

Hologic® RespDirect™ Collection Kit

For Emergency Use Authorization (EUA) only
 For *in vitro* diagnostic use
 Rx only

Instructions for SARS-CoV-2 Specimen Collection

The Hologic® RespDirect™ Collection Kit is intended to be used for the collection of nasopharyngeal (NP) (collected by a healthcare professional) and nasal (collected under observation of or by a healthcare professional) swab specimens for testing with Aptima® SARS-CoV-2 assay to detect the presence of RNA from SARS-CoV-2. The Hologic RespDirect Collection Kit has not been evaluated for home use.

Materials Provided

50 Hologic RespDirect Collection Kits (Cat. No. PRD-07788)

Each kit contains:

Component	Quantity	Description
RespDirect Swab	1	Individually wrapped, sterile swab
Enhanced Direct Load Tube (eDLT)	1	Tube containing Enhanced Specimen Transport Medium (eSTM), 2.9 mL

Warnings and Precautions

- A. For use under an Emergency Use Authorization (EUA) only.
- B. This product has not been FDA cleared or approved for use with the Aptima SARS-CoV-2 assay, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- C. This product is for use with the Aptima SARS-CoV-2 assay authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- D. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- E. Use the provided swab only. Failure to use the provided swab may invalidate the test results.
- F. Do not use if the swab, tube, or packaging is visibly damaged (e.g., if the swab tip or shaft is bent or broken).
- G. 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.
- H. Do not apply the eSTM directly to skin or mucous membranes or take internally.
- I. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.

- J. 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.
- K. If the contents of the transport tube are spilled at any time during the collection procedure, collect a new specimen using a new Hologic RespDirect Collection Kit. Failure to use a new kit may invalidate the test results.
- L. 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.
- M. Do not use the kit after expiration date to collect specimens.
- N. 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
- O. Avoid contamination by adhering to good laboratory practices and to the procedures specified in this package insert.
- P. Some reagents in the kit are labeled with hazard information.

Note: Hazard communication information for labeling of globally marketed products reflects the US Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com. For more information on the symbols, refer to the symbol legend on www.hologic.com/package-inserts.

US Hazard Information



Enhanced Specimen Transport Media

HEPES 1-5%
Subtilisins (proteolytic enzymes) <1%
1,2-Benzisothiazolin-3-one <1%

DANGER

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P284 - In case of inadequate ventilation wear respiratory protection P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor
 P501 - Dispose of contents/ container to an approved waste disposal plant

Limitations

- A. The Hologic RespDirect Collection Kit is not approved for home collection.
- B. Use this collection kit only with the Aptima® SARS-CoV-2 assay. Performance has not been established with other products.
- C. The patient-collected RespDirect swab specimen application are limited to clinical settings where support/counseling is available to explain the procedures and precautions.

Kit Storage Requirements

Prior to use store collection kit at room temperature (15°C to 30°C).

¹ [https://www.who.int/publications/i/item/laboratorybiosafety-guidance-related-to-coronavirus-disease-\(covid-19\)](https://www.who.int/publications/i/item/laboratorybiosafety-guidance-related-to-coronavirus-disease-(covid-19)).

RespDirect Specimen Performance

Assay performance characteristics and specimen handling using the RespDirect swab specimens are provided in the Aptima SARS-CoV-2 assay package insert.

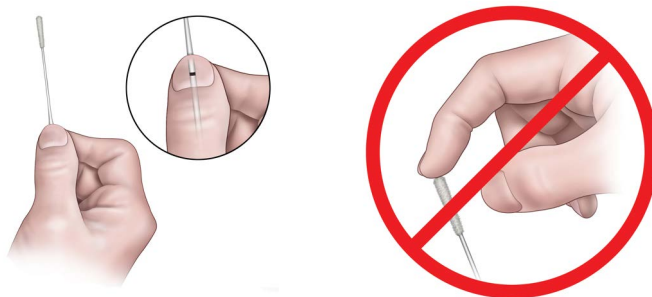
Nasal Swab Specimen Collection and Handling

Note: For patient-collected nasal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

Instructions for nasal swab specimens collected under observation of or by a healthcare professional:

1. Wash hands with soap and water. If soap and water are not available, use hand sanitizer.
2. 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, laid down, or dropped, discard and get a new Hologic RespDirect Collection Kit.
3. Hold the swab, placing your thumb and forefinger at the score line.

Note: Actual product may appear slightly different from the one shown in this section.



Note: Carefully insert the swab into the first nostril until the swab tip is no longer visible, i.e. $\frac{1}{2}$ 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 nostril as possible in a large circular path inside the nose at least 4 times (approximately 10-15 seconds) against the nasal wall and remove from nostril. Repeat collection in the other nostril using the same swab.² Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample. **You must collect the sample from both nostrils.**

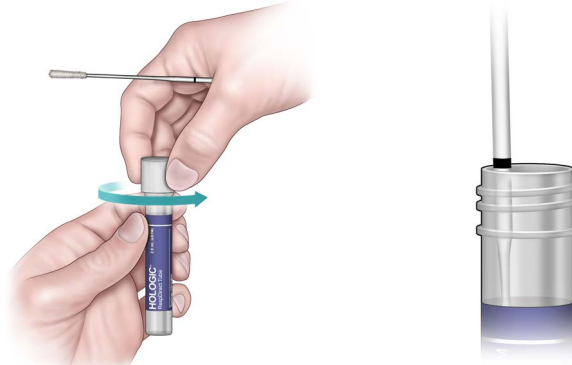


² <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

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, collect a new specimen using a new Hologic RespDirect Collection Kit.

Warning: If you come into contact with liquid from the tube, wash your hands with soap and water for 30 seconds.

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. Discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Note: The tube label includes a field to record the specimen source.

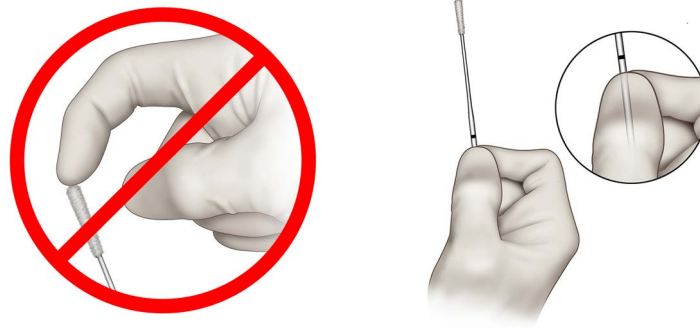


Nasopharyngeal Swab Specimens Collection and Handling

Instructions for nasopharyngeal swab specimen collection (healthcare professional collection only):

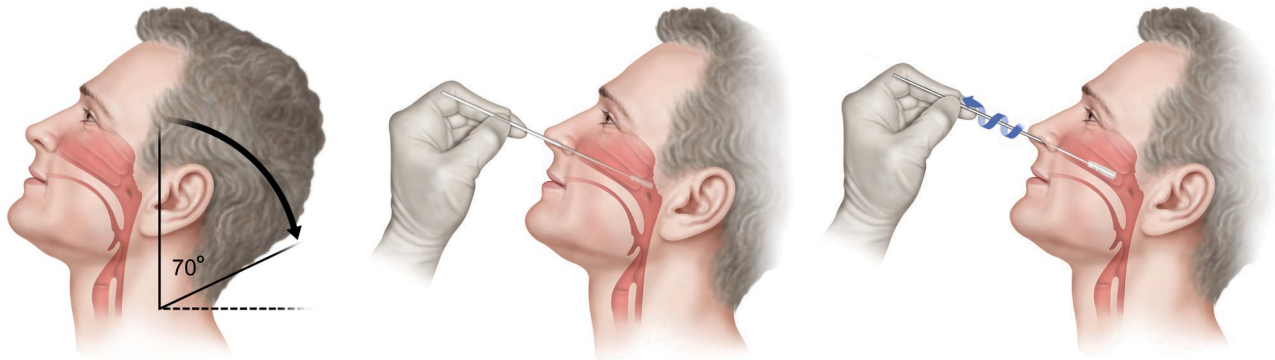
1. Wash hands with soap and water. If soap and water are not available, use hand sanitizer.
2. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and use a new Hologic RespDirect Collection Kit.
3. Hold the swab, placing your thumb and forefinger below the score line.

Note: Actual product may appear slightly different from the one shown in this section.



4. Tilt patient's head back 70 degrees. Gently and slowly insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach the depth equal to the distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave the swab in place for several seconds to absorb secretions. Slowly remove the swab while rotating it.³

Note: If the swab is saturated with fluid from the first collection, it is not necessary to collect specimens from both sides. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

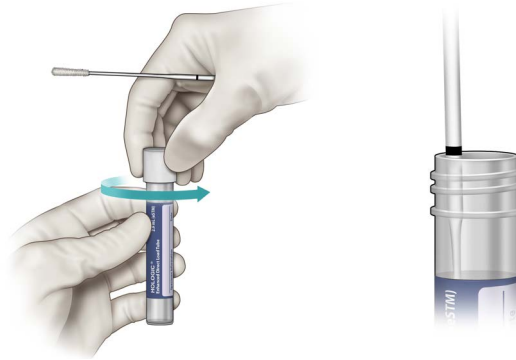


5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, collect a new specimen using a new Hologic RespDirect Collection Kit.

Warning: If your skin comes into contact with liquid from the tube, wash with soap and water for 30 seconds.

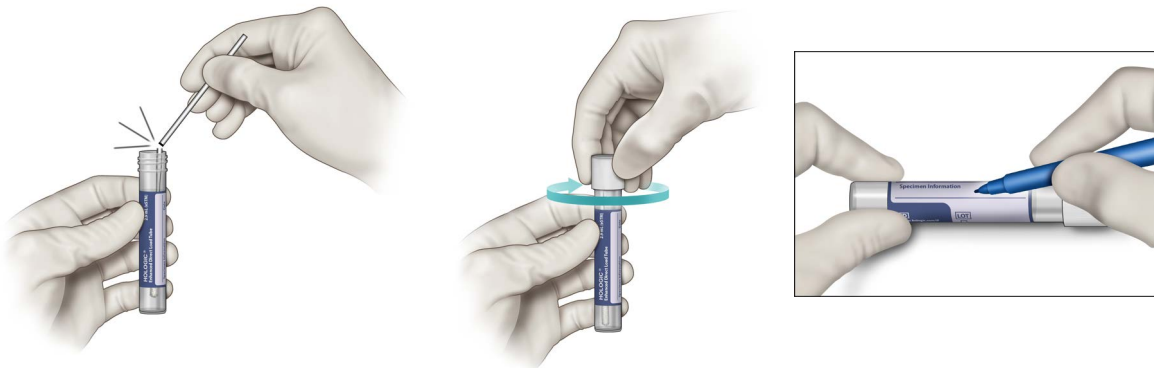
6. Immediately place the swab into the tube so that the score line is at the top of the tube.

³ <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>



7. Carefully break the swab shaft at the score line against the side of the tube.
8. Discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

Note: *The tube label includes a field to record the specimen source and additional patient information.*



Specimen Transport and Storage

Swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube. Refer to the Aptima SARS-CoV-2 assay package insert for proper specimen storage conditions.

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

Contact Information



10210 Genetic Center Drive
San Diego, CA 92121 USA

Customer Support: +1 800 442 9892
customersupport@hologic.com

Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

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