CORONAVIRUS DISEASE (COVID-19) TESTING

COVID-19 is a disease caused by a newly identified coronavirus called SARS-CoV-2 (2019 Novel Coronavirus). Michigan Medicine, in coordination with state and local health departments, is closely monitoring developments in this rapidly evolving situation and will offer guidance as it becomes available.

Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing).

Michigan Medicine guidelines for testing include:

- Patients fulfill at least 2 out of 5 criteria:
  - Fever (T>100.4 degrees C).
  - Cough
  - Shortness of breath or difficulty breathing.
  - High-risk exposure (within six feet of COVID-19 case for prolonged time or having direct contact with infectious secretions of a COVID-19 case)
  - Presence of >=1 risk factor for COVID-19 infection or severe outcomes
- Risk Factors:
  - Age >= 70 years
  - Compromised immune system (AIDS, organ or HSC transplant, immunosuppressive therapy)
  - International or domestic travel within 2 weeks of symptom onset
  - Healthcare worker
  - Resident of nursing home or other long-term care facility.

Currently there is a national-wide shortage of collection kits, transport media, and reagents for performing COVID-19 testing. Due to resource and capacity constraints, MLabs is not able to accept COVID-19 testing from our clients at this time.

Specimens from ambulatory patients suspected of having COVID-19 should not be sent to MLabs for SARS-CoV-2 testing at this time. Please direct questions regarding testing to your local health department and if testing is approved, make arrangements for sending directly to the state health department for COVID-19 testing. The number for Washtenaw County is 734-544-6700. If you are unable to reach your local health department, please call the Michigan Department of Health and Human Services (MDHHS) Communicable Disease (CD) Division at: 517-335-8165 during business hours, or at: 517-335-9030 after-hours and on holidays.

MLabs offers a Respiratory Viruses by PCR (Influenza & RSV) (order code PCRSC) as well as a Respiratory Pathogen Panel by PCR (order code RPAN) testing which may be required as part of MDHHS COVID-19 risk assessment criteria. The Respiratory Pathogen Panel by PCR does not test for COVID-19.

Collection Instructions for PCRSC or RPAN: Use a flocked swab, dacron or rayon swab to obtain a nasopharyngeal specimen and place into M4-RT transport medium. Refrigerate.
IMPORTANT TEST UPDATES
TEST UPDATE 709

Additional information regarding Coronavirus disease is available at the following websites:

- http://www.michigan.gov/Coronavirus
- https://www.michigan.gov/documents/mdhhs/MDHHS_CDC_PUI_Form_and_Cover_Sheet_Fillable_v02.03.2020_680230_7.pdf

EFFECTIVE DATE: NOTICE

IMPORTANT INFORMATION REGARDING GENETIC TESTING FOR HYPERCOAGULABILITY / THROMBOPHILIA FOR MEDICARE PATIENTS

Please be advised that testing for Factor V Leiden Mutation (order code FINV), Prothrombin 20210 Mutation (order code PROIN), and MTHFR C677T Mutation (order code MMTHF) are not a covered benefit under Medicare except for pregnant patients.

Per Medicare LCD L36400 MolDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR), genetic testing for thrombophilia testing for the Factor V Leiden (FVL) variant in F5 gene, the 20210G>(G20210A) variant in the F2 gene, and the MTHFR gene which encodes the 5,10-methylenetetrahydrofolate reductase enzyme. Genetic testing for these genes for all risk factors, signs, symptoms, diseases, or conditions, including cardiovascular risk assessment, are non-covered except for pregnant patients.

Testing for FVL and F2 G20210A mutations is indicated for pregnant patients who have a history of personal venous thromboembolism (VTE) associated with a non-recurrent (transient) risk factor who are not otherwise receiving anticoagulant prophylaxis. The results of genetic testing can inform risk stratification for VTE recurrence and subsequent need for antenatal prophylaxis. However, Medicare will not add coverage of thrombophilia testing for pregnant women because they likely represent a very small group of potential Medicare (disabled) patients. Claims submitted on this limited Medicare population will deny per the policy, but should be appealed for coverage with submission of medical records supporting the necessity for testing, and specify how testing changed anticoagulant prophylaxis management for the patient.

Therefore, charges for any of the above testing referred to MLabs for a Medicare patient will be client billed to the referring facility, must be accompanied by an ABN signed by the patient and agreeing to payment, or must be accompanied by appropriate documentation of medical necessity for pregnant patients.

EFFECTIVE DATE:  March 18, 2020

TEST DOWN

Beta 2 Microglobulin, Serum
Order Code: B2MIC
IMPORTANT TEST UPDATES
TEST UPDATE 709

CPT Code 82232

Effective March 18, 2020, Beta 2 Microglobulin, Serum (B2MIC) testing is down to reagent issues.

EFFECTIVE DATE: March 18, 2020

TEST DOWN

Neuron-Specific Enolase
Order Code: NSES
CPT Code 83520
Referral Laboratory: Mayo Medical Laboratories

Effective March 18, 2020, Neuron-Specific Enolase (NSES) testing is down to reagent issues per Mayo Medical Laboratories.