QUIDEL | MicroVue™ Bone

PYD EIA

Supplemental Information Frequently Asked Questions

Supplemental Information

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

What is the CMS suggested CPT code and National Limit amount for the MicroVue PYD EIA?
The suggested* CPT code is 82523 (Collagen Cross-links). The Medicare National Limit amount** for Urine is $25.43. 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 PYD EIA Standards and Controls in duplicate.

Can I purchase reagents individually?
The PYD 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 Bone Health assays:
http://www.quidel.com/sites/quidel.com/files/product/documents/microvue_bh_wash_technique_tb_4.pdf

When interpreting results, do I need to account for the 1:10 sample dilution factor?
Since all Standards, Controls, and samples are diluted 1:10 with the Assay Buffer Solution included in the kit, the 10-fold sample dilution does not need to be taken into account for results interpretation. However, if a sample is diluted in any ratio other than 1:10, then the dilution will need to be correctly accounted for. For example, if a sample is diluted 1:20 instead of 1:10, a dilution factor of 2 would need to be accounted for in this particular sample.

Frequently Asked Questions

What is the clinical significance of PYD measurement?
PYD (pyridinoline) crosslink levels can be measured in urine as an indicator of Type 1 collagen resorption to monitor bone remodeling. This measurement can be used in monitoring bone resorption changes in postmenopausal women or in individuals with osteoporosis. Other diseases that are characterized by abnormalities in bone remodeling include Paget's Disease and bone cancers. For an expanded description of this significance, please refer to page 1 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_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. More information regarding Quality Control recommendations can be found on page 6 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_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. Please refer to the ASSAY PROCEDURE section on pages 4-6 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.pdf

What is the specificity of the MicroVue PYD EIA?
What is the sensitivity of the MicroVue PYD EIA?
Information regarding the sensitivity, specificity, and precision for the MicroVue PYD EIA can be located on pages 4-5 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.pdf

What is the target in this assay and how is it detected?
The MicroVue PYD EIA targets PYD and DPD crosslinks excreted in urine. The crosslinks are detected by a monoclonal anti-pyridinium crosslink antibody in an ELISA protocol. Please refer to pages 1-2 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.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 4 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.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 4 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.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 Enzyme Conjugate?
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 pages 4-5 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.pdf

What are the wavelength requirements for absorbance reading, and when should the absorbance be read?
Do I need to correct my results for variations in urine concentration by Creatinine?
What do I do if an absorbance value of > 2.0 is not compatible with my plate reader?
What type of curve-fitting equation do I need to analyze PYD results?
How do I proceed if my OD value for Standard A is < 0.8?
Instructions and guidelines for interpretation of results for the MicroVue PYD EIA can be found on pages 5-7 of the MicroVue PYD EIA Package Insert:
http://www.quidel.com/sites/quidel.com/files/product/documents/8010_microvue_pyd_english_0.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

0227BH1214D (01/15)