ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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MEMORANDUM

TO: Local Health Departments & Regional Offices of the Illinois Department of Public Health (IDPH), Hospital Laboratories, Hospital Administrators, PIOs, ED Personnel, Nursing Directors, EMS Staff, Laboratory Staff, ID/INEDSS, EMS Partners and IL Local EMAs

FROM: E. Matt Charles
Chief, Division of Laboratories

DATE: February 7, 2020

SUBJECT: 2019-Novel Coronavirus (2019-nCov) Real – Time RT-PCR Diagnostic Panel Implementation

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Effective today, the Illinois Department of Public Health (IDPH) Division of Laboratories will begin offering the CDC 2019-Novel Coronavirus (2019-nCov) Real – Time RT-PCR Diagnostic Panel, in order to support the novel coronavirus response. Details of the testing, including the specimen collection, transport conditions and resulting mechanisms are summarized in the accompanying technical bulletin. This test requires Local Health Department (LHD) approval which is indicated through completion of the CDCS Lab Authorization online form located on the IDPH portal. A completed CDC PUI form must also be included with the shipment.

Current criteria for approval are as follows:

1) Individuals meeting the patient under investigation (PUI) criteria as outlined in CDC Guidance.

Note: The PUI criteria are intended to serve as guidance for evaluation. Patients should be evaluated and PUI classification should be discussed with LHDs on a case-by-case basis if their clinical presentation or exposure history is equivocal (e.g., uncertain travel or exposure) or otherwise concerning.

Serum is currently not an acceptable specimen source for the CDC 2019-nCov rRT-PCR. However, serum may be requested by the IDPH lab for supplemental testing by CDC if respiratory specimens are positive. If you have specific questions relating to the content of this communication, please contact:

Dr. Mohammad Nasir
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IDPH Laboratory, Chicago
2121 W. Taylor Street
Chicago, IL 60612
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IDPH Communicable Diseases Program
525 West Jefferson Street
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Technical Bulletin for CDC 2019-Novel Coronavirus (2019-nCov) Real – Time RT-PCR Diagnostic Panel

Test Information	Description
Test Name	CDC 2019-Novel Coronavirus (2019-nCov) Real – Time RT-PCR Diagnostic Panel
Test Method	The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel is a real-time RT-PCR intended for the presumptive qualitative detection of nucleic acid from the 2019-Novel Coronavirus.
Approval	Testing authorization must be obtained before submitting a specimen. Approval can be obtained through the patients Local Health Department or through the state Communicable Diseases Program staff. An IDPH Communicable Diseases Laboratory Test Requisition must accompany specimens and include the: test ordered, full patient name and identifiers (including sex and date of birth), source of specimen, date of collection, the submitting organization, referring physician if appropriate, and contact information. A CDC PUI form must also be completed and submitted with the specimen(s).
Specimen Requirements	Specimen type includes upper and lower respiratory specimens such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate collected from individuals who meet CDC criteria for 2019-nCoV testing. The minimum sample volume required is 2ml in VTM. Collection should occur as quickly as possible and performed according to standard technique and placed in viral transport media (VTM). The optimum specimen type and timing for peak viral levels during infections caused by 2019- nCov have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.
Storage of Specimens	Clinical specimens should be stored refrigerated after collection at (2-8°C) and shipped on cold packs immediately to IDPH. If specimens can't be shipped immediately, contact the IDPH laboratories to discuss transport and prioritization. If specimens are not tested within 72 hours of collection, they may be stored at -70°C or lower and shipped on dry ice.
Criteria for Specimen Rejection	Rejection criteria include but are not limited to those with: 1. Mismatched requisitions 2. Specimens without patient identifiers 3. Specimens stored or shipped incorrectly 4. Specimens collected using expired viral transport media 5. Specimens without IDPH Communicable Disease Program /Local Health Department (LHD) testing pre-approval and for which approval cannot be obtained after specimen receipt.
Specimen Shipping	Either use a courier service or ship specimens overnight to the Chicago Laboratory (address below). Specimens should be shipped cold (refrigerated and on ice packs, or frozen with dry ice). **ATTN: Viral Diagnostics Laboratory** **Illinois Department of Public Health** **2121 W. Taylor Street** **Chicago, IL 60612**
Test Location	IDPH Chicago Laboratory. The laboratory is open Monday through Friday from 8:00 am to 4:30 pm. All specimen deliveries must be made through the rear of the building.
Test Frequency	Testing is performed Monday through Friday except Federal holidays. Testing may also be arranged by special request on holidays and weekends in consultation with the IDPH Communicable Disease Control Section.
Turnaround Time	Turn Around Time: Less than 3 business days of receiving specimens. Additional time will be needed for specimens which must be referred to CDC for supplemental testing.
Results	Sent by Fax with indication of Detected/Not Detected for the following pathogens: ***2019-nCoV detected*** – Presumptive positive 2019-nCoV (will require confirmatory testing by CDC). ***Inconclusive*** – Additional testing and discussion with CDC may be warranted. ***Not Detected*** – Consider testing for other respiratory pathogens. ***Invalid*** – Internal control does not amplify; consider collection of a new specimen.
Reference Range	Not Detected for all targets on panel (Detected for Internal Control)

Note: ***Please copy this chart, place in a plastic protective sleeve and post in a prominent location for Staff reference.*** **Questions on specimen approval or submission should be directed to the Chicago Laboratory main number @ 312-793-4760 or the IDPH Communicable Disease Program Staff @ 217-782-2016.**