



## CIC-Raji Cell Replacement EIA

### Supplemental Information and Frequently Asked Questions

#### *Supplemental Information*

##### **Do you have a proficiency recommendation to validate the MicroVue CIC-Raji Cell Replacement EIA?**

At this time, the CIC-Raji Cell Replacement 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-Raji Cell Replacement. Please check back with us for any future developments.

##### **What is the CMS suggested CPT code and National Limit Amount for the MicroVue CIC-Raji Cell Replacement 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](http://quidel.com) or contact Quidel directly at **800.874.1517 Option 2**, or via e-mail at [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).

##### **Can I purchase reagents individually?**

The Raji-Cell Replacement 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](mailto:technicalsupport@quidel.com) for availability of individual reagents.

#### *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-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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 9 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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 7-8 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_english_0.pdf)

**How sensitive is the MicroVue CIC-Raji Cell Replacement EIA?**

The sensitivity is 4 µg Eq/mL. This information can be found on page 13 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_english_0.pdf)

**What is the specificity of the MicroVue CIC-Raji Cell Replacement EIA?**

**How reproducible is this assay?**

The information regarding the specificity and reproducibility studies that were performed can be found on page 13 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_english_0.pdf)

**What is the target in this assay and how is it detected?**

The MicroVue CIC-Raji Cell Replacement EIA targets circulating immune complexes (CIC) based on the ability of Raji cell CR2 receptors to bind CIC that contain fragments of C3, the third complement component. An expanded description of the principle of this assay can be found on page 2 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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-Raji Cell Replacement EIA can be found on page 5 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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 2-4 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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?**

**How long is the Wash Solution stable for once it is prepared per the instructions in the Package Insert?**

**I prepared the Wash Solution as described in the Package Insert, but the solution appears cloudy and discolored. Can I still use the reagent?**

**When should I prepare the Substrate Solution?**

**The Substrate Concentrate I received is dark green in color. Can I still use this reagent?**

**I prepared the Substrate Solution per the instructions in the package insert. The prepared Substrate Solution is now a dark green color. Can I still use this reagent?**

**I have finished reconstituting the CIC Controls per the instructions in the package insert. Do I need to further dilute the reconstituted controls before using them in the assay?**

Information regarding stability and preparation of reagents can be found on pages 5 and 6 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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?**

Information about sample preparation can be found on pages 5 and 6 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_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-Raji EIA. Are my results valid?**

**When interpreting results from a valid assay, what are considered normal and abnormal results?**

**How should results be reported if a specimen has a CIC concentration greater than CIC-Raji Standard E?**

**What do I do if a specimen has a result that is greater than 15 µg Eq/mL but less than 20 µg Eq/mL?**

Instructions and guidelines for interpretation of results for this assay should be carefully reviewed, and can be found on pages 8-11 of the MicroVue CIC-Raji Cell Replacement EIA Package Insert: [http://www.quidel.com/sites/quidel.com/files/product/documents/a002\\_microvue\\_cic\\_raji\\_english\\_0.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/a002_microvue_cic_raji_english_0.pdf)

The performance of any test is dependent on sample collection and handling and the adherence to the Package Insert.

Refer to the Package Insert on our website at **quidel.com** for additional performance claims.

\*For State by state fee schedule, go to [www.cms.gov](http://www.cms.gov).

\*\*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 coding and payment levels can vary greatly from payer to payer and change over time. Quidel strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

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