IMPORTANT TEST UPDATES
TEST UPDATE 711

NOTICE DATE: April 1, 2020
EFFECTIVE DATE: April 1, 2020

TEST CHANGE

Clozapine
Order Code: CLOZ
CPT Code 80159
Referral Laboratory: Mayo Medical Laboratories

Effective April 1, 2020, MLabs has changed the specimen stability for Clozapine (CLOZ) per Mayo Medical Laboratories.

<table>
<thead>
<tr>
<th>Current Specimen Stability</th>
<th>New Specimen Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Temperature</td>
</tr>
<tr>
<td>Serum Red</td>
<td>Refrigerated (preferred)</td>
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EFFECTIVE DATE: April 1, 2020

TESTING RESUME

Procollagen I Intact N-Terminal, Serum
Order Code: FPNTS
CPT Code 83519
Referral Laboratory: Mayo Medical Laboratories

Effective April 1, 2020, Procollagen I Intact N-Terminal, Serum (FPNTS) testing has resumed per Mayo Medical Laboratories.

EFFECTIVE DATE: April 1, 2020

NEW TEST

NR4A3 (9q22-9q31) Rearrangement by (FISH)
Order Code: MNR4A
CPT Code 88377-TC

Effective April 1, 2020, MLabs will offer NR4A3 (9q22-9q31) Rearrangement by (FISH) [MNR4A] testing.

Test Usage: NR4A3 encodes an orphan nuclear receptor. Rearrangements of NR4A3 occur in more than 80% of extraskeletal myxoid chondrosarcoma (EMC) as well as in salivary acinic cell carcinoma (AcIC), driving tumorigenesis. With EMC, NR4A3 rearrangements fuse the 3’ end of NR4A3, including its DNA binding domain, to a variety of 5’ oncogenic transcription activator fusion partners. With AcIC, NR4A3 rearrangement translocates highly active chromatin regions to the upstream region of NR4A3. The detection of NR4A3...
rearrangements can be useful in diagnosing EMC and AciCC – including uncommon histologic variants – and in distinguishing these neoplasms from other myxoid neoplasms and salivary gland tumors, respectively.

**Test Limitations:** This test will detect rearrangements involving NR4A3 but will not identify the translocation partner. The test may fail to detect NR4A3 rearrangements involving a submicroscopic insertion or with a breakpoint outside of the region interrogated by the probes used in this assay.

**Methodology:** Fluorescence In Situ Hybridization (FISH)

**Analytic Time:** 3 – 10 days

**Specimen Requirements:** A formalin-fixed, paraffin-embedded tissue block (containing sufficient neoplastic cells) is preferred. Unstained slides (3 slides cut at 4-microns) with associated H&E-stained slide are also acceptable. Decalcified tissue or tissues with other fixatives will be accepted and the assay attempted; however, these specimens may result in failed testing due to degraded nucleic acid. Both blocks and slides should be stored at room temperature.

**EFFECTIVE DATE:** April 9, 2020

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**NEW TEST**

**Golimumab and Anti-Golimumab Ab**

**Order Code:** FGAGA  
**CPT Code:** 80299, 82397  
**Reference Laboratory:** Mayo Medical Laboratories

Effective April 9, 2020 MLabs will offer Golimumab and Anti-Golimumab Ab (FGAGA) testing via Mayo Medical Laboratories.

**Specimen Collection:** Collect approximately 6 mL of whole blood in a red or serum separator tube (SST). Centrifuge the specimen within 45 minutes of collection. Aliquot the serum into a plastic vial and freeze. Ship the specimen frozen within 7 days of collection.

**Methodology:** Electrochemiluminescence immunoassay (ECLIA)

**Analytic Time:** Approx. 2 days, test performed on Tuesdays

**Reference Range:** See Below

<table>
<thead>
<tr>
<th>Golimumab:</th>
<th>Anti-Golimumab Antibody</th>
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<tbody>
<tr>
<td>Quantitation Limit: &lt;0.5 ug/mL</td>
<td>Quantitation Limit: &lt;20 ng/mL</td>
</tr>
</tbody>
</table>
| Results of 0.5 ug/mL or higher indicate detection of Golimumab | Results of 20 or higher indicate detection of anti-Golimumab antibodies.
| In the presence of serum anti-golimumab antibodies, the golimumab drug level reflects the antibody-unbound (free) fraction of golimumab in serum |