MAYO CLINIC LABORATORIES

MULTIPLE MYELOMA SCREENING AND MONITORING

A Groundbreaking Approach to Identifying Monoclonal Proteins

Our comprehensive multiple myeloma assessments provide valuable information and treatment guidance for health care providers.

MAYO CLINIC APPROACH

We have developed a new methodology shown to be more clinically sensitive and specific than immunofixation. This innovative methodology marks the first major breakthrough in multiple myeloma testing since the development of electrophoresis in 1967.

Overcoming electrophoresis's sensitivity and specificity limitations in detecting multiple myeloma, these tests include the matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) to weigh monoclonal proteins.

This approach allows providers to monitor and identify multiple myeloma patients using blood samples, and it can prevent unnecessary bone marrow biopsies. Novel biomarkers assist in determining patients' risks for AL amyloidosis.

SUPERIOR TESTING FOR OPTIMAL PATIENT CARE

The new MALDI-TOF MS testing method provides:

- Best-in-class screening for multiple myeloma.
- Early identification of myeloma relapse.
- Confirmation if patients have higher risks for AL amyloidosis.
- Verification if monoclonal therapeutics or residual disease cause the IgG kappa mass.
- An approach that follows the International Myeloma Foundation guidelines.
- Convenient, cost-effective, and clinically relevant information.
- Industry-leading turnaround times for results.

SCREENING AND DIAGNOSIS

Monoclonal Gammopathy Screen, Serum

Mayo ID: SMOGA | Analytic time: 1 day

SMOGA assesses monoclonal proteins for progression risks of plasma cell proliferative disorders from monoclonal gammopathy of undetermined significance (MGUS). This test profile includes total protein, serum protein electrophoresis, heavy- and light-chain typing (kappa and lambda), quantitation of kappa and lambda free light chains, and M-protein isotype MALDI.

The free light-chain assay increases diagnostic sensitivity in disorders that often do not have serum monoclonal protein concentrations for detection by conventional techniques. M-protein detection is performed by new MALDI-TOF MS methodologies, which have demonstrated higher sensitivity and specificity in comparison to electrophoresis.

Appropriate Ordering Scenario:
Assessing the risk of progression from MGUS to multiple myeloma.

SCREENING AND DIAGNOSIS

Protein Electrophoresis and Isotype, Serum

Mayo ID: SPISO | Analytic time: 1 day

SPISO is a traditional, gel-based technique for detecting an M-protein. This test includes total protein, serum protein electrophoresis, heavy- and light-chain typing (kappa and lambda), and M-protein isotype MALDI.

Appropriate Ordering Scenario:
Diagnosing monoclonal gammopathies, when used in conjunction with locally performed serum free light-chain studies.

DIAGNOSIS AND MONITORING

M-Protein Isotype by Matrix-Assisted Laser Desorption/Ionization-Time of Flight Mass Spectrometry (MALDI-TOF MS), Serum

Mayo ID: MALDO | Analytic time: 1 day

Immunotyping of monoclonal (M-) proteins identifies the monoclonal immunoglobulin heavy chain type (gamma, alpha, mu, delta, or epsilon) and light chain type (kappa or lambda) in serum specimens. This test can aid in the diagnosis of monoclonal gammopathies when used in conjunction with free light chain studies.

Appropriate Ordering Scenario:
When protein electrophoresis and free light chain testing is performed in house. M-protein isotyping by MASS-FIX only.

MONITORING

Monoclonal Gammopathy Monitoring, Serum

Mayo ID: MMOGA | Analytic time: 1 day

The updated protein electrophoresis and monoclonal gammopathy tests with the new mass spectrometry approach, which identifies M-proteins using high-resolution mass measurements that achieve superior sensitivity compared to traditional methods. The MMOGA test includes total protein and serum protein electrophoresis. When appropriate, M-protein detection is performed by new MALDI-TOF MS methodologies.

Testing will reflex to perform M-protein isotype MALDI at an additional charge when a discrete electrophoresis band is not identified.

Appropriate Ordering Scenario:
Determining if IgG kappa mass changes are caused by monoclonal therapeutics or residual disease.

MAYO CLINIC RELEVANT PUBLICATIONS

Kohlhagen MC, Barnidge DR, Mills JR, et al. Screening methods for M-proteins in serum using nanobody enrichment coupled to MALDI-TOF mass spectrometry. Clin Chem. 2016;62(10):1345-1352. doi:10.1373/clinchem.2015.253781.

Kourelis T, Murray DL, Dasari S, et al. MASS-FIX may allow identification of patients at risk for light chain amyloidosis before the onset of symptoms. Am J Hematol. 2018;93(11):368-E370. doi:10.1002/ajh.25244.

Kumar S, Murray D, Dasari S, et al. Assay to rapidly screen for immunoglobulin light chain glycosylation: a potential path to earlier AL diagnosis for a subset of patients. Leukemia. 2018 Jan;33(1):254-257. doi.org/10.1038/s41375-018- 0194-x.

Milani P, Murray DL, Barnidge DR, et al. The utility of MASS-FIX to detect and monitor monoclonal proteins in the clinic. Am J Hematol. 2017;92:772-779. doi:10.1002/ajh.24772.

Mills JR, Barnidge DR, Dispenzieri A, and Murray DL. High sensitivity blood-based M-protein detection in sCR patients with multiple myeloma. Blood Cancer J. 2017;7(590). doi:10.1038/bcj.2017.75.

Mills JR, Kohlhagen MC, Dasari S, et al. Comprehensive assessment of M-proteins using nanobody enrichment coupled to MALDI-TOF mass spectrometry. Clin Chem. 2016 Oct;62(10):1334-1344.

Mills JR, Kohlhagen MC, Willrich MAV, et al. A universal solution for eliminating false positives in myeloma due to therapeutic monoclonal antibody interference. Blood. 2018 Aug;132(6):670-672. doi:10.1182/ blood-2018-05-848986.

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