

Serum Monoclonal Gammopathy Evaluation

Effective Date: March 7, 2023

Laboratory Bulletin

Available orders to evaluate for serum monoclonal proteins are changing to align with new College of American Pathologists guidelines published May 2022. These changes will go into effect March 7, 2023.

CAP Guidelines recommend screening for monoclonal gammopathy with serum protein electrophoresis and serum free light chain analysis, with reflex to immunofixation at pathologist discretion (to characterize a new monoclonal protein). If there is concern for amyloidosis or neuropathy, CAP Guidelines recommend serum protein electrophoresis, serum immunofixation, and serum free light chain analysis, as well as urine protein electrophoresis; no changes will be made to urine protein electrophoresis orders.

Screen by either serum protein electrophoresis alone or by serum immunofixation alone is not recommended. Similarly, total immunoglobulins are useful in only limited circumstances in evaluation of monoclonal gammopathies and will not be included in the new order sets. Total immunoglobulins are still available to order separately. Serum immunofixation is not recommended for monitoring of known monoclonal proteins, as many of these are visible on serum protein electrophoresis, and immunofixation will be added by the pathologist if needed.

In addition, monoclonal protein quantitation will now be charted as a separate field in Epic, making it easier to evaluate the trend over time.

Please contact Dr. Caitlin Schein or section manager Leah Korodan with any questions regarding these changes.

New/Changed Monoclonal Gammopathy Orders:

| Test Name | Test Code | Includes | Reflex Testing |
|---|-----------|--|--|
| Monoclonal Gammopathy Evaluation | SMGE | Serum protein electrophoresis, free light chains | Serum immunofixation at pathologist discretion |
| Amyloidosis/Neuropathy Monoclonal Gammopathy Evaluation | NMGE | Serum protein electrophoresis, serum immunofixation, and free light chains | None |
| Serum protein electrophoresis | SPE | Serum protein electrophoresis | Serum immunofixation at pathologist discretion |

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Unchanged Orders:

| Test Name | Test Code | Includes | Reflex Testing |
|---------------------------------|----------------|--|----------------------|
| Free Light Chains | FRLC | Kappa free light chain, lambda free light chain, and kappa to lambda ratio | None |
| Immunoglobulins (IgG, IgA, IgM) | GAM | IgG, IgA and IgM quantitation | None |
| Protein Electrophoresis, Urine | UPEUR UPE24 | Urine protein electrophoresis; Kappa and Lambda Immunofixation; Protein, Urine | Urine immunofixation |

Discontinued Tests:

| Test Name | Test Code |
|-------------------------------|-----------|
| Protein Immunofixation, Serum | SIFE |

Reference:

Keren DF, et al. Laboratory Detection and Initial Diagnosis of Monoclonal Gammopathies: Guideline from the College of American Pathologists in Collaboration with the American Association for Clinical Chemistry and the American Society for Clinical Pathology. *Arch Pathol Lab Med* (2022) 146 (5): 575–590.

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