## **Phosphorus**

# At-Home Collection Guide

FOR PRESCRIPTION, IN VITRO DIAGNOSTIC AND EMERGENCY USE AUTHORIZATION ONLY

#### **Collection Kit Contents**



Phosphorus Kit Box



Biohazard Bag and Absorbent Pouch



DNA Genotek OGD-510 Saliva Collection Device



Prepaid FedEx Return Shipment Pack



Sample Collection Instructions



Pre-populated Test Requisition Form

#### **COLLECTION NOTE**

You must be 18 years or older to use the product.

Please follow collection instructions carefully to ensure an adequate specimen is collected for testing.

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

To ensure timely receipt of intact specimen, be sure to drop your packet with FedEx the same day that you collect your sample.

Your sample must be received within 56 hours of specimen collection.

This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of nucleic acid from SARS- CoV-2, not for any other viruses or pathogens; and, 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 Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

### Instructions for Collecting and Returning Saliva Specimen

1

Wash hands thoroughly for 20 seconds with soap upon receipt of package. Confirm that the information on your pre-populated test requisition form is correct.



2

Read and sign the test authorization and consent on the pre-populated requisition form to be returned. Write your name, date of birth and date/time of specimen collection on one of the label stickers found at the bottom of the requisition form.



3

Place the completed label sticker on the sample collection tube.



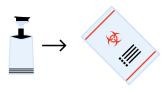
4

Wash your hands thoroughly for 20 seconds with soap. Follow the instructions provided with the saliva collection device. After collecting your sample, wash your hands again thoroughly for 20 seconds with soap.



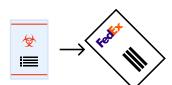
5

Place the filled sample tube into absorbent pouch and then with signed requisition form into the biohazard bag and seal the bag. Wash your hands thoroughly for 20 seconds with soap after placing sample in the biohazard bag. Place the biohazard bag in the Phosphorus kit box.



6

Wash your hands thoroughly for 20 seconds with soap before placing the Phosphorus box within the prepaid UN3373 FedEx Return Shipment Pack. Drop the package at the nearest FedEx store or call 1.800.463.3339 to schedule a same day pickup.



7

Your sample will be shipped to the Phosphorus Diagnostics laboratory in Secaucus, NJ, and results will be available within 72 hours. Your results will be sent directly to you. A copy of your results will also be sent to your provider.



You will have the option to talk to a physician should you have any questions about your results.





Questions about collecting your specimen? Please get in touch.

To view video guided instructions on collection, please visit: <a href="https://youtu.be/ql2dc39nZ94">https://youtu.be/ql2dc39nZ94</a>.

To view a copy of the collection instructions, please visit: https://www.dnagenotek.com/US/support/collectioninstructions/oragenedx/OGD-510andOGD-610.





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