QUIDEL

MicroVue™ Complement

# MicroVue CH50 Eq EIA

## Supplemental Information and Frequently Asked Questions

### *Supplemental Information*

**Do you have a proficiency recommendation to validate the MicroVue CH50 Eq EIA?**

At this time, the CH50 Eq 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 CH50. Please check back with us for any future developments.

**What is the CMS suggested CPT code and National Limit Amount for the MicroVue CH50 Eq EIA?**

The suggested **CPT code is 86162 (Complement; total, CH50). The 2015 Medicare National Limit Amount* for Serum is $27.65. 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.

**How many samples can be tested with each kit?**

Each kit contains enough reagents for testing approximately 40 specimens plus MicroVue CH50 Eq EIA Standards and Controls in duplicate.

**Can I purchase reagents individually?**

The CH50 Eq EIA 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/sites/quidel.com/files/product/documents/ELISA_wash_technique_sample_handling_tb_10.pdf

**Is it acceptable to prepare the controls in batches and activate them, then store the activated controls frozen until I am ready to use them?**

No. Quidel strongly recommends preparation of fresh Low and Normal Controls with each run. The controls are composed of human sera with no complement inhibitors, and should not be subjected to freeze-thaw cycles.

## *Frequently Asked Questions*

**What is the clinical significance of CH50 measurement?**

Traditional measurement of CH50 is the lytic assay, which indirectly measures the Terminal Complement Complex (TCC) to determine activity of the classical complement pathway. The MicroVue CH50 Eq EIA directly measures TCC by quantifying the amount of TCC generated under standard conditions. An expanded description of this can be found on page 3 of the MicroVue CH50 Eq EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.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 CH50 Eq EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.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 5-7 of the MicroVue CH50 Eq EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.pdf

**How sensitive is the MicroVue CH50 Eq EIA?**

**What is the specificity of the MicroVue CH50 Eq EIA?**

The sensitivity is 93.2%. The specificity is 99.4%. For additional information regarding sensitivity and specificity, please refer to pages 8-9 of the MicroVue CH50 Eq EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.pdf

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

The MicroVue CH50 Eq EIA targets the Terminal Complement Complex (TCC) generated after activation of the Classical Complement Pathway in serum. TCC is detected by ELISA using a monoclonal antibody to bind the TCC analyte. Additional information regarding the target and method of detection in this assay can be found on page 1 of the MicroVue CH50 Eq EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.pdf

**What sample types can be used with this assay?**

**What are the storage conditions for samples, and requirements for sample handling?**

**I have samples frozen at –70°C or below that I need to thaw in order to perform testing. What is the proper way to thaw these samples?**

Proper sample storage and handling are critical to the success of the MicroVue CH50 Eq EIA. The detailed information regarding acceptable sample types, storage conditions, handling, and thawing technique can be found on pages 4-5 of the MicroVue CH50 Eq EIA Package Insert, which should be carefully reviewed:
http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.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 conditions can be found on pages 2 and 4 of the MicroVue CH50 Eq EIA Package Insert:

http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.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?**

**There are visible particles in the Activator reagent. Can I still use this?**

Information about reagent preparation and stability can be found on pages 4 and 5 of the MicroVue CH50 Eq EIA Package insert:

http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.pdf

**Can I store my specimen dilutions for future use?**

Specimens should **not** be stored after dilution; however, they can be stored immediately after the Activation step has been completed but prior to the dilution step. For more detailed information, please refer to page 5 of the MicroVue CH50 Eq EIA Package Insert:

http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.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 CH50 Eq EIA. Are my results valid?**

**A few of my samples did not fall in the range of the standard curve. Can I adjust my dilution factor accordingly so that the range falls within the limits?**

**If my samples are diluted according to the Package Insert instructions, do I need to account for the dilution factor when calculating results?**

Information pertaining to interpretation of results should be carefully reviewed, and can be found on pages 7-9 of the MicroVue CH50 Eq EIA Package Insert:

http://www.quidel.com/sites/quidel.com/files/product/documents/a018_microvue_ch50_eq_english_1.pdf

* For State by state fee schedule, go to 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 Corp. strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.