC in these Controls can also be confirmed by following the Confirmation Procedure described in the same Package Insert.

QUALITY CONTROL

The quality control ranges printed on the CIC-C1q Low and High Controls Certificate of Analysis (CoA) were obtained at Quidel Corporation. The control values are intended to verify the validity of the curve and sample results. Each laboratory should establish its own parameters for acceptable assay limits, as results obtained by each laboratory may differ. If the control values are NOT within your laboratory's acceptance limits, the results should be considered questionable, and the samples should be repeated.

Certain users may wish to employ these controls in other CIC assays. For those individuals, the expected Low or High designations may not be in agreement with the user's assay calibrators since the process of preparation and value assignment may differ. No warranty is made or implied if these Controls are used in test kits other than the MicroVue CIC-C1q EIA kit.

INTERPRETATION OF RESULTS

The CIC $\mu\text{g Eq/mL}$ obtained for the Low and High Controls should fall within the range. If the calculated value of either vial does not fall within the specified range, then do not use the results.

PERFORMANCE CHARACTERISTICS

The range of expected microgram equivalents per milliliter ($\mu\text{g Eq/mL}$) of CIC present in the Controls, when assayed with the MicroVue CIC kit, is shown on the certificate of analysis.

ASSISTANCE

To place an order or for technical support, please contact a Quidel representative at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 8:00 a.m. to 5:00 p.m., Eastern time. Orders may also be placed by fax at 740.592.9820. For e-mail support contact customerservice@quidel.com or technicalsupport@quidel.com.

For services outside the U.S.A., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com.

REFERENCES

1. Abrass, C.K., Nies, K.M., Louie, J.M., Border, W.A., Glassock, R.J., Correlation and Predictive Accuracy of Circulating Immune Complexes with Disease Activity in Patients with Systemic Lupus Erythematosus, *Arthritis Rheum.*, Vol. 23, p. 273, 1980.
2. Duquesnoy, B., Circulating Immune Complexes and Complement in Rheumatoid Arthritis, *Ann. Biol. Clin.*, Vol. 42, p. 71, 1984.
3. McDougal, J.S., McDuffie, F.C., Immune Complexes in Man: Detection and Clinical Significance, *Advances in Clinical Chemistry*, Vol. 24, p. 1, 1985.
4. Theofilopoulos, A.N., The Raji, Conglutinin, and Anti-C3 Assays for the Detection of Complement-Fixing Immune Complexes, *Methods in Enzymology*, Vol. 74, p. 5111, 1981.
5. Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. *MMWR* 1987;36 (suppl no. 2S):001.

REF

A013 – MicroVue CIC-C1q Controls

IVD



EC

REP

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Revision Changes:

- Added references.

GLOSSARY

REF

Catalogue number



CE mark of conformity

EC REP

Authorized Representative
in the European Community

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use

Rx ONLY

Prescription use only



Consult e-labeling
instructions for use



Biological risks

IVD

For *In Vitro* diagnostic use

CONT

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CONTROL

Control
