Criteria to Guide Evaluation of Patients Under Investigation (PUI) for 2019-nCoV

Patients in the United States who meet the following criteria should be evaluated as a PUI in association with the outbreak of 2019-nCoV in Wuhan City, China.

Clinical Features	&	Epidemiologic Risk
Fever[1] **and** symptoms of lower respiratory illness (e.g., cough, difficulty breathing)	and	In the last 14 days before symptom onset, a history of travel from Wuhan City, China. *– or –* In the last 14 days before symptom onset, close contact[2] with a person who is under investigation for 2019-nCoV while that person was ill.
Fever[1] **or** symptoms of lower respiratory illness (e.g., cough, difficulty breathing)	and	In the last 14 days, close contact[2] with an ill laboratory-confirmed 2019-nCoV patient.

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

Footnotes

[1]Fever may not be present in some patients, such as those who are very young, elderly, immunosuppressed, or taking certain fever-lowering medications. Clinical judgment should be used to guide testing of patients in such situations.

[2]Close contact is defined as—

a) being within approximately 6 feet (2 meters), or within the room or care area, of a novel coronavirus case for a prolonged period of time while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection); close contact can include caring for, living with, visiting, or sharing a health care waiting area or room with a novel coronavirus case.– *or* –

b) having direct contact with infectious secretions of a novel coronavirus case (e.g., being coughed on) while not wearing recommended personal protective equipment.

See CDC's Interim Healthcare Infection Prevention and Control Recommendations for Patients Under Investigation for 2019 Novel Coronavirus

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with novel coronavirus (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to those exposed in health care settings.

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)

January 17, 2020

Health care providers should contact their local/state health department immediately to notify them of patients with fever and lower respiratory illness who traveled to Wuhan, China within 14 days of symptom onset. Local and state public health staff will determine if the patient meets the criteria for a patient under investigation (PUI) for 2019 Novel Coronavirus (2019-nCoV). Clinical specimens should be collected from PUIs for routine testing of respiratory pathogens at either clinical or public health labs. Note that clinical laboratories should NOT attempt viral isolation from specimens collected from 2019-nCoV PUIs.

At this time, diagnostic testing for 2019-nCoV can be conducted only at CDC.

State and local health departments who have identified a PUI should immediately notify CDC's Emergency Operations Center (EOC) at 770-488-7100 to report the PUI and determine whether testing for 2019-NCoV at CDC is indicated. The EOC will assist local/state health departments to collect, store, and ship specimens appropriately to CDC, including during afterhours or on weekends/holidays.

Testing for other respiratory pathogens by the provider should be done as part of the initial evaluation and should not delay specimen shipping to CDC.

If a PUI tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a PUI.

Specimen Type and Priority

To increase the likelihood of detecting infection, CDC recommends:

Collection of three specimen types, lower respiratory, upper respiratory and serum specimens for testing is recommended. If possible, additional specimen types (e.g., stool, urine) should be collected and should be stored initially until decision is made by CDC whether additional specimen sources should be tested. Specimens should be collected as soon as possible once a PUI is identified regardless of symptom onset. Maintain proper infection control when collecting specimens.

General Guidelines

Store specimens at 2-8°C and ship overnight to CDC on ice pack. Label each specimen container with the patient's ID number (e.g., medical record number), unique specimen ID (e.g., laboratory requisition number), specimen type (e.g., serum) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted. In the upper left box of the form, 1) for *test requested* select "Respiratory virus molecular detection (non-influenza) CDC-10401" and 2) for *At CDC, bring to the attention of* enter "Stephen Lindstrom: 2019-nCoV PUI".

I. Respiratory Specimens

A. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

Sputum

Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

B. Upper respiratory tract

Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)

Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. NP and OP specimens should be kept in separate vials. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

Nasopharyngeal swab: Insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nasopharyngeal areas with the same swab.
Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx, avoiding the tongue.

Nasopharyngeal wash/aspirate or nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship overnight to CDC on ice pack.

II. Serum

Minimum volume required:

Children and adults: Collect 1 tube (5-10 mL) of whole blood in a serum separator tube.

Infant: A minimum of 1 mL of whole blood is needed for testing pediatric patients. If possible, collect 1 mL in a serum separator tube.

Serum separator tubes should be stored upright for at least 30 minutes, and then centrifuged at 1000–1300 relative centrifugal force (RCF) for 10 minutes before removing the serum and placing it in a separate sterile tube for shipping (such as a cryovial). Refrigerate the serum specimen at 2-8°C and ship overnight to CDC on ice-pack.

III. Shipping

Specimens PUI's must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulationsexternal icon. Store specimens at 2-8°C and ship overnight to CDC on ice pack. If a specimen is frozen at -70°C ship overnight to CDC on dry ice. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV)

January 17, 2020

To date, we do not fully understand the pathogenic potential and transmission dynamics of 2019 Novel Coronavirus (2019-nCoV). Until more information becomes available, precautions should be taken in collecting and handling specimens that may contain 2019-nCoV. Timely communication between clinical and laboratory staff is essential to minimize the risk incurred in handling specimens from patients with possible 2019-nCoV infection. Such specimens should be labeled accordingly, and the laboratory should be alerted to ensure proper specimen handling. General and specific biosafety guidelines for handling 2019-nCoV specimens are provided below.

For additional detailed instructions please refer to the following:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) – Fifth Edition
- Laboratory Biosafety Manual – Third Editionexternal icon

General Guidelines (for working with potentially infectious materials)

Laboratory workers should wear appropriate personal protective equipment (PPE) which includes disposable gloves, laboratory coat/gown and eye protection when handling potentially infectious specimens.

Any procedure with the potential to generate fine-particulate aerosols (e.g., vortexing or sonication of specimens in an open tube) should be performed in a Class II Biological Safety Cabinet (BSC). Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation. Ideally, rotors and buckets should be loaded and unloaded in a BSC. Perform any procedures outside a BSC in a manner that minimizes the risk of exposure to an inadvertent sample release.

After specimens are processed, decontaminate work surfaces and equipment with appropriate disinfectants. Use any EPA-registered hospital disinfectant. Follow manufacturer's recommendations for use-dilution (i.e., concentration), contact time, and care in handling.

All disposable waste should be autoclaved.

Specific Guidelines

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of 2019-nCoV specimens are NOT recommended at this time.

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Electron microscopic studies with glutaraldehyde-fixed grids
- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of fixed smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, decontaminated primary container.
- Inactivated specimens (e.g., specimens in nucleic acid extraction buffer)

The following activities involving manipulation of potentially infected specimens should be performed as above and in a Class II BSC:

- Aliquoting and/or diluting specimens
- Inoculating bacterial or mycological culture media
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid extraction procedures involving potentially infected specimens
- Preparation and chemical- or heat-fixing of smears for microscopic analysis

Clinical Laboratory Testing

Clinical laboratories performing routine hematology, urinalysis, and clinical chemistry studies, and microbiology laboratories performing diagnostic tests on serum, blood, or urine specimens should follow standard laboratory practices, including Standard Precautions, when handling potential 2019-nCoV specimens. For additional information, see Biosafety in Microbiological and Biomedical Laboratories (BMBL) – Fifth Edition (page 225).

Packing, Shipping and Transport

Packaging, shipping, and transport of specimens from suspect cases or PUI's of 2019-nCoV infection must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulationsexternal icon.

Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.

Resources

- Packaging Checklist, see Category B Saf-T-Pakpdf icon
- Packing Instructions 650 for UN 3373external icon
    - Click on "Infectious substances" and there is an option to download the packing instructions.
- Labels for UN 3373
    - When using cold pack pdf icon – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
    - When using dry ice pdf icon – Include the name and telephone number of the person who will be available during normal business hours who knows the content of the shipment (can be someone at CDC). Place the label on one side of the box and cover the label completely with clear tape (do not tape just the edges of the label).
- Schematic for packaging, UN 3373 Category Bpdf icon

Internal use
CDC nCoV ID _____

Interim 2019 novel coronavirus (2019-nCoV) patient under investigation (PUI) form

As soon as possible, notify and send completed form to: 1) your local/state health department, and 2) CDC: email (eocreport@cdc.gov, subject line: nCoV PUI Form) or fax (770-488-7107). If you have questions, contact the CDC Emergency Operations Center (EOC) at 770-488-7100.

Today's date_____ **State patient ID**_____ **NNDSS local record ID/Case ID**[1] _____ **State**___ **County**_____

Interviewer's name_____ **Phone**_____ **Email**_____

Physician's name _____ **Phone**_____ **Pager or Email**_____

Sex ☐ M ☐ F **Age**_____☐ yr ☐ mo **Residency** ☐ US resident ☐ Non-US resident, country_____

PUI Criteria

Date of symptom onset_____

Does the patient have the following signs and symptoms (check all that apply)?

☐ Fever[2] ☐ Cough ☐ Sore throat ☐ Shortness of breath

In the 14 days before symptom onset, did the patient:

Spend time in Wuhan City, China? Does the patient live in Wuhan City? ☐ Y ☐ N ☐ Unknown Date traveled **to** Wuhan City_____ Date traveled **from** Wuhan City_____ Date **arrived** in US_____	☐ Y ☐ N ☐ Unknown
Have close contact[3] with a person who is under investigation for 2019-nCoV while that person was ill?	☐ Y ☐ N ☐ Unknown
Have close contact[3] with a laboratory-confirmed 2019-nCoV case while that case was ill?	☐ Y ☐ N ☐ Unknown

Additional Patient Information

Is the patient a health care worker? ☐ Y ☐ N ☐ Unknown

Have history of being in a healthcare facility (as a patient, worker, or visitor) in Wuhan City, China? ☐ Y ☐ N ☐ Unknown

Is patient a member of a cluster of patients with severe acute respiratory illness (e.g., fever and pneumonia requiring hospitalization) of unknown etiology in which nCoV is being evaluated? ☐ Y ☐ N ☐ Unknown

Does the patient have these additional signs and symptoms (check all that apply)?

☐ Chills ☐ Headache ☐ Muscle aches ☐ Vomiting ☐ Abdominal pain ☐ Diarrhea ☐ Other, Specify_____

Diagnosis (select all that apply): Pneumonia (clinical or radiologic) ☐ Y ☐ N Acute respiratory distress syndrome ☐ Y ☐ N

Comorbid conditions (check all that apply): ☐ None ☐ Unknown ☐ Pregnancy ☐ Diabetes ☐ Cardiac disease ☐ Hypertension ☐ Chronic pulmonary disease ☐ Chronic kidney disease ☐ Chronic liver disease ☐ Immunocompromised ☐ Other, specify

Is/was the patient: Hospitalized? ☐ Y, admit date_____ ☐ N **Admitted to ICU?** ☐ Y ☐ N

Intubated? ☐ Y ☐ N **On ECMO?** ☐ Y ☐ N **Patient died?** ☐ Y ☐ N

Does the patient have another diagnosis/etiology for their respiratory illness? ☐ Y, Specify_____ ☐ N ☐ Unknown

Respiratory diagnostic results

Test	Pos	Neg	Pending	Not done
Influenza rapid Ag ☐ A ☐ B	☐	☐	☐	☐
Influenza PCR ☐ A ☐ B	☐	☐	☐	☐
RSV	☐	☐	☐	☐
H. metapneumovirus	☐	☐	☐	☐
Parainfluenza (1-4)	☐	☐	☐	☐
Adenovirus	☐	☐	☐	☐

Test	Pos	Neg	Pending	Not done
Rhinovirus/enterovirus	☐	☐	☐	☐
Coronavirus (OC43, 229E, HKU1, NL63)	☐	☐	☐	☐
M. pneumoniae	☐	☐	☐	☐
C. pneumoniae	☐	☐	☐	☐
Other, Specify_____	☐	☐	☐	☐

Specimens for 2019-nCoV testing

Specimen type	Specimen ID	Date collected	Sent to CDC?
NP swab			☐
OP swab			☐
Sputum			☐
BAL fluid			☐
Tracheal aspirate			☐

Specimen type	Specimen ID	Date collected	Sent to CDC?
Stool			☐
Urine			☐
Serum			☐
Other, specify____			☐
Other, specify____			☐

[1] *For NNDSS reporters, use GenV2 or NETSS patient identifier.*

[2] *Fever may not be present in some patients, such as those who are very young, elderly, immunosuppressed, or taking certain medications. Clinical judgement should be used to guide testing of patients in such situations.*

[3] *Close contact is defined as: a) being within approximately 6 feet (2 meters) or within the room or care area for a prolonged period of time (e.g., healthcare personnel, household members) while not wearing recommended personal protective equipment (i.e., gowns, gloves, respirator, eye protection); or b) having direct contact with infectious secretions (e.g., being coughed on) while not wearing recommended personal protective equipment. Data to inform the definition of close contact are limited. At this time, brief interactions, such as walking by a person, are considered low risk and do not constitute close contact.*