

Notification Date: October 31, 2023 Effective Date: Immediately

# Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA and Influenza Virus Type A and Type B RNA Detection, PCR, Varies

Test ID: COFLU

# **Explanation:**

Due to assay performance issues, this test will be made non-orderable, effective immediately. Specimens in transit or on site will be processed. Alternatives for testing these analytes can be accomplished with a combination of the tests listed below.

#### **Recommended Alternative Test:**

# Influenza Virus Type A and Type B, and Respiratory Syncytial Virus (RSV) RNA, Molecular Detection, PCR, Varies

Test ID: HPFLU

# Methodology:

Multiplex Real-Time Polymerase Chain Reaction (RT-PCR)

#### **Reference Values:**

Undetected

#### **Specimen Requirements:**

**Preferred:** 

Specimen Type: Nasopharyngeal swab

Container/Tube: Sterile container with transport media

Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.

**Collection Instructions:** 

- 1. Collect specimen by swabbing back and forth over mucosa surface to maximize recovery of cells.
- 2. Swab must be placed into viral transport media (eg, M4-RT, M4 or M5), saline, or phosphate buffered saline (PBS). **Media should not contain guanidine thiocyanate (GTC).**

#### Acceptable:

Specimen Type: Oropharyngeal (throat) swab, nasal mid-turbinate, or nares/nasal swab

Supplies:

- -Culturette (BBL Culture Swab) (T092)
- -Mid-turbinate (MT) Swab (Copan FLOQSwab) (T864)
- -Swab, Sterile Polyester (T507)

Container/Tube: Sterile container with transport media

Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media.

Preferred: BBL Culture Swab, COPAN Mid-turbinate Swab

Acceptable: Dacron-tipped swab with plastic handle

Collection Instructions: Swab must be placed into viral transport media (eg, M4-RT, M4, or M5), saline, or

PBS. Media should not contain guanidine thiocyanate (GTC).

**Specimen Type:** Lower respiratory tract

Sources: Bronchoalveolar lavage (BAL), bronchial washings, endotracheal aspirate, sputum

Container/Tube: Sterile container Specimen Volume: 0.6 mL

Additional Information: Do not aliquot into viral transport media.

# **Specimen Stability Information:**

Specimen Type	Temperature	Time
Varies	Frozen (preferred)	14 days
	Refrigerated	72 hours

#### **CPT Code:**

87631

**Day(s) Performed:** Monday through Sunday **Report Available:** Same day/1 to 2 days

## **Recommended Alternative Test:**

# Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA Detection, PCR, Varies

Test ID: COVID

# Methodology:

Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR)

## **Reference Values:**

Undetected

#### **Specimen Requirements:**

**Specimen Type:** Nasopharyngeal (NP), oropharyngeal (OP ie, throat), nasal mid-turbinate, or nares/nasal

swab

# Supplies:

- -Swab, Sterile Polyester, 10 per package (T507)
- -Dacron-tipped swab with plastic shaft is acceptable

**Container/Tube:** Universal transport media, viral transport media, or equivalent (eg, Copan UTM-RT, BD VTM, MicroTest M4, M4-RT, M5)

## Media should not contain guanidine thiocyanate (GTC).

For more information on acceptable transport media, see <a href="https://www.fda.gov/medical-devices/emergency-situations-medical-devices/fags-diagnostic-testing-sars-cov-2">www.fda.gov/medical-devices/emergency-situations-medical-devices/fags-diagnostic-testing-sars-cov-2</a>

Specimen Volume: Entire specimen with a minimum of 1.5 mL (maximum 3 mL) of transport media. Collection Instructions:

- 1. Collect specimen by swabbing back and forth over nasal or pharyngeal mucosa surface to maximize recovery of cells.
- 2. NP and OP swab specimens may be combined at collection into a single vial of transport media but only one swab is required for analysis.
- 3. Swab must be placed into transport medium. Swab shaft should be broken or cut so that there is no obstruction to the sample or pressure on the media container cap.
- 4. Do **not** send in glass tubes, vacutainer tubes, or tubes with push caps.
- 5. Do not overfill with more than 3 mL total volume of media.

Specimen Type: Nasopharyngeal aspirate or nasal washings

Container/Tube: Sterile container
Specimen Volume: Minimum of 1.5 mL

Additional Information: Do not aliquot into viral transport media, glass tubes, vacutainer tubes, or

tubes with push caps.

Specimen Type: Lower respiratory tract

Sources: Bronchoalveolar lavage (BAL) fluid, bronchial washings, endotracheal aspirate, sputum

Container/Tube: Sterile container Specimen Volume: Minimum of 1.5 mL

Additional Information: Do not aliquot into viral transport media, glass tubes, vacutainer tubes, or

tubes with push caps.

## **Specimen Stability Information:**

Specimen Type	Temperature	Time
Varie	Frozen (preferred)	14 days
	Refrigerated	72 hours

#### **CPT Code:**

87635

**Day(s) Performed:** Monday through Sunday **Report Available:** Same day/1 to 3 days

#### Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.