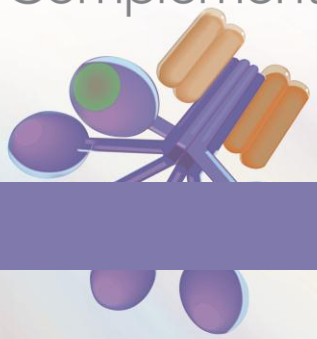
QUIDEL

MicroVue™ Complement



Bb Plus EIA

Supplemental Information and Frequently Asked Questions

Supplemental Information

Do you have a proficiency recommendation to validate the MicroVue Bb Plus EIA?
At this time, the Bb Plus 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 Bb Plus. Please check back with us for any future developments.

What is the CMS suggested CPT code and National Limit Amount for the MicroVue Bb Plus 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.

How many samples can be tested with each kit?
Each kit contains enough reagents for testing approximately 40 specimens plus MicroVue Bb Plus EIA Standards and Controls in duplicate.

Can I purchase reagents individually?
The Bb Plus 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/sites/quidel.com/files/product/documents/microvue_elisa_wash_and_sample_technique_tb_3.pdf

The Package Insert indicates that the mean Bb concentration values for normal EDTA plasma and normal serum samples are 0.96 ug/mL and 3.53 ug/mL, respectively, but the LLOQ and ULOQ are 0.033 ug/mL and 0.836 ug/mL, respectively. How is this possible?
The LLOQ and ULOQ were determined based on concentration values of diluted samples, whereas the mean Bb concentration values are *true*, undiluted sample values. When following the Package Insert, if plasma samples are diluted 1:10 and serum samples are diluted 1:20, the diluted average for plasma calculates to 0.096 ug/mL and for

serum it is 0.1765 ug/mL. Both of the diluted averages fall between the LLOQ and ULOQ. Due to this, most samples' concentration values will fall between the ULOQ and LLOQ, and will therefore be within the range of the standard curve. Once the dilution factor is applied to the concentration value from the standard curve, you then have your *true* sample value.

I performed dilutions according to the Package Insert, but I still have a sample with a concentration value that falls outside the standard curve. Can I adjust my dilution factor?
Yes. Some samples may have Bb concentration values that are still too high or too low after diluting according to the instructions. If this occurs, the dilution factor can be adjusted appropriately, so that the value will fall within the range of the standard curve. You will need to ensure that the correct dilution factors are used when calculating results for any samples that required a different dilution factor.

Frequently Asked Questions

What is the clinical significance of Bb fragment measurement?
Measurement of Bb fragment present in serum and plasma samples is performed to assess the extent of Alternative Pathway Complement activation in individuals with autoimmune disease. Please refer to pages 1-2 of the MicroVue Bb Plus EIA Package Insert for an expanded description:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

What is Quidel's quality control recommendation for this assay?
Quidel recommends that positive and negative controls be included in each assay. Additional information can be found on page 5 of the MicroVue Bb Plus EIA Package Insert for an expanded description:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

Can I use incubation times and/or temperatures that are different than what is 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 4-5 of the MicroVue Bb Plus EIA Package Insert for an expanded description:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

What are the LOD, LLOQ, and ULOQ for the MicroVue Bb Plus EIA?
Information regarding the LOD, LLOQ, and ULOQ for this assay can be found on page 5 of the MicroVue Bb Plus EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.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 Bb Plus EIA because the Bb fragment is susceptible to proteolysis if samples are collected, stored, and/or handled improperly. The detailed information regarding acceptable sample types, collection, storage conditions, handling, and thawing technique

can be found on page 4 of the MicroVue Bb Plus EIA Package Insert, which should be carefully reviewed:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

Can I use Heparin plasma instead of EDTA plasma?
Heparin plasma cannot be used with this assay. Please refer to the Interfering Substances section on page 6 of the MicroVue Bb Plus EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

What is included in the kit?
What are the storage conditions for the kit and its components?
Information regarding kit components and storage conditions can be found on pages 2 and 4 of the MicroVue Bb Plus EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

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/or discolored. Can I still use the reagent?
Information about the preparation, storage, and stability of reagents can be found on pages 3 and 4 of the MicroVue Bb Plus EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

What dilution factor should I use when diluting my specimens for use in this assay?
Can I store my specimen dilutions for future use?
After diluting the samples, how quickly must they be added to the microassay wells?
Specific instructions for sample dilution and adding diluted samples to the microassay can be found on page 4 of the MicroVue Bb Plus EIA Package Insert, which should be carefully reviewed:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.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 Bb Plus EIA. Are my results valid?
When calculating my results, do I need to include the dilution factor for each specimen?
Information regarding interpretation of results including calculation of Bb concentration present in samples can be found on page 5 of the MicroVue Bb Plus EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/a027_microVue_bb_plus_english.pdf

The performance of any molecular 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.
**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.