QUIDEL

MicroVue™ Complement

CIC-C1q EIA

Supplemental Information and Frequently Asked Questions

Supplemental Information

Do you have a proficiency recommendation to validate the MicroVue CIC-C1q EIA?
At this time, the CIC-C1q assay is not covered by any of the commercial proficiency programs. Quidel recommends the laboratory use the accepted alternative method of split testing every 6-months with a partner laboratory also testing for CIC-C1q. Please check back with us for any future developments.

What is the CMS suggested CPT code and National Limit Amount for the MicroVue CIC-C1q EIA?
The suggested **CPT code is 86161 (Complement; functional activity, each component). The Medicare National Limit Amount* for Serum/Plasma is $16.38. For reimbursement information and support, please visit our website at quidel.com or contact Quidel directly at **800.874.1517 Option 2**, or via e-mail at technicalsupport@quidel.com.

Can I purchase reagents individually?
The CIC-C1q assay is intended to be sold as a complete kit. Please contact Quidel Technical Support at 800.874.1517 Option 2, or via e-mail at technicalsupport@quidel.com for availability of individual reagents.

What is the proper wash technique for this assay?
Quidel strongly recommends use of an automated plate washer or a wash bottle apparatus. Plates should be washed with a method validated with the kit. Please visit Quidel's website for more information, including a Technical Bulletin with additional information regarding proper wash technique for complement assays. http://www.quidel.com/immunoassays/rapid-inflammatory-autoimmune-tests/microvue-cic-c1q-eia

What does the MicroVue CIC-C1q Control Set contain?
The Set contains one high and one low control that consist of human serum with **heat-aggregated gamma globulins (HAGG)**, 20mM EDTA, and 0.01% Thimerosal.

How many tests can I get out of the MicroVue CIC-C1q Control Set (A013)?
Each vial each of Low (Normal) and High (Abnormal) Control contains a sufficient volume for a single use.

Frequently Asked Questions

What is the clinical significance of CIC measurement?
CIC measurement can be performed to evaluate certain diseases, such as autoimmune disorders and neoplastic proliferative diseases, as well as for monitoring therapy efficiencies in patients with systemic lupus erythematosus (SLE) and some forms of rheumatoid arthritis (RA). This information can be found on page 1 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

What is Quidel's quality control recommendation for this assay?
Quidel recommends that positive and negative controls be included in each assay. This information can be found on page 8 ofthe MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

Can I use incubation times and/or temperatures that are different than what are listed in the protocol?
Using incubation times and/or temperatures that differ from what is listed in the Package Insert may give erroneous results, and is therefore discouraged. The ASSAY PROCEDURE can be found on pages 7 and 8 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

How sensitive is the MicroVue CIC-C1q EIA?
The analyte sensitivity is 1.0 µg Eq/mL. This information can be found on page 11 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

What is the specificity of the MicroVue CIC-C1q EIA?
How reproducible is this assay?
The information regarding the specificity and reproducibility studies that were performed can be found on page 11 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

What is the target in this assay and how is it detected?
The MicroVue CIC-C1q EIA targets circulating immune complexes (CIC) in human serum or plasma, based on the principle that CIC will bind to immobilized C1q protein. An expanded description of the principle of this assay can be found on page 2 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

What sample types can be used with this assay?
What are the storage conditions for samples, and requirements for sample handling?
The specimen collection, storage and handling requirements for the MicroVue CIC-C1q EIA can be found on page 4 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

What kit format is available and what is included in the kit?
What are the storage conditions for the kit and its components?
Information about kit contents and storage can be found on pages 2, 3, and 4 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_english_0.pdf

The 20x Wash Solution Concentrate was stored at 2°C to 8°C, and when I went to prepare it, I noticed crystals had formed in the bottle. Can I still use the reagent?
I prepared the Wash Solution as described in the Package Insert, but the solution appears cloudy and discolored. Can I still use the reagent?
Information about the Wash Solution reagent can be found on page 4 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_microvue_cic-c1q_ english_ 0.pdf

What dilution factor should I use when diluting my specimens for use in this assay?
Can I store or reuse my specimen dilutions for future use?
Each specimen to be tested should be diluted 1:50 using the Complement Specimen Diluent provided with the kit. Additional information regarding proper specimen dilution can be found on pages 5 and 6 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/product/documents/a001_ microvue_cic-c1q_english_0.pdf

What are the wavelength requirements for absorbance reading, and when should the absorbance be read?
My correlation coefficient, slope, and/or y-intercept values for the standard curve do not fall within the ranges listed in the Package Insert for the MicroVue CIC-C1q EIA. Are my results valid?
Instructions and guidelines for interpretation of results for the MicroVue CIC-C1q EIA can be found on pages 8-11 of the MicroVue CIC-C1q EIA Package Insert: http://www.quidel.com/sites/quidel.com/files/ product/documents/a001_microvue_cic-c1q_english_0.pdf

* For state by state fee schedule, go to www.cms.gov.
This information is being provided as a reference, for informational purposes only, with no expressed or implied warranty and does not purport to provide legal or certified coding advice. ***Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.* Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims.

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