

**Hologic® Direct Load Capture Cap Collection Kit —
CLASSIQSwabs™**

Instructions for Use

Intended Use

The Hologic® Direct Load Capture Cap Collection Kit – CLASSIQSwabs™ is intended to be used for clinician collection of throat and nasal swab specimens for testing with Hologic assays to detect the presence of RNA from SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B).

Materials Provided

100 Hologic Direct Load Capture Cap Collection Kit — CLASSIQSwabs™ (Cat. No. PRD-06951)

Each kit contains:

| Component | Quantity | Description |
|------------------------------|-----------------|---|
| Swab | 1 | Individually wrapped, sterile swab |
| Direct Load Capture Cap tube | 1 | Tube containing Specimen Transport Medium (STM), 2.9 mL |

Warnings and Precautions

- A. Wash hands with soap before opening collection kit.
- B. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- C. Do not use if the swab is visibly damaged (i.e., if the swab tip or shaft is broken, or pouch is damaged or open).
- D. Do not bend or shape the swab before collection. Do not use excessive force, pressure or bending when collecting the specimen as this may result in accidental breakage of the swab.
- E. Fiber adhesion to the shaft has been tested for instantaneous specimen collection: longer contact between the swab and the collection area may cause fiber detachment.
- F. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- G. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- H. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- I. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs. Failure to use a new kit may invalidate the test results.
- J. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

- K. Do not use the kit after its expiration date to collect specimens.

Kit Storage Requirements

Store collection kit at room temperature (15°C to 30°C).

Direct Load Capture Cap Collection Kit – CLASSIQSwabs Specimen Performance

Assay performance characteristics for the types of specimens collected with the Direct Load Capture Cap Collection Kit – CLASSIQSwabs provided in the appropriate package insert for use with Hologic® assays. Hologic assay package inserts may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label includes a field to record each unique specimen source.

Throat Swab Specimens Collection and Handling

Instructions for throat swab specimen collection:

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Nasal Swab Specimens Collection and Handling

Instructions for nasal swab specimen collection:

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.

3. Carefully insert the swab into the first nostril until resistance is met at the level of the turbinates ($\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril). Rotate the swab with moderate pressure against as much of the wall of the anterior nares regions as possible in a large circular path inside the nose at least 4 times (approximately 10 to 15 seconds per nostril) against the nasal wall and remove from nostril.
4. Using the same swab, carefully insert the swab into the second nostril until resistance is met at the level of the turbinates ($\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril). Rotate the swab with moderate pressure against as much of the wall of the anterior nares regions as possible in a large circular path inside the nose at least 4 times (approximately 10 to 15 seconds per nostril) and remove from nostril.
5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
7. Carefully break the swab shaft at the score line against the side of the tube.
8. Immediately discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

Note: Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10 to 15 seconds, is not proper technique and may result in an insufficient sample.

Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with Hologic assays detecting SARS-CoV-2, Flu A and/or Flu B. Refer to the appropriate Hologic assay package insert for proper specimen storage conditions.

Note: Specimens must be shipped in accordance with applicable national and international regulations.

Limitations

- A. Use this collection kit only with appropriate Hologic assays. Performance has not been established with other products.
- B. Use appropriate personal protective equipment (PPE) when collecting and handling specimens from individuals suspected of being infected with SARS-CoV-2 as outlined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV).¹

Contact Information and Revision History



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¹ World Health Organization's (WHO) Laboratory biosafety guidance related to coronavirus disease (COVID-19): interim guidance. [https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19)).

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AW-26527-001 Rev. 002
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| Revision History | Date | Description |
|-----------------------|----------|--|
| AW-26527-001 Rev. 001 | May 2022 | <ul style="list-style-type: none">Created Hologic Direct Load Capture Cap Collection Kit IFU AW-26527-001 Rev. 001 based on AW-20100-001 Rev. 003 for regulatory compliance with IVDRUpdated contact information including: EC Rep, Australian Rep information, and technical support |
| AW-26527-001 Rev. 002 | May 2022 | <ul style="list-style-type: none">Revised to correct administrative/clerical typos in the metadata of this file |