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Des Moines Laboratory Update

Date: April 14, 2022

Lead Capillary Testing Update

Effective immediately, MercyOne Des Moines Laboratory will resume Lead capillary testing, in house.

In July 2021, Magellan Diagnostics issued a recall notice concerning the use of certain LeadCare Blood Lead test lots. The specific kits and lot numbers were recalled due to a manufacturing issue with the potential to cause a significant risk of falsely low blood lead level results. MercyOne Des Moines quarantined all Magellan LeadCare products, performed a patient audit and retested certain populations using venous samples, as recommended by the FDA. Magellan has corrected the issue and resumed production of LeadCare Blood Lead kits. A thorough validation has taken place at MercyOne Des Moines Laboratory and we are confident in resuming this testing.

We are also updating our reference range to \leq 3.5 ug/dL for children less than or equal to 5 years old, as recommended by the CDC and IDPH.

Please collect an EDTA microtainer and utilize the LEADCAP order code. Additional information regarding Lead, Capillary testing can be found through the link below:

https://mercyonedesmoineslaboratory.testcatalog.org/show/LEAD-CAP

Please contact Jennifer Lehman, Manager - Core Laboratory at 515-247-4484 with any questions.

SARS-CoV-2 Interpretation Clarification

Due to a number of recent questions about test utilization and clinical interpretation of results for our SARS-CoV-2 IgG (antibody) assay, MercyOne Des Moines Clinical Laboratory would like to clarify the following.

The Abbott Architect SARS-CoV-2 IgG antibody assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating a recent or

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prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. This assay should not be used to diagnose acute SARS-CoV-2 infection and is not intended to detect antibodies to the spike protein that would be inferred from vaccination. If you have any questions regarding this assay, please contact Jennifer Lehman at 515-247-4484.

Effective Immediately

Update Orderables:

Test Name: Gastrointestinal Panel by PCR (STOOLPCR)

Performing Laboratory: MercyOne Laboratory

Acceptable Specimens: Serum from Red Top Tube or Gold SST.

CPT: 87507 (0097U deleted) Effective 04/01/2022