CRL COVID-19 SELF-COLLECTION TESTING KIT

FOR RX USE ONLY • FOR USE IN INDIVIDUALS AGE 18 YEARS AND OLDER
FOR IVD USE ONLY • FOR EMERGENCY USE AUTHORIZATION ONLY

1

IMPORTANT: You must activate your test by registering and completing the online process at CRLCLEAR.COM. The lab cannot report your test results unless you complete the online process.

2 COLLECTION PRECAUTIONS:

- **DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva.**
- DO NOT remove the plastic film from funnel lid.
- Should stabilizing liquid come into contact with eyes or skin, wash with water. DO NOT ingest.

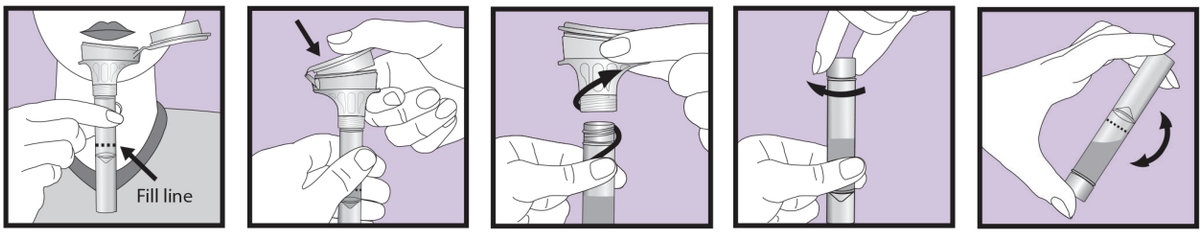
3 PREP:

- Collection of saliva first thing in the morning is recommended, but not required.
- View the collection video at www.crlcorp.com/covid-19-testing/videos.
- IMPORTANT: Wash your hands **thoroughly for 20 seconds** then dry your hands **before** starting the collection.

4 COLLECT:

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

- Collect sample by closing mouth and sucking. Spit into funnel until the amount of liquid (not bubbles) reaches the fill line shown in picture #1. DO NOT overfill tube.
- 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.
- Hold the tube upright. Unscrew the funnel from the tube.
- Use the small cap located in the plastic clamshell to close the tube tightly.
- Shake the capped tube for five seconds. Discard or recycle the funnel.
- IMPORTANT: Wash your hands **thoroughly for 20 seconds** again, then dry your hands **after** completing the collection.



Saliva Collection Using OMNIgene•ORAL® | OM-505 Device by DNA Genotek™

5 LABEL YOUR COLLECTION DEVICE:

- Write your first and last name on the barcode label. The name on the barcode label must match the name on your online registration.
- Affix barcode label to the saliva collection device as shown, after completing collection.
- Label placement should start below the cap, with barcode running lengthwise down tube.
- **Testing may be delayed or not performed if saliva tube is received unlabeled or mislabeled.**

Remove Label Here

Align name with device barcode

DO NOT overlap barcodes

DO NOT adhere barcode vertically

6 RETURN:

STOP

Before returning sample, you MUST activate your kit at CRLCLEAR.COM.

- DO NOT return the funnel with the sample. Prior to shipping, the tube should be sealed with the small cap. Funnel and the clamshell that the device arrived in can be discarded.
- **Note:** Saliva sample must be shipped within 24 hours of collection. Place the saliva collection tube into the small pouch of the plastic zip top bag with the absorbent pad and seal the bag.
- Unless you have been provided with alternative return instructions, place sealed plastic zip top bag containing the sample and the absorbent pad into the original kit box provided and close the lid. Place the box that contains the sample inside the return shipping pouch and seal pouch. Place FedEx shipping label on exterior of shipping pouch.
- Shipment can be placed in any FedEx Drop Box or dropped at an approved FedEx location. Or, contact FedEx at 1-800-463-3339 to schedule a pickup. Specify you have a prepaid shipment for overnight delivery.

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by Clinical Reference Laboratory, Inc. located in Lenexa, Kansas. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

QUESTIONS: Visit www.crlcorp.com/covid-19-testing/faq.