From: Dunn, Kathleen **On Behalf Of** Davidson, Peter
Sent: Thursday, June 18, 2020 3:48 PM
Subject: CDH COVID Clinical Update 6.15.20

Dear CDPHO Colleague:
See below FAQ update from Dr. Joanne COVID testing, Re-Testing, Infectivity and Serology. Related documents are attached.

Peter Davidson, MD
CDPHO Medical Director

From: Broadcast CDHC <BCDHC@Cooleydickinson.org>
Sent: Wednesday, June 17, 2020 4:43 PM
Subject: Clinical Update 6.15.20

CDH COVID Clinical Update: FAQs re COVID Testing, Re-testing, Infectivity, and Serology
6.15.20

I have heard many questions about interpreting test results, when to retest, what to do with results, and how to use serology testing. New data has come out about the meaning of repeatedly positive tests, and that has led to changes in policies and quite a bit of confusion. I will attempt to clarify here.

Q1: How long are patients with COVID considered contagious?

A: Current data shows that patients with COVID are contagious from about 2 days prior to symptoms until about 7 days after the start of symptoms. Those who had worse disease (i.e. hospitalized with pneumonia) may have a longer period of transmissibility. Therefore, our (CDH/MGB) current policy is to consider patients infectious:

- If the patient remained an outpatient during their course of disease: for 14 days after start of symptoms per MGB policy. (CDC says 10 days.) They also should have 3 days of resolution of fever without fever-reducing medications and improvement in respiratory symptoms.
- For patients who required inpatient care: for 14 days after DISCHARGE per CDH/MGB policy. They also should have 3 days of resolution of fever without fever-reducing medications and improvement in respiratory symptoms.
- If a patient tested positive for COVID-19 but was asymptomatic at the time and remained asymptomatic, resolution of infection status is permitted after 10 days from the positive test.
- **For EPIC users: If the patient has a red infection status flag, your patient is considered potentially infectious. Do not send them for usual care!**

See policy re "Infection Statuses" such as "Covid-19", "Covid-Presumed", "Covid- Exposed", "CoV-Risk"
https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/infection_statuses_and_resolution_

Q2: What do I do if my patient is in the infectious period (see above) but needs medical care?

A: For the safety of staff as well as other patients:

- Delay care whenever possible. Delay elective procedures, including labs and imaging when possible
- If care cannot be delayed safely, decide where and how care is best provided:
  - Phlebotomy- Patient may call the Respiratory Clinic (413-582-2881) to schedule phlebotomy.
  - Imaging: Call radiology to alert and discuss
  - Offices: Call ahead to alert and discuss whether the office is prepared to care for a COVID patient. Many offices are not.

- Respiratory Illness Clinic: Can see patients by appointment for respiratory illness for patients who need evaluation but may not need ED level of care. Non-Epic provider may call 413-582-2966 with referral.
- ED: Call ahead to alert and discuss
- Rehab: Call and discuss. Many rehab offices can do remote visits as needed

Q3: My patient had COVID, now feels better, but continues to have positive tests. Do they need to stay in quarantine?

A: Early in the pandemic, CDH/MGB used very conservative policies based on having two negative tests, to allow employees to come back to work and patients to come off precautions. Since then, there has been research showing that by 7 days after the start of symptoms, viable virus is not detectable. PCR testing, however, can detect non-viable virus and may show positive results for many weeks after initial symptoms. We have also seen patients who have had a positive test while symptomatic, followed by a negative test followed by a positive test ("re-positive"). These results probably are caused by very low titers of virus fragments that are just at the limit of detection of the test, and may occasionally meet the threshold and occasionally not meet the threshold to be labelled a "positive" PCR test. These patients are not considered infectious if they have met the criteria above. If patients meet the "time-based" criteria, they do not need to be retested. Once recovered from COVID by EPIC criteria, their banner will have a flag "COVID Recovered". Do not retest these patients when you see this flag.

Q4: There is a red warning on the EPIC banner that says "CoV-Risk". What does that mean and what should I do about it?

A: The red "CoV-Risk" warning is placed automatically by EPIC when a patient either has COVID symptoms (found on the COVID order) or high risk epidemiology AND a negative test. This means that further evaluation should be done to decide if this patient might actually have COVID or not. This flag can be removed by Infection Prevention (582- 2135) if you provide further clinical information. This flag auto-resolves at 14 days after the test. Do not send patients for care (except as above) until this flag is resolved. For information about all Infection Statuses, please see policy:

https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/infection_statuses_and_resolution

Q5: What is the sensitivity of the NP and nasal tests that we do at CDH?:

A: None of the PCR tests that are in use have received full approval of the FDA. They were approved through "Emergency Use Authorization" based on little data, and without a clear gold standard for comparison. Data from China initially quoted that NP swabs tested by PCR had about 70% sensitivity. Mass General, where we send many of our NP swabs, believes their test is 80-95% sensitive. The rapid nasal swab we perform on the Abbott platform has shown variable results in the literature, but when this test was performed head-to-head against a PCR test locally, it had 93% sensitivity compared to PCR. This translates to about 80% total sensitivity.
Therefore when an inpatient appears to have COVID by clinical assessment, but has a negative rapid nasal test, we routinely repeat testing using a NP swab for a PCR test.

Q6: How reliable is a negative PCR test?

A: The reliability of a negative test ("negative predictive value") is based not only on the characteristics of the test (sensitivity and specificity) but ALSO the prevalence of the disease in the community. For example, as of May 21st, MGB determined that across all of the MGB hospitals, the percent of asymptomatic patients with positive tests was 1.1% (CDH numbers were even lower). Using an 85% sensitivity and 99.5% specificity, and 1.1% prevalence, the negative predictive value is 99.8! If prevalence went up to 10%, the negative predictive value would be 98.4%.

Q7: My outpatient has symptoms consistent with COVID, but an NP swab was negative. What should I do?

A: The patient should stay in quarantine for 14 days after the onset of symptoms. If you want to continue evaluation for COVID, 7 days or more after the onset of symptoms, you could order a COVID serology test. From day 7 through day 14 after the onset of symptoms, however, that patient should be considered potentially infectious. If lab work is ordered during that time, it should be arranged to be done in the RIC (582-2881). However, be aware that serology is more likely to be positive after day 14. If this patient requires other medical care before day 14, please call ahead to discuss with the receiving department. Unless the diagnosis needs to be known sooner, having the patient stay home and then have a serologic test done when they are out of the infectious period would be best.

Q8: How accurate is serologic testing, and when should it be performed?
A: The accuracy of serologic testing is very dependent on the test that is used. Antibodies, both IgM and IgG, start to be measurable around day 7 of illness. The test used at CDH on the Roche platform is thought to be >90% sensitive and >99% specific by day 14 after the onset of symptoms. It approaches 100% sensitivity by day 21. Therefore testing day 21 or later is most reliable. A test cannot be ordered in EPIC unless 7 days have passed after the onset of symptoms. Please remember that patients may be infectious up to 14 days (or longer for those who have been inpatients) after symptom onset (see above), so please do not send these patients to a routine lab until you know they are out of the infectious period. Patients will need to check with their insurance company to find out if insurance will pay for the test.
https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/outpatient_sarscov2_serology_testing_guidance

Q9: My patient has a known exposure to a COVID positive household member. When can they leave quarantine?
A: A COVID-exposed patient is potentially infectious for 14 days after exposure. If exposure is ongoing, then the family member must remain in quarantine for 14 days after the household member is cleared.

Q10: My patient has recovered from COVID and would now like to donate plasma. How do they do that?
A: Refer your patient to uscovidplasma.org. There is a section for patients—they need to see if they qualify. The closest locations are Holyoke and Springfield. The patient does not need to have a serologic test before they go.

Q11: What are the latest CDH testing criteria?
A: CDH and MGB are now closely aligned, so we will use the MGB criteria (which is embedded in the EPIC order and on the paper order sheet). Any CDH-associated provider can order a COVID test for any patient "at provider discretion". Non--epic users please use the paper order sheet attached, and fax to 413-582-2638.
https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/covid19_clinical_policies/sarscov2_testing_policy

This document will be posted on the CDH Intranet:
CDH Intranet →Infectious Disease and Prevention→COVID-19 →CDH COVID Updates

Thank you!

Please send questions or comments to

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