



### Supplemental Information Frequently Asked Questions

#### *Supplemental Information*

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

Check with your Local and State regulation for proficiency requirements. If you are using the CAP proficiency, the recommended evaluation is Bone Markers and Vitamin survey for Bone Specific Alkaline Phosphatase (BMV2).

**What is the CMS suggested CPT code and National Limit amount for the MicroVue BAP EIA?**

The suggested\* CPT code is 84080 (Alkaline phosphatase; isoenzymes). The Medicare National Limit amount\*\* for Serum is \$20.12. 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).

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

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

**Can I purchase reagents individually?**

The BAP 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.

**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 Bone Health assays:

[http://www.quidel.com/sites/quidel.com/files/product/documents/microvue\\_bh\\_wash\\_technique\\_tb\\_4.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/microvue_bh_wash_technique_tb_4.pdf)

#### *Frequently Asked Questions*

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

BAP (bone-specific alkaline phosphatase) levels can be measured in serum as an indicator of osteoblastic activity, which can aid in diagnosis and management of osteoporosis, Paget's Disease, and hormonal therapy. For an expanded description of this significance, please refer to page 1 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

**What is Quidel's quality control recommendation for this assay?**

Quidel recommends that positive and negative controls be included in each assay. More information regarding Quality Control recommendations can be found on page 3 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.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. Please refer to the ASSAY PROCEDURE section on page 3 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

**What is the specificity of the MicroVue BAP EIA?**

**What is the sensitivity of the MicroVue BAP EIA?**

Information regarding the sensitivity, specificity, and precision for the MicroVue BAP EIA can be located on pages 4-5 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

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

The MicroVue BAP EIA targets BAP present in serum. The BAP enzyme is detected by a monoclonal antibody to BAP in an ELISA protocol. Please refer to pages 1-2 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

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

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

**How many freeze/thaw cycles can my samples undergo?**

Information regarding proper sample type, storage, and handling can be found on page 3 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

**What is included in the kit?**

**What are the storage conditions for the kit and its components?**

A list of kit components and storage conditions can be found on pages 2 and 3 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

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

**How long before use do I need to prepare the Working Substrate Solution?**

Specific information about preparation, storage, and stability of reagents can be found on page 3 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

**What are the wavelength requirements for absorbance reading, and when should the absorbance be read?**

**When interpreting results, what does 1 unit represent?**

**What type of curve-fitting equation do I need to analyze BAP results?**

**How do I proceed if my OD value for Standard F is < 1.0?**

Instructions and guidelines for interpretation of results for the MicroVue BAP EIA can be found on pages 3-4 of the MicroVue BAP EIA Package Insert:

[http://www.quidel.com/sites/quidel.com/files/product/documents/8012\\_microvue\\_bap\\_english\\_9.pdf](http://www.quidel.com/sites/quidel.com/files/product/documents/8012_microvue_bap_english_9.pdf)

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

*\*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 Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.*

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