ALLINA HEALTH LABORATORY

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LabConnect

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Allina Health LABORATORY

COVID-19 UPDATES

Patient service center changes

In an effort to limit patient exposure to COVID-19, effective Monday, May 4, 2020, Allina Health Laboratory temporarily closed and relocated a number of our Patient Service Centers.

The following patient service centers are *unavailable for patients draws*.

- Abbott Northwestern Hospital
- Mercy Hospital - Mercy campus
- Mercy Hospital - Unity campus
- Owatonna Hospital

Please see updated list of patient service centers on our website for optional specimen collection sites.

These changes do not affect hospital laboratory testing, inpatient hospital services or the ability to collect samples from patients that are having other hospital services.

All Allina Health Laboratory Patient Service Center locations, including the above closed locations, will continue to accept drop-off specimens. Screeners are present at all hospitals and clinic entrances, and everyone entering must check in with them.

We appreciate your understanding and support as we try to provide the safest care possible for all patients during this time.

Serology (antibody) testing

In preparation for the expected increase in COVID-19 patients, Allina Health Laboratory is focusing resources on SARS-CoV-2 molecular (RT-PCR) swab testing. RT-PCR is currently the only method that can diagnose or exclude SARS-CoV-2 infection. We are working to increase collection supplies and molecular testing capacity for our hospitals and clients to support surgery and other needed hospital services before the expected surge as well.

In partnership with the state health department, we will evaluate serology (antibody) testing for SARS-CoV-2 in the near future, but this is not an immediate priority for our technical or sendout resources. Evidence collected so far indicates that while serology may be useful for epidemiologic purposes, results can't be used for clinical care, specifically:

- Serology results don't reduce PPE utilization.
- Serology results can't be used to implicate authentic infection, protective immunity, or to rule out infection.

In a recent briefing from the Minnesota Governor's COVID-19 Task Force, Dr. Mike Osterholm, epidemiologist at the University of Minnesota, cautioned against antibody testing, even for epidemiologic reasons, at this point in the pandemic because the prevalence is still low in our region. Dr. Osterholm explained that even a very good antibody test with 95% sensitivity and 95% specificity will produce an unacceptably high rate of false positives if performed too early in a pandemic.

There are some local consumer laboratories offering COVID-19 antibody tests to the public with misleading claims and patients may request the test based on wide publicity. We have placed the following on our patient FAQ web page:

Q: How can I get COVID-19 antibody testing?

A: At this time, Allina Health does not offer COVID antibody (also called serology) testing, and does not encourage patients to obtain testing through outside laboratories. This is because the testing is not able to accurately identify individuals who currently have COVID-19, or who have had COVID-19 in the past. Though some advertising claims that current COVID-19 antibody tests are reliable, this is not true. Allina Health is working closely with the state health department on the plan to provide clinically proven antibody testing in the near future.

Please see the following for an overview of SARS-CoV-2 antibody testing, limitations, and potential future advantages.

Overview of SARS-CoV-2 serology testing:

- Serology detects presence of antibodies (IgM, IgA and IgG) in blood, produced as a result of immune response to SARS-CoV-2 virus infection. Because COVID-19 is a new disease, currently available serology tests were released without a full clinical validation and, despite vendor claims, the true clinical utility and accuracy is not yet known. The international laboratory community has reported problems with accuracy when the tests are used on real-world specimens, including patients who recovered from lab-confirmed COVID-19 infection.
- Based on evidence to date, IgG antibody appears to be the most useful serologic marker for SARS-CoV-2 exposure.
- IgG antibody typically appears in 1 to 2 weeks after acquiring the infection, so IgG testing is generally recommended 14 days after onset of symptoms.
- IgM and IgA are considered markers of acute infection; however, it still takes one week or longer for these antibodies to be detectable in most patients, making them limited as markers of recent infection. Compared to IgG antibody testing, tests for IgM and IgA antibody have a concerning false positive rate in studies using real-world specimens
- Lab-based IgG assays (vs. rapid cartridge tests) have the highest sensitivity and specificity for SARS-CoV-2 antibodies, and are the only methods that can provide a quantitative value

Limitations of SARS-CoV-2 serology (antibody) testing

- Cannot rule out infection
- Positive results may be due to either past or recent infection with common coronavirus strains known to cause 5-10% of all viral respiratory illness, so a positive test may give false reassurance of immunity to SARS-CoV-2 virus
- There is no confirmatory method available to distinguish true positive from false positive antibody results, such as we have for Lyme disease where a positive Lyme antibody screen is followed by Western Blot
- The titer or serum level required to confer protection is unknown
- The duration of protection conferred by the antibody is unknown
- Some infected patients, such as those who are immunosuppressed, do not develop detectable antibodies
- Some patients with antibodies may still have SARS-CoV-2 detected by RT-PCR. It isn’t clear whether such patients are still infectious

Potential benefits of SARS-CoV-2 serology (antibody) testing

- Potential identification of individuals who have been exposed to the infection (symptomatic or asymptomatic) and developed an immune response. It is hoped that in the future, the test can help to determine individuals who are no longer susceptible to infection and can return to work
- Potentially identify individuals who are at risk for infection
- Gives CDC surveillance data needed to know national prevalence of disease and plan response to a pandemic
- May be helpful in the future to identify potential convalescent plasma donors but is not currently used to select donors

References:

- Abbasi, J; The Promise and Peril of Antibody Testing for COVID-19; JAMA, April 11, 2020.
- FDA; Important Information on the Use of Serological (Antibody) Tests for COVID-19 -Letter to Health Care Providers, April 17, 2020

Supply procurement and specimen drop offs

As the need for home care visits increases due to Covid-19, we wanted to take this opportunity to share a few reminders with you regarding supplies and specimen drop-off.

- Review your supply inventory regularly to ensure that you have adequate supplies on hand
  - Additional supplies should be ordered using the Allina Health Laboratory Supply catalog
  - Supplies should not be obtained from Allina Health hospitals or clinics

- The Allina Health Laboratory patient service centers (PSC's) are open for specimen drop off
- There have been changes at many Allina Health Clinic sites. Some have changed their hours and/or clinic designations, and others have become dormant or virtual
  - You should only drop specimens at sites listed only as *non-respiratory*
  - You will not be able to drop off specimens at dormant or virtual clinics
  - Samples cannot be dropped at any department other than the lab, i.e. pharmacy

- All Allina Health hospitals have screeners at their entrance door(s) that will stop you. They may ask questions prior to either taking the specimen from you, or allowing you to proceed to the laboratory.

We appreciate your cooperation and understanding during this time.

Questions?

If you have any questions about COVID-19 testing, contact your account representative for assistance.

REFERRAL TESTING

Bile acids assay update

LabCorp announced changes to the specimen requirements for the Bile acids assay (13347/LAB13347) which went into effect on May 11, 2020.

Requirement	Current	New
Specimen type (preferred)	Serum – Gold SST	No change
Specimen type (alternate)	Serum - Red	Serum (red), EDTA plasma (lavender) or heparin plasma (Dk green)
Processing	Gold SST – Spin Red – spin and separate	Gold SST – Spin Red/lavender/Dk green – spin and separate

Metanephrines, fractionated, plasma free reference range change

LabCorp has announced a reference range change for the Metanephrines, fractionated, plasma free assay (13578/LAB13578) which will go into effect on June 1, 2020.

CURRENT

Normetanephrine: 0 - 145 pg/mL
Metanephrine: 0 - 62 pg/mL

Concentrations of normetanephrine between 146 and 487 pg/mL and metanephrine between 63 and 255 pg/mL are considered indeterminate

NEW

Metanephrine: 0 – 88.0

Normetanephrine:
0 – 4 years: *Not established*
5 – 17 years: 0 – 86.1
18 – 29 years: 0 – 107.7
30 – 39 years: 0 – 110.1
40 – 49 years: 0 – 125.8
50 – 59 years: 0 – 136.8
≥60 years: 0 – 191.8

Paraneoplastic Ab, CSF assay update

On May 19, 2020, the Paraneoplastic autoantibody, CSF assay (994/LAB994), referred to LabCorp, became orderable with a unique test code, and no longer requires use of the Miscellaneous sendout (994/MSO).

	Current	New
Test #	994	14306
Excellian order	LAB994	LAB14306
Abbreviation	MSO	PAC1

Interfaced clients:
If this is a test that you will utilize at your practice, contact your AHL account representative for build information and testing.

Thank you for choosing Allina Health Laboratory -

We appreciate your business!