

RT-PCR Diagnostic Test Saliva Specimen Collection Instructions

This set of instructions is specific to collection of a saliva specimen to be utilized for SARS-CoV-2 diagnostic testing. Aegis does not offer influenza testing for saliva specimens. Collection must be completed using the OMNIgene•ORAL OM-505® or OME-505® device provided by Aegis Sciences Corporation.

COVID-19 Specimen Collection

1. Please note that specimens for RT-PCR nucleic acid testing are not being collected by Aegis Specimen Collectors. Specimens may be collected by or under the supervision of properly trained medical professionals in accordance with federal and state-level requirements.
2. The collection site must have all the supplies needed to complete a specimen collection (e.g. collection kits, ink pens, Aegis Laboratory Request Forms, leak-resistant plastic bags, absorbent material, shipping containers, UN3373 Category B shipping labels (if shipping via FedEx), and appropriate personal protective equipment).
3. It is up to your organization to ensure that appropriate personal protective equipment (PPE) is available and that you have been trained in proper use prior to performing specimen collection. CDC defines recommendations for healthcare personnel involved in collecting specimens from patients here: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>.
4. Ensure that there is a means for washing hands, suitable clean surface for the collector to use as a work area, and a secure temporary storage area for maintaining specimens until they are transferred to the laboratory.
5. Ensure access to collection supplies is restricted only to the collector(s)/donor(s) and other authorized personnel.

COVID-19 Specimen Collection

Complete all fields of the Laboratory Request Form Diagnosis Code(s)

NOTE: All requisitions must have a valid ICD-10 code provided by the physician to support the medical necessity of the order.

Diagnosis codes are 3-7 characters (e.g., U07.1). The first digit is alpha, 2nd and 3rd are numeric and 4-7 can be alpha and/or numeric.

1. Codes beginning with a numeric digit are not valid. All diagnosis codes must begin with a letter.
2. Examples of allowable codes: Z20.828; U07.1

Billing/Insurance Information

Obtain insurance information and ALWAYS validate it with the patient. Mark the appropriate check box on the Laboratory Request Form.

Patient Information

Fill in patient's complete First Name, Middle Initial, Last Name, Sex, Date of Birth, Address, City, State, Zip Code, Phone Number, Email Address (if requested), Social Security Number, Race and Ethnicity.

Collector's Initials

Legibly write your initials in the box.

Date Collected

This is the Date of Service (DOS).

Specimen Type

Select the type of specimen collected.

Requesting Provider

Select the appropriate requesting provider (Choose only one). Write in name legibly if not pre-printed.

Sample Label

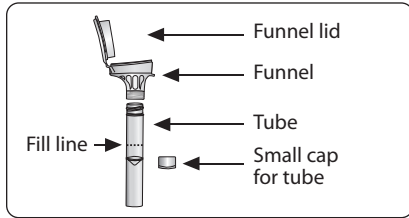
With the patient present and after completing the patient information, remove the label and place it on the side of the specimen device.

Provider Signature

Obtain the ordering provider's signature.

RT-PCR Diagnostic Test Saliva Specimen Collection

1. Saliva specimens collected using the OMNIgene•ORAL OM-505® or OME-505® device will be accepted for SARS-CoV-2 diagnostic testing by our laboratory.
2. Appropriate specimen collection is detailed in the manufacturer instructions included on the next page. It is of utmost importance that these directions are utilized for collection. **Specimen donor should not eat, drink, smoke, or chew gum for 30 minutes before providing a sample.**
3. Upon completion of specimen collection, place the closed transport tube into the specimen bag with the absorbent pad.
 - a. Fold and place the completed Laboratory Request Form in the back pouch of the Aegis specimen bag.
4. DO NOT seal the Laboratory Request Form in the sealed part of the pouch with the primary specimen. It is important that the specimen be in one compartment and the paperwork in the other to avoid contamination of the requisition in the event of specimen leakage.
5. Seal the bag using the zip-top closure.
6. Place the sealed specimen bag(s) into a UN3373 labeled kit box provided (up to 5 samples per kit box). Place the kit box(es) with samples inside the UN3373 Category B clinical pack with FedEx return label affixed if you are shipping or into a convenience container for courier transport. Consult FedEx instructions for [Packaging UN 3373 Shipments](#) for additional shipping information.
7. Transport collected specimens to the laboratory at room temperature within 24 hours of collection using the preprinted FedEx labels affixed to the UN3373 clinical pack provided by Aegis or through local courier pickup. Client Services can be contacted at 800.533.7052 to schedule a FedEx or courier pickup.


Collection precautions:

Do NOT eat, drink, smoke or chew gum for 30 minutes before giving your sample.

Do NOT remove the plastic film from the funnel lid.

Contents: Kit contains stabilizing liquid.

Warnings and precautions:

Wash with water if stabilizing liquid comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com.








Small cap may pose a choking hazard.

Storage: 15°C / 30°C

Summary and explanation of the kit:

OMNigene-ORAL is a collection kit that provides the materials and instructions for collecting, stabilizing and maintaining during transport saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).

Label legend:

	Consult package insert
	Collect sample by (Use by)
	In vitro diagnostic medical device
	Catalog number
	Caution, consult instructions for use
15°C / 30°C	Storage instructions
	Manufacturer
	Lot number
Rx	For Prescription Use Only

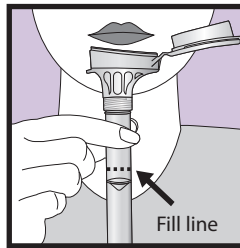
Collected specimen is potentially infectious and should be handled with appropriate biosafety practices.

Ship in accordance to applicable regulations covering transport of biological specimens.

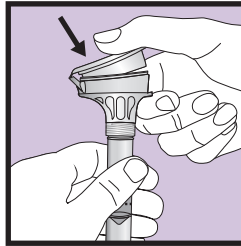
For donor collection instructions in other languages, see www.dnagenotek.com

USER INSTRUCTIONS

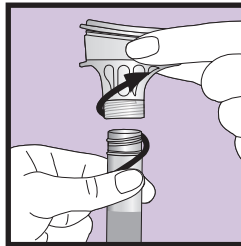
Most people take between 2 and 5 minutes to deliver a sample following steps 1 to 5.



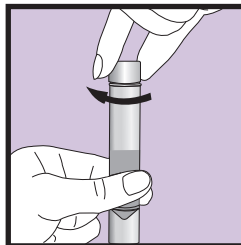
- 1** Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1.



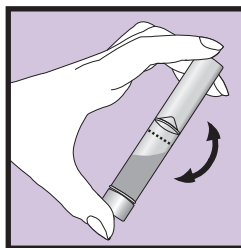
- 2** Hold the tube upright with one hand. Close the funnel lid with the other hand (as shown) by firmly pushing the lid until you hear a loud click. The liquid in the lid will be released into the tube to mix with the sample. Make sure that the lid is closed tightly.



- 3** Hold the tube upright. Unscrew the funnel from the tube.



- 4** Use the small cap to close the tube tightly.



- 5** Shake the capped tube for 5 seconds. Discard or recycle the funnel.

For IVD, Rx and For Use Under Emergency Use Authorization.

This sample collection device has not been FDA cleared or approved.

This sample collection device has been authorized by FDA under an EUA.

This sample collection device has been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens.

This sample collection device is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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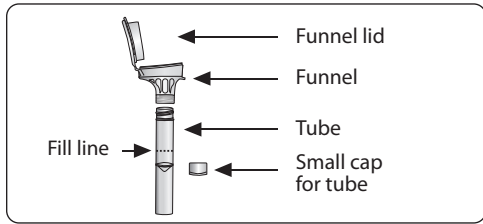
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Superior samples • Proven performance

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Patent (www.dnagenotek.com/legalnotices)
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Collection precautions:

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Do NOT remove the plastic film from the funnel lid.

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Warnings and precautions:

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
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Label legend:

-  Collect sample by (Use by)
-  In vitro diagnostic medical device
-  Catalog number
-  CE Marking
-  Consult package insert
-  Caution, consult instructions for use
-  15°C / 30°C Storage instructions
-  Manufacturer
-  Authorized Representative
-  Lot number
- Rx For Prescription Use Only

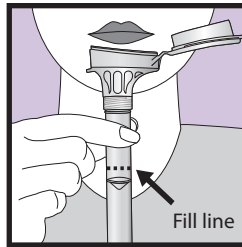
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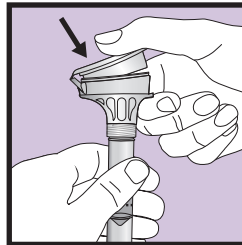
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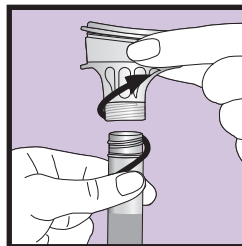
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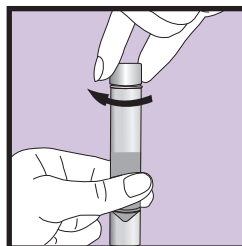
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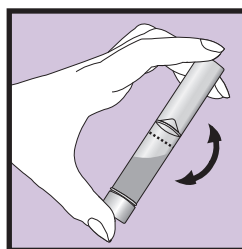
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