March 3, 2020

IMMUNOLOGY

MONOCLONAL PROTEIN INVESTIGATION

Date effective: March 16, 2020

Background Information:
In an effort to align laboratory practice and international guidelines, changes to the testing algorithm for monoclonal protein investigations will be implemented on March 16, 2020.

The International Myeloma Working Group guidelines recommend:

1. Serum Free Light Chain quantitation in combination with serum protein electrophoresis (SPE) and serum immunofixation electrophoresis (IFE) in the initial diagnostic workup (screen) for pathological monoclonal plasma cell proliferative disorders.
2. When performed at screening, Serum Free Light Chains can replace the 24hr urine protein IFE for all diagnoses except amyloidosis. However, once a diagnosis of monoclonal gammopathy is made, the 24hr urine protein IFE should be done.

Change in Test Procedure:

1. All Serum Protein Electrophoresis (PE) orders, both initial and follow-up, will automatically reflex Serum Free Light Chains (FLCH). Note: FLCH will remain orderable as a stand-alone test.
2. Random urines will no longer be accepted for Urine Protein Electrophoresis (24hr urine only).
3. Free Light Chain Reports will now include the following comment:
   "A Free LC Ratio Reference Range of 0.37 to 3.10 is suggested for patients with chronic kidney disease (CKD). The ratio demonstrates a stepwise increase through the CKD stages and remains elevated in patients on hemodialysis.
   Hutchison CA et al, Clin J Am Soc Nephrol. 2008 Nov;3(6):1684-90.

   Normal Free LC Ratio with both Kappa and Lambda Free Light Chains increased is usually seen in patients with renal failure or other inflammatory causes.
   Abnormal Free LC Ratio can be consistent with a clonal plasma cell disorder.
   Clinical correlation is required."

References/Resources:
Dispenzieri A, Kyle R, et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. Leukemia (2009) 23, 215-224.

Patient Impact:

- Improved sensitivity. The combination of Serum IFE and FLCH assay can detect an abnormal result in 99% of patients with amyloidosis.

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