SARS-CoV Laboratory Investigation Protocol for the SARS Post-Outbreak Period

This document provides guidance for determining the circumstances under which SARS-associated coronavirus (SARS-CoV) testing should be conducted for public health investigations of Severe Respiratory Illness (SRI) in the SARS post-outbreak period. A sample Case Tracking Form for laboratory specimens is also provided.

Rationale for limiting SARS-CoV testing:

- The positive predictive value of a SARS-CoV test in the SARS post-outbreak period is very low. Any positive test results will initiate a substantial chain of public health actions that are both labour intensive and expensive. As well, any false-positive results have the potential for negative social and economic impacts that may be difficult to mitigate.
- SARS-CoV diagnostics are undergoing rapid development and the specificity of the current tests needs further investigation.
- There are many research questions pertaining to SARS diagnostics tests that remain to be answered. Public health investigations should not be used to answer such research questions. Research questions are best addressed by formal research protocols with appropriate research designs and controls.

Circumstances under which SARS-CoV testing should be considered

There are currently two circumstances under which SARS-CoV testing might be considered: (1) persons with a potential epidemiologic link who are hospitalized with SRI and (2) clusters of SRI within a health care unit[1] in an acute care facility

1. Persons with a potential epidemiologic link who are hospitalized with SRI:
   a) **A person admitted to hospital with:**

      Respiratory symptoms, i.e.:
      - Fever (over 38 degrees Celsius) AND Cough or breathing difficulty

      AND Radiographic evidence consistent with SRI, i.e.:
      - Radiographic evidence of infiltrates consistent with pneumonia or respiratory distress syndrome (RDS).

      AND No alternate diagnosis within the first 72 hours of hospitalization, i.e.:

[1] The definition of the health care unit in which the cluster occurs will depend on the local situation. Unit size may range from an entire health care facility if small, to a single department or ward of a large tertiary hospital. A jurisdiction may chose, based on its own risk assessment and experience, to increase the minimum period for defining a cluster beyond 10 days.

- Results of preliminary clinical and/or laboratory investigations, within the first 72 hours[2] of hospitalization, cannot ascertain a diagnosis (i.e. SARS or other emerging respiratory pathogen cannot be ruled out).

AND one or more of the following exposures/conditions, i.e.:

- Residence, recent travel or visit to a potential zone of emergence/re-emergence (i.e. including mainland China, Taiwan Province and Hong Kong Special Administrative Region) within the 10 days prior to onset of symptoms; OR close contact (including health care providers) of a symptomatic person who has been to a potential zone of emergence/re-emergence within the 10 days prior to onset of symptoms.
- The admitted person is a laboratory worker handling live SARS-CoV

OR

b) A deceased person with:

A history of respiratory symptoms, i.e.:

- history of unexplained acute respiratory illness (including fever, and cough or difficulty breathing) resulting in death

AND Autopsy performed with findings consistent with SRI, i.e.:

- autopsy findings consistent with the pathology of RDS without an identifiable cause

AND one or more of the following exposures/conditions, i.e.:

- Residence, recent travel or visit to a potential zone of emergence/re-emergence i.e. including mainland China, Taiwan Province and Hong Kong Special Administrative Region) within the 10 days prior to onset of symptoms; OR close contact (including health care providers) of a symptomatic[3] person who has been to a potential zone of emergence/re-emergence within the 10 days prior to onset of symptoms.
- The deceased person is a laboratory worker handling live SARS-CoV

2. Clusters of SRI within a health care unit[1] in an acute care facility
   a) 2 or more health care workers or 3 or more persons (health care workers and/or other hospital staff and/or patients and/or visitors) within a health care unit[1] with onset of illness in the same 10-day period and with:

Respiratory symptoms, i.e.:

- Fever (over 38 degrees Celsius) AND Cough or breathing difficulty

[2] Laboratory investigation, including laboratory testing for influenza and other respiratory pathogens should be started immediately upon presentation (i.e. do not wait 72 hours to initiate testing). Testing for SARS-CoV should not be initiated within the first 72 hours.

[3] Symptoms consistent with SARS include, at a minimum, fever and cough or breathing difficulty. A jurisdiction may choose to include, based on its own risk assessment and experience, only contacts of severely ill (i.e. persons with radiographic evidence consistent with SARS) returned travellers.

AND Admitted to hospital

AND Radiographic evidence OR Autopsy finding consistent with SRI, i.e.:

- Radiographic evidence of infiltrates consistent with pneumonia or respiratory distress syndrome (RDS), **OR**
- Autopsy findings consistent with the pathology of RDS without an identifiable cause

AND No alternate diagnosis within the first 72 hours[2]

- Results of preliminary clinical and/or laboratory investigations, within the first 72 hours[2] of hospitalization, cannot ascertain a diagnosis (i.e. SARS or other emerging respiratory pathogen cannot be ruled out).

Routine investigation for SARS-CoV is **NOT** recommended for respiratory infection clusters in Long Term Care Facilities (LTCF) unless there is a strong epidemiologic link to an affected health care unit[1] within an acute care facility (e.g., a patient/health care worker is transferred from an affected acute care facility to the LTCF).

Alternate diagnoses:
In the SARS post-outbreak period, tests for all common/standard respiratory pathogens which are consistent with the clinical/epidemiologic picture should be conducted before considering any SARS-CoV testing. If any of the tests are positive and can fully explain the illness, then SARS-CoV testing should not be conducted. For a list of diagnostics tests to be considered for patients with SRI NYD, please refer to CPHLN document on *Laboratory Testing for Patients with SRI NYD:* http://www.sars.gc.ca/

What specimens should be collected for SARS-CoV testing?
Please refer to the CPHLN document on *Recommended Specimens for the Diagnosis of SARS-CoV*: http://www.sars.gc.ca/

Where should SARS-CoV testing be conducted?
As per the WHO recommendation, if SARS-CoV testing is conducted at a laboratory other than the national or provincial public health laboratories, confirmation of SARS-CoV results should be conducted at the national or a provincial public health laboratory.

How should SARS-CoV test results be interpreted?
Please refer to the CPHLN document on *Laboratory Evidence of SARS-CoV Infection:* http://www.sars.gc.ca/.

Case Tracking Systems:
Health Canada recommends that all jurisdictions have in place a case tracking system to link SRI cases under investigation with their laboratory specimens using unique identifying numbers. Such a system is crucial to ensure that appropriate public health measures, including contact tracing, are implemented. A case tracking systems will also help to

1. ensure the linkage of test results to confirmed or probable cases, or Persons Under Investigation (PUIs);

2. improve efficiencies and cost-savings by triaging specimens and ensuring that urgent specimens are prioritized;
3. improve public health surveillance of and information generation about SARS by providing clinical, epidemiologic and laboratory information for each case.

At a minimum, any case tracking system must include a request for a SARS test, the province or territory where the specimen originated, current case status and a unique identifying number assigned to that case.

Click here for a sample case tracking form http://www.sars.gc.ca/

Appendix A:

Case Tracking Form for SARS-CoV Testing In the SARS Post-Outbreak Period

Please complete and attach this slip to the laboratory requisition

(PT) (unique number)

TRACKING CODE: SRI- __ -_____

(This patient id number should be obtained from public health and used for all specimen submissions)

SRI Case Status: [Please check one]

☐ **Hospitalized SRI (severe respiratory illness) patient OR** ☐ **Deceased SRI** **With at least one of the following:** □ **travel history to China** (or other zone of emergence / re-emergence if applicable – specify travel history below) □ **close contact** (including health care providers) of a symptomatic person who has been to a potential zone of emergence/re-emergence □ **laboratory worker who has been in direct contact with live SARS-CoV**	☐ **Patient is being investigated as part of a cluster of hospital acquired SRI in ≥ 2 health care workers (HCW) or ≥ 3 persons (HCW and/or other hospital staff and/or patients and/or visitors) within a health care unit with onset of illness in the same 10-day period**
Date of onset of symptoms: ___/___/_____ **dd/mm/yyyy**	**COMMENTS:**

☐ **travel history, please specify location**:_____

Important Transportation Notes:

1. **Address and contact information for shipment to the National Microbiology Laboratory (NML) in Winnipeg** should be appended to the laboratory requisition.
2. **Please communicate with local provincial laboratories FIRST** before sending samples to the provincial labs or to the NML.
3. **Please e-mail Dr. Theodore Kuschak** at the NML (Theodore_kuschak@hc-sc.gc.ca) to indicate that specimens are en-route.

Recommended SARS-CoV Laboratory Investigation of SRI

1. **Serology:**
   a. **Acute and convalescent serum (**if no seroconversion after 14 or 21 days, collect a third specimen after 28 days) in a red tube (**10mL**, minimum)
2. **PCR:**
   a. **Nasopharyngeal swab or aspirate** in viral transport medium **(2mL)**
   b. **Stool or rectal** swab fresh or in a sterile container.
   c. **Lower respiratory tract specimens**, (BAL, sputum, lung biopsy if collected)
3. **Autopsy for PCR:**
   a. **Lung, bowel, spleen, lymph nodes. FRESH FROZEN: DO NOT place autopsy specimens for SARS CoV PCR in formalin.**