

Aptima® Multitest Swab Specimen Collection Kit

US Only: For Emergency Use Authorization (EUA) Only

Rx Only



Instructions for SARS-CoV-2 Specimen Collection

The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for clinician collection of oropharyngeal and anterior nasal (nasal) swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima® SARS-CoV-2 assay and Panther Fusion® SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of nasal swab specimens and patient collection of nasal swab specimens in a health care setting for testing with the Aptima® SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A), and/or influenza B virus (Flu B). The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use.

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. Do not apply the specimen transport medium directly to skin or mucous membranes or take internally.
- F. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- G. This product has not been FDA cleared or approved for use with the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- H. When used with the Aptima SARS-CoV-2 assay and/or Panther Fusion SARS-CoV-2 assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- I. When used with the Aptima SARS-CoV-2/Flu assay the following applies: This product is for use with a test authorized only for the detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.
- J. 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.

- K. 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.
- L. If the contents of the transport tube are spilled at any time during the collection procedure, use a new Aptima Multitest Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
- M. 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.
- N. 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).

Multitest Swab Specimen Performance

Assay performance characteristics using the Multitest swab specimens are provided in the Aptima SARS-CoV-2 assay package insert, Aptima SARS-CoV-2/Flu assay package insert, and Panther Fusion SARS-CoV-2 assay package insert. Package inserts for the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay may be referenced online at www.hologic.com.

When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification of each specimen.

Oropharyngeal Swab Specimens Collection and Handling – Aptima SARS-CoV-2 Assay and Panther Fusion SARS-CoV-2 Assay

Instructions for oropharyngeal swab specimen collection (clinician collection only):

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 Aptima Multitest Swab Specimen Collection Kit.
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 Aptima Multitest Swab Specimen Collection Kit.
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 – Aptima SARS-CoV-2 Assay, Aptima SARS-CoV-2/Flu Assay, and Panther Fusion SARS-CoV-2 Assay

Note to Patient: If you have any questions about this procedure, please ask your healthcare provider.

Instructions for nasal swab specimen collection: clinician collection and patient self-collection

1. Wash hands with soap and water for 30 seconds before starting.
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, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
3. 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.

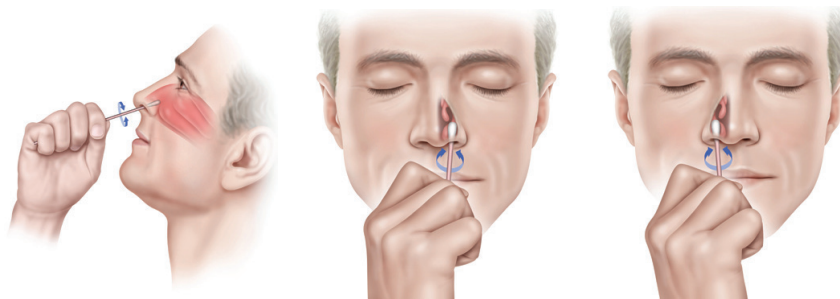


4. Carefully insert the swab into the first nostril until the swab **tip** is no longer visible, i.e. $\frac{1}{2}$ to $\frac{3}{4}$ of an inch or 1.25 to 2 cm into the nostril. Rotate the swab with moderate pressure against as much of the wall of the nostril as possible in a large circular path inside the nose at least 4 times (approximately 10 to 15 seconds per nostril) against the nasal wall and remove from nostril.

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.

5. Using the same swab, carefully insert the swab into the second 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 to 15 seconds per nostril) and remove from nostril. **Do not force the swab any further up and into nose at any point.**

Note: You must collect the sample from both nostrils!



6. 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 Aptima Multitest Swab Specimen Collection Kit.

Note to Patient: Inform your doctor or healthcare worker if liquid is spilled and a new kit is required.

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

7. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
8. Carefully break the swab shaft at the score line against the side of the tube.
9. Immediately discard the top portion of the swab shaft.
10. 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.

Note to Patient: Return the collection kit to your doctor or healthcare worker.

Specimen Transport and Storage

Multitest swab specimens are intended to be transported to the laboratory in the provided swab specimen transport medium and tube for use with the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, and Panther Fusion SARS-CoV-2 assay. Refer to the Aptima SARS-CoV-2 assay package insert, Aptima SARS-CoV-2/Flu assay package insert, and Panther Fusion SARS-CoV-2 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 the Aptima SARS-CoV-2 assay, Aptima SARS-CoV-2/Flu assay, Panther Fusion SARS-CoV-2 assay, and other Hologic products. 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).
- C. The patient-collected Aptima Multitest Swab Specimen Collection Kit nasal swab application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.
- D. Oropharyngeal swabs are authorized for use with the Aptima SARS-CoV-2 assay and Panther Fusion SARS-CoV-2 assay only.



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