Phosphorus

Pinpoint by Phosphorus COVID-19 Test Home Collection Kit

AT-HOME COLLECTION GUIDE

For Prescription, In Vitro Diagnostic and Emergency Use Authorization ONLY

Collection Kit Contents



Phosphorus Kit Box



FedEx Clinical Pak



Biohazard Bag and Absorbent Pouch



DNA Genotek OGD-510 Saliva Collection Device



Sample Collection Instructions



Pre-populated Test Requisition Form

Follow directions for use. Keep out of reach of children. Avoid contact with skin and eyes. Wash with water if stabilizing liquid comes in contact with eyes or skin. If irritation persists, seek medical advice. Do NOT ingest stabilizing liquid. It is recommended to use eyewear when performing the collection procedure.

COLLECTION NOTE

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

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 for emergency use 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, 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 Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization

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.



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 two sticky notes.



Place one on the sample collection tube; place the other in a space provided on the requisition form.



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









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.



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

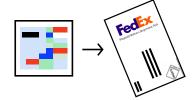
7

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: https://youtu.be/ql2dc39nZ94.

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



