NEW/REPLACEMENT TEST
NOTIFICATION DATE: February 24, 2023
EFFECTIVE DATE: February 22, 2023

CHANGES IN TESTING USED TO DETECT MONOCLONAL PROTEINS (PROTEIN ELECTROPHORESIS AND IMMUNOTYPING)

Epic Test Codes: VARIOUS (see below)

EXPLANATION: The Clinical Chemistry Laboratory at WVUH is making changes to protein electrophoresis (PE) testing to support the growing demand for this testing across the WVU Medicine Health System. Many immunotyping (IT, formerly called immunofixation) studies are ordered on serum and urine samples to screen patients who have lower likelihoods of harboring a monoclonal protein. The advanced protein electrophoresis methodology used by the lab will detect clinically significant monoclonal proteins found in serum and urine samples.

This algorithmic testing strategy - developed in collaboration with Mary Babb Randolph Cancer Center clinicians who for large numbers of patients with monoclonal gammopathies - will safely reduce the costs for testing by reducing the number of more expensive IT tests. Furthermore, testing turnaround times will shorten.

The following changes have been implemented system-wide to the Epic ordering system:

1. Immunosubtraction (immunotyping) studies were removed from facility lists. Clinical pathologists will initiate IT studies based on the results of serum and/or urine protein electrophoresis testing.
    a. The following tests remain laboratory-orderable for reflexing abnormal PE studies:
        i. LAB304189 (Immunosubtraction, Serum)
        ii. LAB304207 (Immunosubtraction, Urine Random)
        iii. LAB304220 (Immunosubtraction, Urine Timed)
    b. Clinicians will order one of the following that will initiate the testing algorithm:
        i. LAB304164 (Protein Electrophoresis, Serum)
        ii. LAB304807 (Protein Electrophoresis, Urine Random)
        iii. LAB304176 (Protein Electrophoresis, Urine Timed)
2. Duplicate SPEP or UPEP orders submitted <21 days after the prior study of the same type will be automatically canceled. For unusual instances in which a shorter interval is required, please reach out to the clinical pathologist/chemistry laboratory.
3. A single orderable test is under development combining SPEP and sFLC testing that is compliant with current guidelines for screening & monitoring patients with monoclonal gammopathies; this test is expected April 2023.

References:

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3. Sive J, Cuthill K, Hunter H, et al. Guidelines on the diagnosis, investigation and initial treatment of myeloma: a British Society for Haematology/UK Myeloma Forum Guideline. Bri J Haematol 2021;193:245-268. https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.17410

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5. Kyle RA, Durie BGM, Rajkumar SV, et al. Monoclonal gammopathy of undetermined significance (MGUS) and smoldering (asymptomatic) multiple myeloma: IMWG consensus perspectives risk factors for progression and guidelines for monitoring and management. Leukemia 2010;24(6):1121-1127. https://www.nature.com/articles/leu201060
6. Leung N, Bridoux F, Batuman V, et al. Expert consensus document – The evaluation of monoclonal gammopathy of renal significance: a consensus report of the International Kidney and Monoclonal Gammopathy Research Group. Nature Rev Nephrol 2018 Dec;15:45-59. https://doi.org/10.1038/s41581-018-0077-4
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8. Dispenzieri A, Kyle ER, Merlini G, et al. International Myeloma Working group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia 2009;23:215-224. https://doi.org/10.1038/leu.2008.307
9. Dejoie T, Corre J, Caillon H, et al. Responses in multiple myeloma should be assigned according to serum, not urine, free light chain measurements. Leukemia 2019;33:313-318. https://doi.org/10.1038/s41375-018-0339-y

QUESTIONS ABOUT THIS TESTING

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QUESTIONS

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ADDITIONAL INORMATION AVAILABLE ONLINE:

https://jdos.nicholsinstitute.com/dos/JWRubyMemorial