EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE PINPOINT BY PHOSPHORUS COVID-19 TEST HOME COLLECTION KIT DTC

For *In vitro* Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only
For Use by Individuals 18 Years of Age or Older

Direct to consumer (DTC) home self-collected saliva specimens collected by individuals 18 years or older (unobserved) with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC will be sent to high complexity laboratories that have been designated by Phosphorus Diagnostics LLC. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests and that run specimens collected using Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC for self-collection of saliva specimens.

INTENDED USE

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is a direct to consumer (DTC) product for self-collecting (unobserved) a saliva specimen by an individual 18 years or older at home (which includes in a community-based setting), that are sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC for self-collection of saliva specimens, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

Testing is limited to laboratories designated by Phosphorus Diagnostics LLC that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

All test results are delivered to the user via an online portal. Individuals with positive, inconclusive, or invalid results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is for use by adults 18 years and older, to self-collect saliva specimens, including for use by such individuals without symptoms or other reasons to suspect COVID-19.

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS FOR USE STATEMENTS
For *In vitro* Diagnostic Use
For Use Under Emergency Use Authorization (EUA) Only
For Use by Individuals 18 Years of Age or Older

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC collection device is only authorized for use in conjunction with an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 indicated for use with this collection device for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

DEVICE DESCRIPTION AND TEST PRINCIPLE
The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is available direct to consumer (DTC) without a prescription for any individual 18 years and older. When ordering a kit via the Phosphorus website or when purchasing a kit through partnering grocery stores, pharmacies, and online retailers, individuals must verify they are 18 years of age or older. Once the individual receives the collection kit, the user must activate their kit online by scanning the QR code located on the collection instruction booklet or by visiting covid-19.phosphorus.com/register. As part of the registration process, the individual is prompted to enter the 14-digit barcode found on the side of the sample collection tube, along with personally identifiable information and the date and time of saliva collection. During kit activation, it is recommended that the user complete a screening questionnaire as a means for data collection. The medical information collected will not impact the ability to process the individual's saliva sample. Individuals are notified by email when their test results are ready for viewing. The email contains information for accessing Phosphorus' online HIPAA-compliant post-test portal to view their test results. Additionally, individuals with positive, inconclusive, and invalid results are contacted by a healthcare provider (HCP) via phone. The HCP will be part of a contracted third-party company that has prescribing privileges in the state of residency of the tested individual. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC is composed of a cardboard shipping box, a biohazard bag with an absorbent pouch, the OGD-510 saliva collection device with barcode, instructions for use containing a QR code, fact sheet for individuals, and a shipping envelope with a prepaid return label. Instructions included in the kit guide users on how to collect the saliva specimen appropriately. After collection, the specimen is placed into the absorbent pouch, followed by placement into the biohazard bag which is then sealed. The prepared biohazard bag is placed into the cardboard Phosphorus kit box and into the FedEx clinical shipping pak for transport to a designated testing laboratory. The completed Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC must be dropped off at a FedEx location or scheduled for FedEx pickup on the same day the specimen is collected to ensure timely receipt of the specimen at the testing location. Each Pinpoint by Phosphorus

COVID-19 Test Home Collection Kit DTC is intended to be returned via 48-hour shipping at ambient conditions and tested within 56 hours of collection.

Specimens received for testing at Phosphorus Diagnostics and designated high complexity certified laboratories (Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a) will undergo a thorough review and accessioning prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated to process saliva specimens per the Instructions for Use.

REAGENTS AND MATERIALS

The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC consists of the following components:

Component
Soft shipping envelope with prepaid return shipping label and UN 3373 Biological Substance Category B label
Biohazard bag and absorbent pouch for collected specimen
Cardboard shipping box
OGD-510 saliva collection device with barcode
Instructions for self-collection and shipping which includes a QR code
Fact sheet for individuals

INSPECTION OF SALIVA SPECIMENS

Applies to specimens received from individuals using the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC

Specimens collected with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC must be checked for the following criteria upon receipt at designated testing laboratories prior to processing as outlined in the "COVID-19 Sample Accessioning for Phosphorus COVID-19 RT-qPCR Test DTC" accessioning SOP:

- Saliva must be specifically collected in the OGD-510 Oragene Dx collection device.
- Sample collection tube must be intact and not visibly damaged or leaking.
- Sample volume meets the minimum required for testing.
- Specimen should not appear turbid or show signs of apparent bacterial contamination.
- Specimen must arrive within the established stability window for testing (i.e., within 56 hours from collection time).
- Specimen was collected using an unexpired collection kit.
- Specimen has a registered barcode with the Phosphorus LIMS.

CONTROLS TO BE USED WITH THE AUTHORIZED SARS-COV-2 MOLECULAR ASSAY

The following controls (at a minimum) must be included in the in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with saliva specimens collected with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC:

1) **No Template Control (NTC)**
   A negative (no template) control must be used to monitor for sample contamination during nucleic acid extraction and RT-PCR assay set-up. Molecular grade, nuclease-free water can be processed as a clinical sample beginning with extraction (optional) or can exclude the extraction step and be added during RT-PCR set-up.

2) **SARS-CoV-2 Positive Control**
   A positive SARS-CoV-2 control is needed to verify that the assay is performing as intended. A positive control prepared at ≤5X LoD must be used on every assay plate starting at master mix addition.

3) **Endogenous Internal Control**
   An internal control targeting RNase P or another endogenous human control gene is needed to verify that nucleic acid is present in every sample and is used for every sample that is processed with the assay. This also serves as a positive extraction control to ensure that samples resulting as negative contain nucleic acid for testing. Detection of the RNase P gene/other applicable endogenous human control in individual test samples verifies successful extraction of the sample, proper assay setup, and collection of human biological material.

4) **A Negative Extraction Control (optional)**
   Typically, a negative extraction control is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that could occur during the nucleic acid extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

INTERPRETATION OF RESULTS

All test controls must be examined prior to interpretation of individual results. If the controls are not valid, the individual results cannot be interpreted.

SARS-CoV-2 test results are divided into SARS-CoV-2 positive/detected, SARS-CoV-2 negative/not detected, and inconclusive.

- Individuals will receive a notification via email containing instructions for accessing Phosphorus' online HIPAA-compliant post-test portal to view their test results.
- Individuals with positive, inconclusive, and invalid results are contacted by a healthcare provider (HCP) via phone. The HCP will inform individuals of their results, provide education, and a recommended course of care or appropriate follow-up action.
- Results are reported by Phosphorus to public health agencies as required.

PERFORMANCE EVALUATION

1) **<u>Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC Sample Stability Studies:</u>**
   To support home use of the Oragene Dx OGD-510 collection device that is part of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC, a simulated shipping study was performed that was designed to evaluate the effect of temperature variation on the

stability of SARS-CoV-2 RNA during transport of saliva specimens. The shipping study was designed to simulate shipping at room temperature as well as the extreme temperature conditions that could be experienced during the summer months. See Table 1 for the summer thermal profile that was evaluated in this study.

Simulated sample stability and shipping studies were performed using contrived positive saliva specimens at 2X (low positive) and 5-10X LoD (high positive) concentrations. After the samples underwent the thermal excursions, they were incubated at 50°C for 1 hour and then equilibrated to room temperature, extracted, and tested with the Phosphorus COVID-19 RT-qPCR Test.

Table 1. Summer Temperature Excursion

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours[1]
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56

[1] Sum of cycle periods

Contrived samples were prepared using pooled known negative patient saliva matrix and spiking with Twist Bioscience synthetic SARS-CoV-2 RNA to establish 20 low positive samples of 2X LoD (LoD previously established as 10 copies/µL) and 10 moderate to high positive saliva samples between 5-10X LoD. Ten negative saliva specimens were also evaluated in the shipping study. For the spiked specimens, saliva was collected in the OGD-510 device and pooled. Saliva specimens were received by Phosphorus from individuals that had tested negative for SARS-CoV-2 using a third-party FDA-authorized molecular assay, following shipment under ambient conditions. The saliva specimens were also screened negative using the Phosphorus COVID-19 RT-qPCR Test within 56 hours of collection.

The contrived positive and negative saliva samples were stored for the duration of the simulated shipping study as shown in Table 1. These temperature range conditions are intended to replicate worst case scenario shipping conditions (for spring/summer) for an 8-hour wait at the customer's house/healthcare location before shipping and then a subsequent 48 hour shipping cycle. At the conclusion of the summer thermal profile, the samples were treated as if they were actual clinical specimens received at the laboratory for processing. The contrived samples were first incubated at 50°C for 1 hour to inactivate any RNases in the collected saliva, followed by equilibration to ambient temperature. Specimens were then extracted using the three extraction kits (MagMAX, Maxwell HT, and Maxwell RSC) and retested with the Phosphorus COVID-19 RT-qPCR Test. Results were compared to those reported upon initial testing when specimens were received and spiked with various concentrations at time 0 (day 0, room temperature).

Ten out of 10 (100%) low positive samples (2X LoD) and 10/10 moderate to high positive contrived samples (100%) ranging from 5-10X LoD were reported as positive after exposure to the summer temperature cycles. The mean and standard deviation of the Ct values for each

gene target were similar before and after each simulated shipping scenario (within ~3 Cts), with no evidence of significant degradation of the SARS-CoV-2 RNA. All SARS-CoV-2 negative specimens were reported as negative after enduring the summer temperature excursion (no amplification of N1 or N2 genes).

A summary of the mean Ct values observed for each SARS-CoV-2 specific target gene is provided in Tables 2-4 for each claimed extraction method.

Table 2. Summary of Results from the Simulated Shipping Study Using Contrived Samples Extracted Using the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit

Sample Group	Test Point	N	Mean Ct (Standard Deviation)			Positive[4] (%)
			N1	N2	RNase P	
Negative	Day 0 (RT)[1]	10	N/A[3]	N/A	23.15 (0.7)	0 (0)
	Summer[2]	10	N/A	N/A	23.60 (0.4)	0 (0)
Low Positive 2X LoD 10 copies/µL	Day 0 (RT)[1]	10	32.97 (0.09)	33.74 (0.12)	23.25 (0.08)	10/10 (100)
	Summer[2]	10	34.84 (0.6)	36.22 (1.2)	23.56 (0.9)	10/10 (100)
High Positive 5X LoD 25 copies/µL	Day 0 (RT)[1]	3	34.37 (0.4)	35.03 (0.7)	24.16 (0.3)	3/3 (100)
	Summer[2]	2	33.46 (0.2)	34.93 (0.1)	24.55 (0.0)	2/2 (100)
High Positive 6X LoD 30 copies/µL	Day 0 (RT)[1]	2	34.50 (0.2)	35.13 (0.7)	23.70 (0.5)	3/3 (100)
	Summer[2]	2	33.12 (0.1)	34.87 (0.3)	24.59 (0.1)	2/2 (100)
High Positive 7.5X LoD 37.5 copies/µL	Day 0 (RT)[1]	2	34.70 (0.8)	35.37 (0.2)	24.15 (0.1)	3/3 (100)
	Summer[2]	2	32.65 (0.0)	33.87 (0.2)	24.55 (0.0)	2/2 (100)
High Positive 9X LoD 45 copies/µL	Day 0 (RT)[1]	3	33.25 (0.5)	33.95 (0.7)	22.32 (0.3)	3/3 (100)
	Summer[2]	2	32.93 (0.10)	34.13 (0.2)	24.36 (0.0)	2/2 (100)
High Positive 10X LoD 50 copies/µL	Day 0 (RT)[1]	3	30.78 (0.09)	31.94 (0.24)	22.96 (0.13)	3/3 (100)
	Summer[2]	2	32.35 (0.2)	33.22 (0.0)	24.26 (0.1)	2/2 (100)

[1] Day 0 (RT) = within 56 hours of collection at room temperature shipping conditions
[2] Testing performed at the conclusion of the thermal excursions described in Table 1
[3] N/A = No detectable Ct value
[4] Positive; Number of replicates positive for SARS-CoV-2 targets only (N1 and N2), not RNase P target

Table 3. Summary of Results from the Simulated Shipping Study Using Contrived Samples Extracted Using the Maxwell HT Viral TNA Kit

Sample Group	Test Point	N	Mean Ct (Standard Deviation)			Positive[4] (%)
			N 1	N2	RNase P	
Negative	Day 0 (RT)[1]	10	N/A[3]	N/A	22.87 (0.4)	0 (0)
	Summer[2]	10	N/A	N/A	23.30 (0.2)	0 (0)
Low Positive 2X LoD 10 copies/µL	Day 0 (RT)[1]	10	33.46 (0.08)	34.79 (0.40)	23.35 (0.14)	10/10 (100)
	Summer[2]	10	35.00 (0.6)	36.58 (1.0)	23.35 (0.5)	10/10 (100)
High Positive 5X LoD 25 copies/µL	Day 0 (RT)[1]	3	34.09 (0.5)	35.48 (0.5)	24.21(0.3)	3/3 (100)
	Summer[2]	2	33.35 (0.3)	34.85 (0.1)	25.13 (0.1)	2/2 (100)
High Positive 6X LoD 30 copies/µL	Day 0 (RT)[1]	3	34.88 (0.6)	35.77 (0.8)	24.20 (0.3)	3/3 (100)
	Summer[2]	2	34.13 (0.1)	35.39 (0.2)	24.67 (0.1)	2/2 (100)

Sample Group	Test Point	N	Mean Ct (Standard Deviation)			Positive[4] (%)
			N 1	N2	RNase P	
High Positive 7.5X LoD 37.5 copies/µL	Day 0 (RT)[1]	3	34.10 (0.7)	35.51 (0.7)	24.11 (0.2)	3/3 (100)
	Summer[2]	2	33.47 (0.5)	34.91 (0.0)	24.66 (0.3)	2/2 (100)
High Positive 9X LoD 45 copies/µL	Day 0 (RT)[1]	3	34.24 (0.3)	35.88 (0.6)	23.09 (0.3)	3/3 (100)
	Summer[2]	2	32.46 (0.1)	33.19 (0.0)	24.72 (0.3)	2/2 (100)
High Positive 10X LoD 50 copies/µL	Day 0 (RT)[1]	3	31.52 (0.13)	32.65 (0.23)	22.79 (0.18)	3/3 (100)
	Summer[2]	2	32.75 (0.2)	33.38 (0.1)	24.82 (0.0)	2/2 (100)

[1] Day 0 (RT) = within 56 hours of collection at room temperature shipping conditions
[2] Testing performed at the conclusion of the thermal excursions described in Table 1
[3] N/A = No detectable Ct value
[4] Positive; Number of replicates positive for SARS-CoV-2 targets only (N1 and N2), not RNase P target

Table 4. Summary of Results from the Simulated Shipping Study Using Contrived Samples Extracted Using the Maxwell RSC TNA Viral Kit on the Maxwell RSC 48 System

Sample Group	Test Point	N	Mean Ct (Standard Deviation)			Positive[4] (%)
			N 1	N2	RNase P	
Negative	Day 0 (RT)[1]	10	N/A[3]	N/A	21.82 (0.5)	0 (0)
	Summer[2]	10	N/A	N/A	22.0 (0.3)	0 (0)
Low Positive 2X LoD 10 copies/µL	Day 0 (RT)[1]	10	34.94 (0.13)	35.50 (0.06)	21.31 (0.20)	10/10 (100)
	Summer[2]	10	35.16 (0.9)	36.04 (1.2)	22.04 (0.3)	10/10 (100)
High Positive 5X LoD 25 copies/µL	Day 0 (RT)[1]	2	35.24 (0.2)	34.10 (0.5)	23.65 (0.2)	3/3 (100)
	Summer[2]	2	32.78 (0.0	33.36 (0.3)	23.49 (0.3)	2/2 (100)
High Positive 6X LoD 30 copies/µL	Day 0 (RT)[1]	2	34.34 (0.4)	35.25 (0.5)	23.43 (0.2)	3/3 (100)
	Summer[2]	2	33.63 (0.1)	33.99 (0.4)	23.52 (0.0)	2/2 (100)
High Positive 7.5X LoD 37.5 copies/µL	Day 0 (RT)[1]	2	33.75 (0.7)	34.64 (0.3)	23.68 (0.6)	3/3 (100)
	Summer[2]	2	32.36 (0.3)	32.70 (0.1)	23.64 (0.1)	2/2 (100)
High Positive 9X LoD 45 copies/µL	Day 0 (RT)[1]	2	34.09 (0.5)	34.55 (0.4)	22.21 (0.2)	3/3 (100)
	Summer[2]	2	32.07 (0.0)	32.67 (0.1)	23.69 (0.0)	2/2 (100)
High Positive 10X LoD 50 copies/µL	Day 0 (RT)[1]	3	32.04 (0.39)	32.42 (0.30)	21.83 (0.22)	3/3 (100)
	Summer[2]	2	32.37 (0.4)	33.05 (0.3)	23.76 (0.0)	2/2 (100)

[1] Day 0 (RT) = within 56 hours of collection at room temperature shipping conditions
[2] Testing performed at the conclusion of the thermal excursions described in Table 1
[3] N/A = No detectable Ct value
[4] Positive; Number of replicates positive for SARS-CoV-2 targets only (N1 and N2), not RNase P target

These results demonstrate that SARS-CoV-2 RNA positive saliva specimens are stable in the Oragene Dx OGD-510 collection device when exposed to a broad range of temperature conditions. The results obtained with the Phosphorus COVID-19 RT-qPCR Test with contrived specimens that had undergone a summer thermal excursion were the same as those obtained when the specimens were tested at time zero. These data support the use of the Oragene

Dx OGD-510 for transport and storage of specimens following self-collection of saliva in the home setting.

Phosphorus Diagnostics will conduct a post-authorization study to verify the stability of SARS-CoV-2 RNA in specimens collected using the OGD-510 device included in the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC that are transported under low ambient temperature conditions, including multiple freeze-thaw cycles.

2) **Home Collection Kit Stability:**

OGD-510 Saliva Collection Device (Reagent) Stability

The expiration date of the OGD-510 saliva collection device from DNA Genotek is printed on the outer package and is 30 months from the date of manufacturing. Therefore, the expiration date of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC will be 30 months and is displayed on the back of the kit's outer box. A specific accessioning criterion is to ensure that the kit's expiration date has not exceeded.

3) **Self-Collection Validation:**

Saliva specimens are self-collected following instructions provided with the OGD-510 collection device by DNA Genotek. The OGD-510 has been cleared by FDA for over the counter use and for prescription use. As part of the validation used to support clearance of K141410, K152556, and K192920, DNA Genotek completed usability studies on lay users in the home environment to assess user comprehension of the OGD-500 instructions (which include the OGD-510) and OGD-600 saliva collection device series.[1] These studies evaluated both collection and packaging of the saliva specimens for shipment to a laboratory for downstream molecular testing. The Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC uses the same instructions for collection as the OGD-500 device. Therefore, an additional usability study was not required.

The results from the usability study performed by DNA Genotek indicate users 18 years of age and older are able to collect a saliva specimen safely and appropriately, with sufficient human biological material for downstream molecular testing.

4) **Additional Requirement:**

In addition to validation studies, Phosphorus Diagnostics and designated laboratories will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC including how many kits were ordered via the Phosphorus website or purchased from an authorized distributor, and activated via the online portal. Designated laboratories will also document the number of kits that were processed, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC lot.

[1] The 600-series (OGD-600 and OGD-610) differs from the 500-series (OGD-510, and OGD-500) in the amount and/or concentrations of the reagents in the tube, which vary because of the difference in the amount of saliva collected. The ratio of final sample to stabilizing liquid volume remains the same for the 600 and 500 models. In addition, the 600 series labeling is in English only where the 500 series has labeling in multiple languages.

WARNINGS

- For *In vitro* Diagnostic Use
- For Use Under and Emergency Use Authorization (EUA) Only
- For Use by Individuals 18 Years of Age or Older
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the self-collection and maintenance of saliva specimens as an aid in 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 medical devices 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.