# EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE P23 LABS TAQPATH SARS-COV-2 ASSAY (P23 LABS)

For *In Vitro* Diagnostic Use
Rx Only
For Use Under Emergency Use Authorization (EUA) Only

**(The P23 Labs TaqPath SARS-CoV-2 Assay will be performed by laboratories designated by P23 Labs, 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, as described in the Standard Operating Procedures that were reviewed by the FDA under this EUA).**

## INTENDED USE

The P23 Labs TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirate or nasal aspirate specimens as well as bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider (HCP).

This test is also for use with saliva specimens that are self-collected at home or in a healthcare setting, with or without the supervision and/or assistance of an HCP, by individuals using the P23 At-Home COVID-19 Test Collection Kit when determined to be appropriate by an HCP.

This test is also for use with anterior nasal swab specimens that are self-collected using either: (1) the binx health At-home Nasal Swab COVID-19 Sample Collection Kit when used consistent with its authorization, or (2) the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization.

Testing is limited to laboratories designated by P23 Labs, 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens and saliva during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations,

patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

Testing with the P23 Labs TaqPath SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR and in vitro diagnostic procedures. The P23 Labs TaqPath SARS-CoV-2 Assay and the P23 At-Home COVID-19 Test Collection Kit are only for use under the Food and Drug Administration's Emergency Use Authorization.

## DEVICE DESCRIPTION AND TEST PRINCIPLE

### Assay Overview

The P23 Labs TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The assay uses primers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the ThermoFisher TaqPath COVID-19 Combo Kit and are designed to detect RNA from SARS-CoV-2 in respiratory specimens from individuals suspected of COVID-19 by their healthcare provider. P23 Labs has also validated the use of HCP supervised self-collected saliva using the OMNIgene·ORAL OM-505 collection device, which is contained within the P23 At-Home COVID-19 Test Collection Kit. Individuals are evaluated by their healthcare provider and determined to be appropriate for saliva collection using the CDC screening guidelines (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html).

### Sample Collection and Transport

The NP swabs that were validated for use with the P23 Labs TaqPath SARS-CoV-2 Assay included the Copan ESwab 480C flocked swab in Amies Media (Cat # 480C.US). Washes/aspirates/BALs can be collected in sterile containers such as the Corning TP52C002 (ThermoFisher Cat # 07-202-025). Once swab/wash/aspirate/BAL samples are received in the laboratory, specimens may be refrigerated (2-8°C) for an additional 3 days before they are extracted and processed if specimens cannot be processed immediately upon receipt.

Saliva specimens must be collected, transported, and stored using the OMNIgene·ORAL OM-505 collection device from the P23 At-Home COVID-19 Test Collection Kit. Collection of saliva can occur using four different approaches:

1) with the assistance of a trained HCP
2) self-collected under the supervision of an HCP in the healthcare setting
3) self-collected under the supervision of an HCP in the home setting via a telehealth appointment, or
4) self-collected without HCP supervision (unsupervised) in the home setting

Saliva specimens must be transported and stored at ambient temperature and tested within 72 hours of collection.

The nasal swab specimens collected with the Everlywell COVID-19 Test Collection Kit include either polyester or foam swabs (Miraclean Cat # MSC-93050, Puritan Cat # 25-1506-1PF-100) and must be placed in the provided saline-containing tube and shipped to the laboratory within 48 hours. The dry nasal swab collected with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit must be placed in the collection tube and shipped to the laboratory within 56 hours of collection to ensure timely receipt of the specimen. All specimens received at the clinical laboratory for testing will undergo review and accessioning prior to acceptance for testing.

Nucleic Acid Extraction and RT-PCR

RNA extraction for all specimen types is performed using the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on the automated KingFisher Duo Primer Purification System (software v4.0). The input sample volume is 400 µL, the elution volume is 50 µL using RNase-free water.

Reverse transcription-PCR (RT-PCR) is performed using the Applied Biosystems TaqPath COVID-19 Combo Kit with 5 µL of the extracted sample. P23 Labs uses the TaqPath COVID-19 Combo Kit per the Instructions for Use. In addition, an RNase P RT-PCR assay will be run on all binx health self-collected dry nasal swabs, Everlywell self-collected nasal samples, HCP-assisted saliva collection, as well as supervised/unsupervised self-collected saliva samples prior to running the P23 Labs TaqPath SARS-CoV-2 Assay. Amplification of the RNase P gene will assess if biological material was collected in the sample and if sufficient nucleic acid was extracted for testing.

**REAL-TIME PCR INSTRUMENT USED WITH THE TEST**

The P23 Labs TaqPath SARS-CoV-2 Assay is for use with the ThermoFisher Applied Biosystems QuantStudio 5 Real-Time PCR System equipped with software v1.3 (Expression Suite).

**COLLECTION KITS USED WITH THE TEST**

- This assay can be used with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit. binx health has granted P23 Labs a right of reference to the data supporting the use of this authorized home collection kit.

- This assay can be used with the Everlywell COVID-19 Test Home Collection Kit. Everlywell has granted P23 Labs a right of reference to the data supporting the use of this authorized home collection kit.

- This assay can be used with the P23 At-Home COVID-19 Test Collection Kit that includes the OMNIgene·ORAL OM-505 collection device for both supervised and/or HCP-assisted collection of saliva as well as unsupervised self-collection of saliva. DNA Genotek has granted P23 Labs a right of reference to the usability data demonstrating user comprehension of the saliva collection instructions into the OM-505 device.

**COMPONENTS OF THE P23 AT-HOME COVID-19 TEST COLLECTION KIT**

- UPS arrival box (Express Box 10kg)
- OM-505 Collection Kit (collection funnel/tube, tube cap, collection instructions)

- Biohazard bag
- Absorbent Sheet
- U-line box (for return shipping to P23 Labs)
- Labeled return overpack (outside package for return shipping to P23 Labs)

**MEDICAL OVERSIGHT AND PROCESS TO BE USED FOR SALIVA COLLECTION**

There are four workflows with respect to how saliva is collected with the P23 At-Home COVID-19 Test Collection Kit for testing with the P23 Labs TaqPath SARS-CoV-2 Assay.

- Patient collection with assistance from a trained healthcare provider in a healthcare setting.
- Patient self-collected under the supervision of a trained healthcare provider in a healthcare setting.
- Patient self-collected under the supervision of a trained healthcare provider in the patient's home via telemedicine.
- Unsupervised patient self-collected in the patient's home environment.

The following depicts three scenarios for self-collection of saliva into the OM-505 collection device:

**For P23 At-Home COVID-19 Test Collection Kit Ordering (Unsupervised)**

1. The patient visits the P23 Labs website to request the P23 At-Home COVID-19 Test Collection Kit (http://www.p23labs/covid19). The patient completes personal information[1] and the COVID-19 Medical Questionnaire via the P23 Labs website which adheres to the CDC COVID-19 screening guidelines. A healthcare provider (HCP), via contracted entities, authenticates the information and determines patient suitability for saliva collection.
2. If the patient is deemed inappropriate, they are offered an optional telehealth visit where the patient will video conference with the HCP to discuss options for the patient.
3. If the patient is determined to be suitable to receive the saliva collection kit, the patient will then pay for the test kit and P23 Labs will ship the kit to the patient's home via 48-hour shipping. Clients are provided the option of overnight shipping for an additional fee.
4. The patient collects the sample following the kit's included instructions and returns the specimen to P23 Labs via a prepaid return shipment pack.
5. When results are available, the patient will receive a notification via email indicating that test results can be accessed on the patient's secure P23 account. After viewing the results, the patient will have the option to discuss with an HCP.

**For P23 At-Home COVID-19 Test Collection Kit Ordering (Supervised via Telemedicine)**

1. The process starts with the patient completing the COVID-19 Medical Questionnaire at the HCP's office which adheres to the CDC COVID-19 screening guidelines. If the patient is considered appropriate to receive the kit, the HCP will order the test for the patient by providing the following information.
   a. The HCP will review the testing process with the patient.

[1] The authorization will not include any private healthcare information according to the Health Insurance Portability Accountability Act (HIPAA).

   b. The patient will be provided with a scheduled appointment to walk through the collection and packaging process. This appointment can be in-person or using telemedicine at the discretion of the healthcare provider.
   c. The patient will be provided with an option for the test to be shipped via P23 Labs.
2. The HCP ordering the test will initiate one of two shipping options:
   a. The HCP office will provide a testing kit and packaging supplies to the patient.
   b. The lab can initiate the shipping process to the patient by gathering the patient's information required for shipping of the kit.
3. The patient's receipt of the kit will initiate the following steps:
   a. Patient will register the kit on P23's website. Authentication of the kit will include ID scan and photo to verify identity of patient if collecting at home.
   b. The patient's registration will allow P23 to authenticate/validate the test order.
   c. The patient will be prompted for a response to the following questions:
      1. Did you elect to receive a kit via the HCP's office?
      2. If the answer is yes, did you receive information on the walk through of the test collection and packaging that must take place under supervision of an HCP?
      3. If the answer is no, please provide the scheduled date of your supervised process walk through.
      4. Do you have an email address to receive your authorization that the test has been approved for you to move to the next step in the process? (The patient can elect to receive the authorization via the United States Postal Service.)
4. The patient's payment will be collected via a link on the secure P23 Patient Portal, if applicable.
5. P23 Labs will overnight a kit to the patient if the lab shipping option was selected.
6. The saliva sample is collected using the kit's included instructions under HCP supervision according to the scheduled appointment day and time. Proceeding collection, the HCP will instruct the patient on how to properly package and ship the specimen to P23 Labs for processing.
7. When results are available, the patient will receive a notification via email indicating that test results can be accessed on the patient's secure P23 account. After viewing the results, the patient will have the option to discuss with an HCP.

**For In Clinic Saliva Collection by the Patient**

1. The patient visits the clinic and the healthcare provider (HCP) evaluates the patient for acceptability for the saliva kit, via the CDC COVID-19 screening guidelines.
2. The HCP will either order the test using the online portal (https://p23.labsvc.net/labgen/) or provides the patient with the collection kit if the physician office has the kits available.
3. The saliva sample is collected by the patient in the clinical setting according to the device's included instructions.
4. The HCP places the sample in a biohazard bag and prepares the box for shipping to P23 Labs. The HCP ships all samples collected from the day to P23 Labs via overnight shipping.
5. When results are available, the HCP will receive a notification and will share the results with the patient.

## INSPECTION OF SELF-COLLECTED SPECIMENS RECEIVED AT P23 LABS FOR TESTING:

Nasal swab specimens collected with the binx and Everlywell collection kits and saliva collected with the P23 At-Home COVID-19 Test Collection Kit must undergo a thorough accessioning procedure upon receipt at P23 Labs prior to processing as outlined in the accessioning section of the assay's SOP.

## REAGENTS AND MATERIALS

**Table 1. Reagents and Materials Required for Use of the P23 Labs TaqPath SARS-CoV-2 Assay and RNase P Assay**

| Reagent | Manufacturer | Catalogue # |
|---|---|---|
| **P23 Labs TaqPath SARS-CoV-2 Assay** | | |
| MagMAX Viral/Pathogen Nucleic Acid Isolation Kit | ThermoFisher Scientific | A43252 or A48310 |
| KingFisher Duo Prime Purification System | ThermoFisher Scientific | 5400110 |
| TaqPath COVID-19 Combo Kit | ThermoFisher Scientific | A47814 |
| TaqPath 1-Step Multiplex Master Mix | ThermoFisher Scientific | A28535 |
| 96 well Deep Well Plates | PerkinElmer | 43001-0120 |
| 384 well PCR plate | ThermoFisher Scientific | 4483273 |
| Optical adhesive PCR plate cover | ThermoFisher Scientific | 4311971 |
| Nuclease-free water | -- | -- |
| Ethanol (96-100%) | -- | -- |
| **RNase P Assay** | | |
| TaqMan RNase P Control Reagents Kit, 1000 reactions<br>• 20X RNase P Primer-Probe (VIC dye) Mix<br>• Human Genomic Control DNA, 10 ng/µL | ThermoFisher Scientific | 4316844 |

## CONTROLS TO BE USED WITH THE P23 LABS TAQPATH SARS-COV-2 ASSAY AND RNASE P ASSAY

The controls used with the P23 Labs TaqPath SARS-CoV-2 Assay and RNase P Assay are described in Table 2.

**Table 2. Controls Used with the P23 Labs TaqPath SARS-CoV-2 Assay and RNase P Assay**

| Control Type | Purpose | Frequency of Testing |
|---|---|---|
| **P23 Labs TaqPath SARS-CoV-2 Assay** | | |
| Negative Extraction Control | To monitor for cross-contamination during RNA extraction and RT-PCR | Once per batch of specimens |
| Positive Control | To monitor the integrity of the RT-PCR reagents and process | Once per run of RT-PCR |
| Internal (MS2 Phage) | To monitor the integrity of nucleic acid extraction and RT-PCR for each specimen | Added to each specimen and the Negative Control prior to extraction |

| | | |
|---|---|---|
| No Template Control | To monitor for contamination of extraction and assay reagents | Once per run of RT-PCR |
| **RNase P Assay** | | |
| Endogenous RNase P Control | To monitor collection of human biological material and nucleic acid extraction | Prior to running the TaqPath assay, this control is run on each binx health dry nasal swab, Everlywell nasal swab in saline, and P23 At-Home COVID-19 Test Collection Kit saliva sample received |
| Human Genomic DNA Control | To monitor the integrity of the RNase P Control Reagents | With every RNase P assay |

The results from the P23 Labs TaqPath SARS-CoV-2 Assay controls are interpreted according to the criteria shown in Table 3. If the results obtained with the Positive, Negative, and No Template Controls do not meet the criteria shown, the results from the entire batch of samples are considered invalid and repeat testing must be performed using residual extracted nucleic acid. If any of the above controls do not exhibit the expected performance as described, the assay may have been improperly set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test. Based on the scientific review of the failure, samples could be repeated from extraction or samples could be repeated from previously extracted material.

An additional control targeting RNase P is run with all nasal swab samples collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit or Everlywell COVID-19 Test Home Collection Kit, or with saliva samples collected with the P23 At-Home COVID-19 Test Collection Kit via the four workflows outlined previously, to verify that nucleic acid is present in every sample and is used for every sample processed. Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.

## INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted (Refer to Table 3 for a summary of control results).

**1)** ***Test Controls – Positive, NTC, Extraction, and Internal:***

a) *P23 Labs TaqPath SARS-CoV-2 Assay:*

**MS2 (Internal Positive Control);** MS2 in a sample indicates that PCR amplification occurred in the well. The presence of MS2 and no detectable SARS-CoV-2 during the analysis indicates that proper RNA extraction and amplification occurred, however, no SARS-CoV-2 is present. If SARS-CoV-2 is present in the specimen, amplification of the target RNA may reduce or abrogate MS2 amplification. In this case, the amplified SARS-

CoV-2 indicates proper RNA extraction and amplification. Therefore, MS2 may or may not be detectable in a positive test with patient specimens.

**External Positive Control;** The positive control must be positive for all three SARS-CoV-2 targets, i.e., the ORF1ab, the N Protein, and the S Protein genes and amplification must have a Ct <37 in order for the test result to be valid. The positive control does not contain MS2.

**Nuclease-Free Water (Negative Control; NTC);** The negative control must be negative (undetermined) for all assay targets in order for the test result to be valid.

**Negative Extraction Control (NEC);** Although not supplied with the Thermo TaqPath Combo Kit, P23 Labs runs a NEC with each batch of samples (characterized negative human specimen). The NEC should only show an amplification curve for MS2 with a Ct of less than or equal to 37 but must be negative for all SARS-CoV-2 targets (Ct undetermined).

**Table 3. Ct Values for Controls that Must be Observed to Obtain Valid Results**

| Control | Ct Value (Optical Channel) | | | |
|---|---|---|---|---|
| | **N Gene (VIC)** | **S Gene (ABY)** | **ORF1ab (FAM)** | **MS2 Phage (JUN)** |
| Negative Extraction Control | Undetermined | Undetermined | Undetermined | ≤ 37 |
| Positive Control | < 37 | < 37 | < 37 | Undetermined [1] |
| No Template Control | Undetermined | Undetermined | Undetermined | Undetermined [1] |
| MS2 Internal Control | Any | Any | Any | < 37 |

Undetermined (No detectable Ct value)

[1] The MS2 Phage Internal Control is not added to the Positive Control or No Template Control and no signal should be obtained.

b) *RNase P Control:*

RNase P controls are run separately to evaluate binx health self-collected dry nasal swabs, Everlywell self-collected nasal swabs in saline, and saliva specimens collected with the P23 At-Home COVID-19 Test Collection Kit for use with the P23 Labs TaqPath SARS-CoV-2 Assay. RNase P monitors the collection and extraction of nucleic acid for each self-collected nasal and saliva sample.

**2) *Examination and Interpretation of Patient Specimen Results:***

a) *P23 Labs TaqPath SARS-CoV-2 Assay:*

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted. Please see the table below (Table 4) for guidance on interpretation and reporting of results.

**Table 4. Result Interpretation for Patient Samples Using the P23 Labs TaqPath SARS-CoV-2 Assay**

| Ct Value (Optical Channel) | | | | Result Interpretation |
|---|---|---|---|---|
| N Gene (VIC) | S Gene (ABY) | ORF1ab (FAM) | MS2 Phage (JUN) | |
| Undetermined | Undetermined | Undetermined | ≤ 37 | Negative |
| Two or more targets < 37 | | | Any value | Positive |
| One of three targets < 37 | | | Any value | Positive |
| Undetermined | Undetermined | Undetermined | Undetermined | Re-test [1] |

Undetermined (No detectable Ct value)

[1] Re-test required from the residual extracted sample and by processing a new aliquot of the original sample if volume permits; if the re-test result is the same as the original then report result as inconclusive, and consider collecting a new specimen.

b) *RNase P Control:*
Specifically, for nasal swab samples collected using the binx health or Everlywell collection kits as well as saliva specimens collected with the P23 At-Home COVID-19 Test Collection Kit, the RNase P assay is performed prior to running the samples with the P23 Labs TaqPath SARS-CoV-2 Assay. A positive result for RNase P (Ct < 29) indicates that human biological material was successfully collected, and the sample can be tested with the P23 Labs TaqPath SARS-CoV-2 Assay. Those specimens that do not exhibit RNase P amplification curves (undetermined or Ct ≥ 29) are re-tested using residual extracted material or are re-extracted from residual clinical sample. If the re-extracted sample fails a second time, the lab reports the result as inconclusive and a new sample is requested.

c) *Reporting of Results to Patients from Collection Kit Samples:*
Results will be reported to patients via the following approaches depending upon sample type.

- For saliva samples collected using the P23 At-Home COVID-19 Test Collection Kit, patient results are either released to the patient via an email notification indicating that results can be accessed using their P23 account (for unsupervised or supervised self-collection in the home setting) or the results are communicated back to the HCP whom relay the information to the patient (supervised self-collection in a healthcare setting).
- For wet nasal swabs collected using the Everlywell COVID-19 Test Home Collection Kit, patient results will be relayed via a mechanism instituted by Everlywell.
- For dry nasal swabs collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit, negative results are communicated through the binx application and positive/invalid results are relayed via outreach calls by a healthcare provider.

## PERFORMANCE EVALUATION

### 1) Analytical Sensitivity

The LoD was determined using SARS-CoV-2 genomic RNA fragments purchased from SeraCare (AccuPlex SARS-CoV-2, Cat # 0505-0126) that was diluted in SARS-CoV-2

negative pooled nasopharyngeal swab matrix (eSwab; NP swab suspended in liquid Amies). An initial estimate of the LoD with the Applied Biosystems QuantStudio 5 Real-Time PCR System was obtained by testing ten replicates at each of four different target levels: 50, 20, 10, and 2.5 copies/µL. The lowest level at which all ten replicates were positive for all three SARS-CoV-2 targets was 10 copies/µL (Table 5). The estimated LoD was confirmed by testing an additional 20 extraction replicates at the same target level. All 20 replicates produced the expected results for each SARS-CoV-2 target, and the LoD was therefore confirmed to be 10 copies/µL (Table 6).

**Table 5. Preliminary LoD Determination Results**

| Concentration (copies/µL) | ORF1ab | | N Gene | | S Gene | | MS2 (IC) | |
|---|---|---|---|---|---|---|---|---|
| | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct |
| 50 | 10/10 (100) | 26 | 10/10 (100) | 25 | 10/10 (100) | 24 | 10/10 (100) | 24 |
| 20 | 10/10 (100) | 28 | 10/10 (100) | 26 | 10/10 (100) | 24 | 10/10 (100) | 24 |
| 10 | 10/10 (100) | 28 | 10/10 (100) | 29 | 10/10 (100) | 26 | 10/10 (100) | 24 |
| 5 | 7/10 (70) | 29 | 9/10 (90) | 31 | 10/10 (100) | 27 | 10/10 (100) | 24 |
| 2.5 | 8/10 (80) | 31 | 9/10 (90) | 32 | 10/10 (100) | 27 | 10/10 (100) | 24 |
| Negative | 0/0 (0) | N/A | 0/0 (0) | N/A | 0/0 (0) | N/A | 10/10 (100) | 24 |

N/A; Not Applicable

**Table 6. Confirmatory LoD Study for Nasopharyngeal Swab Specimen**

| Concentration (copies/µL) | ORF1ab | | N Gene | | S Gene | |
|---|---|---|---|---|---|---|
| | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct |
| 10 | 19/20 (95) | 32 | 20/20 (100) | 31 | 20/20 (100) | 29 |

To validate the use of saliva as an acceptable specimen type, a bridging study (confirmatory LoD study) was completed between nasopharyngeal swabs and healthcare provider supervised self-collection of saliva into the OM-505 collection device (used in the P23 At-Home COVID-19 Test Collection Kit). This study used pooled, negative saliva collected in OM-505 and pooled, negative NP swab matrix spiked with SeraCare material at 2X and 5X LoD (20 copies/µL and 50 copies/µL). Twenty individual extraction replicates of both specimen types at both 2X and 5X LoD were ran on P23 Labs TaqPath SARS-CoV-2 Assay. The data demonstrated that the LoDs for NP swabs and saliva were equivalent.

**Table 7. Bridging Study Between NP Swab and Saliva Collected in OM-505 Collection Device (2X LoD)**

| Concentration (copies/µL) | ORF1ab | | N Gene | | S Gene | | MS2 (IC) | |
|---|---|---|---|---|---|---|---|---|
| | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct |
| **NP Swab-eSwab (Liquid Amies)** | | | | | | | | |
| 20 | 20/20 (100) | 24 | 19/20 (95) | 30 | 20/20 (100) | 25 | 20/20 (100) | 24 |
| **Saliva in OM-505** | | | | | | | | |
| 20 | 19/20 (95) | 26 | 20/20 (100) | 32 | 20/20 (100) | 24 | 20/20 (100) | 24 |

**Table 8. Bridging Study Between NP Swab and Saliva Collected in OM-505 Collection Device**

**(5X LoD)**

| Concentration (copies/µL) | ORF1ab | | N Gene | | S Gene | | MS2 (IC) | |
|---|---|---|---|---|---|---|---|---|
| | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct |
| **NP Swab-eSwab (Liquid Amies)** | | | | | | | | |
| 50 | 20/20 (100) | 23 | 20/20 (100) | 27 | 20/20 (100) | 23 | 20/20 (100) | 24 |
| **Saliva in OM-505** | | | | | | | | |
| 50 | 20/20 (100) | 24 | 20/20 (100) | 28 | 20/20 (100) | 23 | 20/20 (100) | 24 |

To validate that nasal swabs collected and transported in saline using the Everlywell Kit is an acceptable specimen type for testing with the P23 Labs TaqPath SARS-CoV-2 Assay, a spiked LoD confirmatory study was completed. This study used negative human/porcine nasal mucous matrix spiked with positive patient RNA at 2X and 5X LoD concentrations (20 copies/µL and 50 copies/µL). The LoD study design was chosen to mimic the protocol used by Everlywell for their authorization which included pooling of clinical positive samples and extracting RNA. Swab samples were prepared through a procedure that mimicked a nasal swabbing action. Swabs were submerged into a reservoir of either 2X or 5X LoD pools of human/porcine nasal mucous matrix and then abraded against the side of the tube to allow the viral solution to absorb into the polyester or foam swab. Spiked swabs were then placed into 1mL of saline in the provided Everlywell collection tube. Twenty technical replicates at 2X (low positive) LoD and five technical replicates prepared at 5X LoD (moderate positive) were ran on the P23 Labs TaqPath SARS-CoV-2 Assay. Of these 25 replicates, 12 were tested with the foam swabs (Puritan, Cat # 25-1506-1PF-100) including 12 low positive concentrations and 13 were tested with the polyester swabs (Miraclean, Cat # MSC-93050) including 8 low positives and 5 moderate positive swab concentrations. The same number of swab types were tested with the negative samples (12 foam and 12 polyester swabs in saline).

The negative samples were prepared using negative human/porcine nasal mucous and the same procedure described previously. All contrived positive and negative samples were held at ambient temperatures for 24 hours prior to testing with the P23 Assay. The Ct values for each assay target when using RNA extracted from the simulated nasal swabs was consistent with the Ct values for the NP swabs and supervised saliva collected using the OM-505 at the same concentration (2X LoD) with the exception of the N gene Ct values (Table 9). The data showed acceptable performance of the P23 Labs TaqPath SARS-CoV-2 Assay with nasal swabs collected unsupervised in the home environment using the Everlywell Kit.

**Table 9. LoD Confirmation Study (2X and 5X LoD) for Everlywell Nasal Swabs**

| Concentration (copies/µL) | ORF1ab | | N Gene | | S Gene | | MS2 (IC) | |
|---|---|---|---|---|---|---|---|---|
| | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct | Detection Rate (%) | Mean Ct |
| 20 (2X LoD) | 20/20 (100) | 24.0 | 20/20 (100) | 25.9 | 20/20 (100) | 24.0 | 20/20 (100) | 24.7 |
| 50 (5X LoD) | 5/5 (100) | 23.4 | 5/5 (100) | 23.5 | 5/5 (100) | 23.7 | 5/5 (100) | 24.3 |
| Negative | 0/25 | UND | 0/25 | UND | 0/25 | UND | 25/25 | 25.4 |

UND; Undetermined (No detectable Ct value)

**2) Dry Swab Rehydration**

To demonstrate that dry spun polyester swabs was an acceptable specimen type for testing with the P23 Labs TaqPath SARS-CoV-2 Assay, performance of the assay was evaluated using dry swabs resuspended in 2.5 mL of 0.85% saline. Eluates were incubated at room temperature for 30 minutes followed by vigorously vortexing for 20 seconds. The eluted material underwent nucleic acid extraction using the MagMAX kit and tested with the P23 Labs TaqPath SARS-CoV-2 Assay.

Thirty contrived positive specimens at 2X LoD were prepared by spiking Accuplex SARS-CoV-2 material from SeraCare (Cat # 0505-0126) into negative clinical nasal swab matrix. The spun polyester swabs were dipped into the spiked matrix and allowed to dry for 24 hours at room temperature. In addition to the 30 contrived technical positive replicates, 30 negatives (unspiked-only negative clinical matrix) were also assessed using the same technique of dipping the swabs followed by drying. Results are summarized in Table 10. There was 100% agreement with expected results for all positive contrived dry spun polyester swab samples. All negative samples were non-reactive for SARS-CoV-2 assay targets but amplified RNase P as expected.

**Table 10. Dry Swab Rehydration Study Data**

| Swab Type | Concentration | Samples (n) | Detection Rate | | | |
|---|---|---|---|---|---|---|
| | | | N Gene | S Gene | ORF1ab | RNase P |
| Spun Polyester | 2X LoD (20 copies/µL) | 30 | 30/30 | 30/30 | 30/30 | 30/30 |
| | Negative | 30 | 0/30 | 0/30 | 0/30 | 30/30 |

**3) Analytical Specificity**

*Inclusivity:*

The P23 Labs TaqPath SARS-CoV-2 Assay is a modification of the previously authorized ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. The assay targets specific genomic regions of the SARS-CoV-2 nucleocapsid (N) gene, spike (S) gene, and ORF1ab region. Inclusivity was demonstrated under the original ThermoFisher EUA and a right of reference to use their inclusivity data was provided to P23 Labs. Briefly, the primers and probes were mapped against 25,998 complete SARS-CoV-2 genomes that were available in the GenBank and GISAID (Global Initiative on Sharing All Influenza Data) databases as of June 3, 2020. Based upon BLAST analysis, the assay's primers and probes mapped with 100% homology to >99.99% of known SARS-CoV-2 isolates in GISAID and 100% of known isolates in GenBank databases. Mapping was deemed successful for a given isolate if at least two of the three targets (ORF1ab, S gene, N gene) showed 100% identity.

*Cross-Reactivity:*

The analytical specificity of the P23 Labs TaqPath SARS-CoV-2 Assay was demonstrated in silico under the original EUA for the ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. As stated previously, a right of reference to use ThermoFisher's exclusivity data was given to P23 Labs. The analysis included evaluation of the primer and probe homology

with the 43 organisms and viruses listed in Table 11. Based on this analysis, significant amplification of non-target sequences that could result in cross-reaction (false-positive results) or interference (false-negative results were considered unlikely to occur.

**Table 11. Organisms and Viruses Evaluated for Potential Cross-Reaction and/or Interference with the ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit**

| **Viruses** | **Bacteria** |
|---|---|
| Adenovirus | *Bacillus anthracis* |
| Enterovirus | *Bordetella pertussis* |
| Human coronavirus 229E | *Chlamydophila pneumoniae* |
| Human coronavirus HKU1 | *Chlamydophila psittaci* |
| Human coronavirus NL63 | *Corynebacterium diphtheriae* |
| Human coronavirus OC43 | *Coxiella burnetii* |
| Human Metapneumovirus (hMPV) | *Haemophilus influenzae* |
| Influenza A, B and C | *Legionella* (non-*pneumophila*) |
| MERS-coronavirus | *Legionella pneumophila* |
| Parainfluenza 1-4 | *Leptospira* sp. |
| Parechovirus | *Moraxella catarrhalis* |
| Respiratory Syncytial Virus A and B | *Mycobacterium tuberculosis* |
| Rhinovirus/Enterovirus | *Mycoplasma pneumoniae* |
| SARS-coronavirus | *Neisseria elongata* and *Neisseria meningitidis* |
| **Yeast/Fungus** | *Pseudomonas aeruginosa* |
| *Candida albicans* | *Staphylococcus aureus* |
| *Pneumocystis jirovecii* | *Staphylococcus epidermidis* |
| | *Streptococcus pneumoniae* |
| | *Streptococcus pyogenes* |
| | *Streptococcus salivarius* |

## 4) Clinical Evaluation

*Saliva (Paired NP Swab and Saliva Clinical Study):*

A study was performed to evaluate the use of saliva as a specimen type for detection of SARS-CoV-2 in patients who were suspected of COVID-19. The study was conducted with symptomatic patients from one ambulatory care center who were each provided with instructions for self-collection of saliva using the OMNIgene·ORAL OM-505 collection device (included in the P23 At-Home COVID-19 Test Collection Kit). Self-collection of saliva samples was performed under the observation of a healthcare provider, without intervention, who subsequently (within 10 minutes) also collected a nasopharyngeal swab from each patient for parallel testing for SARS-CoV-2. Patients were given the option to ask the HCP for assistance or to complete the collection, if they had remaining questions not covered by the instructions. For this study, patients with previously detected SARS-CoV-2 positive results were re-tested between 7-21 days of an initial positive test using paired samples collected in the clinic as previously described within 10 minutes of each other. The swabs were placed in viral transport medium for shipment to the testing laboratory. NP swabs were evaluated at a different laboratory using an unmodified TaqPath assay as well as with the P23 Labs TaqPath SARS-CoV-2 Assay and results demonstrated 100% concordance (See Table 12). Both the saliva and swabs were transported at ambient temperature and tested

using the P23 Labs TaqPath SARS-CoV-2 Assay within 48 hours of collection. A summary of the results of the study is presented in Table 13 and 14 below.

There was 100% positive and negative agreement between the results obtained from testing of saliva and those obtained from nasopharyngeal swab. Of the 31 previously reported positive NP swab samples, all 31 paired NP and saliva specimens produced positive results for the N gene (31/31; 100%), whereas the S target was positive for 30/31 samples (96.8%) for both NP and saliva samples. For the ORF1ab target, 30/31 (96.8%) NP samples were positive and 29/31 tested saliva samples were positive. According to the result algorithm described in Table 4 above, a sample is considered positive for SARS-CoV-2 RNA if amplification is detected with at least one of the three SARS-CoV-2-specific target sequences. The results of the clinical evaluation with paired nasopharyngeal swabs and saliva were therefore considered acceptable.

**Table 12. Nasopharyngeal Swab Performance When Compared to Another TaqPath Assay Performed at a Different Laboratory**

| | | Nasopharyngeal Swab – TaqPath Comparator Used at a Different Laboratory | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Nasopharyngeal Swab – P23 Labs TaqPath SARS-CoV-2 Assay** | **Positive** | 31 | 0 | 31 |
| | **Negative** | 0 | 11 | 11 |
| | **Total** | 31 | 11 | 42 |
| **Positive Percent Agreement** | | 100% (31/31); 88.98-100.00%[1] | | |
| **Negative Percent Agreement** | | 100% (11/11); 74.12-100.00%[1] | | |

[1]Two-sided 95% score confidence intervals

**Table 13. Summary of Results Obtained From Parallel Testing of Nasopharyngeal Swab Samples and Saliva From Patients Suspected of COVID-19, Stratified by Measurand**

| Number of Patients | Sample Type | Analysis | Target (Optical Channel) | | | |
|---|---|---|---|---|---|---|
| | | | **N Gene (VIC)** | **S Gene (ABY)** | **ORF1ab (FAM)** | **MS2 (JUN)** |
| 31 NP positive | NP swab | Positive (%) | 31/31 (100) | 30/31 (96.8) | 30/31 (96.8) | 31/31 (100) |
| | | Median Ct | 28.3 | 28.6 | 29.0 | 24.8 |
| | Saliva | Positive (%) | 31/31 (100) | 30/31 (96.8) | 29/31 (93.5) | 31/31 (100) |
| | | Median Ct | 28.1 | 28.4 | 29.9 | 24.6 |
| 11 NP negative | NP swab | Positive (%) | 0 (0) | 0 (0) | 0 (0) | 11/11 (100) |
| | | Median Ct | N/A | N/A | N/A | 24.9 |
| | Saliva | Positive (%) | 0 (0) | 0 (0) | 0 (0) | 11/11 (100) |
| | | Median Ct | N/A | N/A | N/A | 24.8 |

NP: Nasopharyngeal; N/A: Not applicable

**Table 14. Summary of Qualitative Results Obtained From Parallel Testing of Nasopharyngeal Swab Samples and Saliva From Patients Suspected of COVID-19**

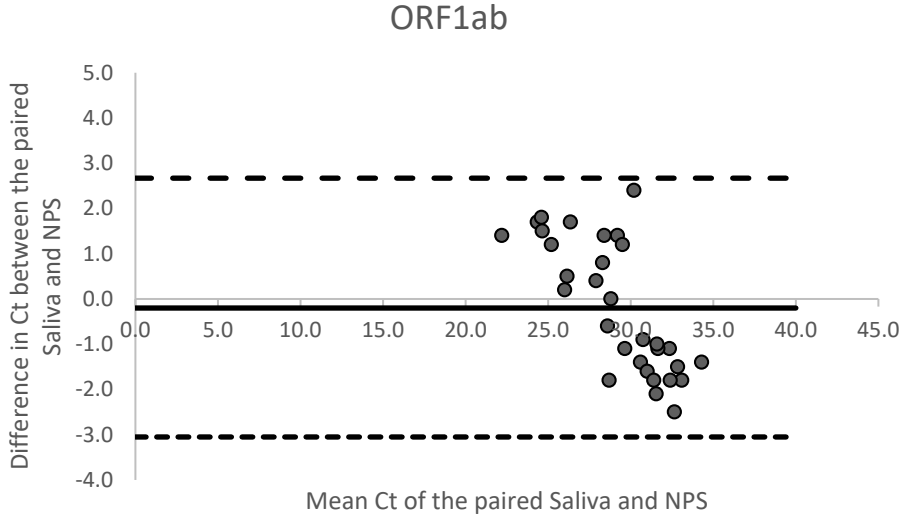
| | | Nasopharyngeal Swab | | |
|---|---|---|---|---|
| | | **Positive** | **Negative** | **Total** |
| **Saliva** | **Positive** | 31 | 0 | 31 |
| | **Negative** | 0 | 11 | 11 |
| | **Total** | 31 | 11 | 42 |
| **Positive Percent Agreement** | | 100% (31/31); 88.98-100.00%[1] | | |
| **Negative Percent Agreement** | | 100% (11/11); 74.12-100.00%[1] | | |

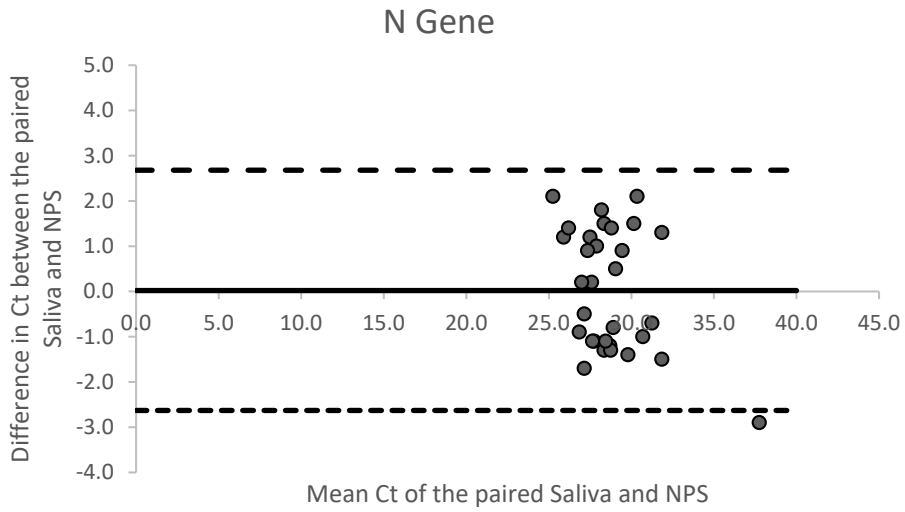
[1]Two-sided 95% score confidence intervals

*Evaluation of Ct Cycle Differences Among Paired Samples:*

The difference between Ct values from the paired samples are shown in Figure 1. Overall median Ct values were similar for saliva and nasopharyngeal swab and demonstrated that there was no systematic difference between testing saliva and NP swab specimens from the same patient within 10 minutes of one another. Figure 2 shows a correlation analysis among the individual Ct values for the 31 paired positive NP and saliva specimens. According to the regression analysis in Figure 2, there appears to be a correlation between the Ct values obtained with the two sample types. The slope of each regression line is close to 1, indicating that the Ct values between the paired NP swabs and saliva samples trend in the same direction as supported by the Bland Altman plots in Figure 1. Based on the R squared values for the three assay targets (ORF1ab, N, and S genes), there is evidence of a correlation between Ct values from the different sample types collected from the same patient. Nevertheless, the results support the use of saliva as a specimen type for use with the P23 Labs TaqPath SARS-CoV-2 Assay.

**Figure 1. Bland Altman Plot for Each SARS-CoV-2 Target Gene**




N Gene
Difference in Ct between the paired Saliva and NPS
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
-2.0
-3.0
-4.0
0.0
5.0
10.0
15.0
20.0
25.0
30.0
35.0
40.0
45.0
Mean Ct of the paired Saliva and NPS

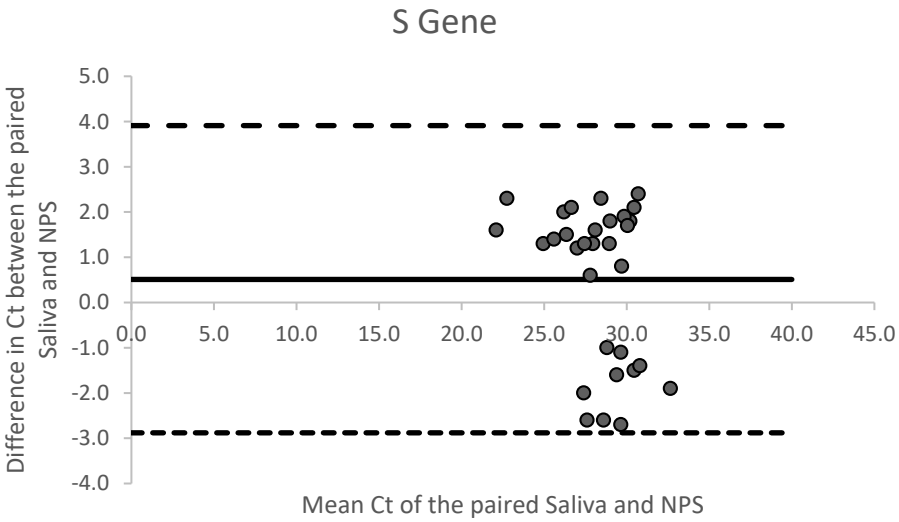
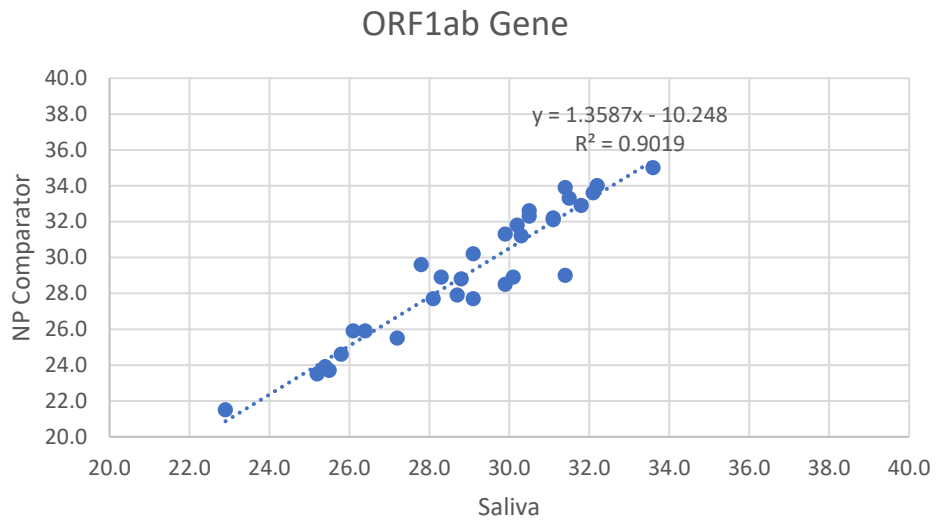
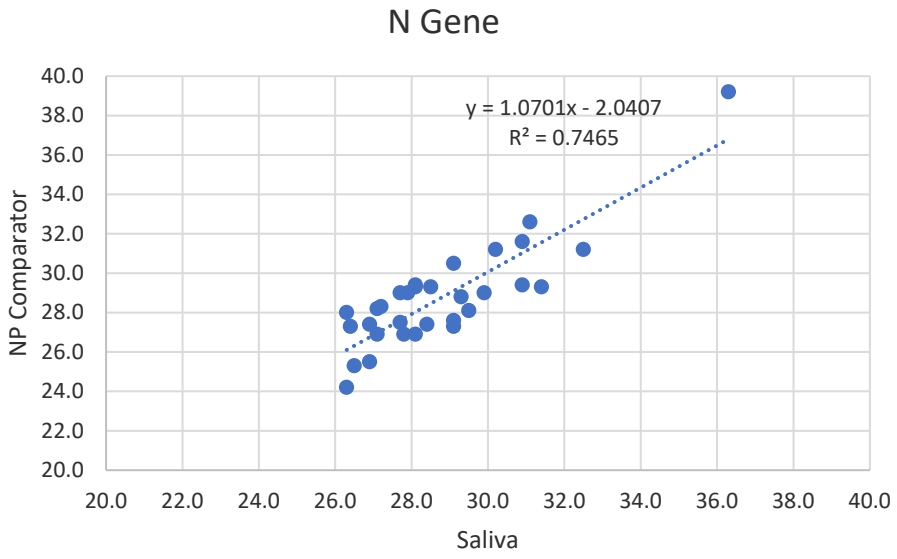
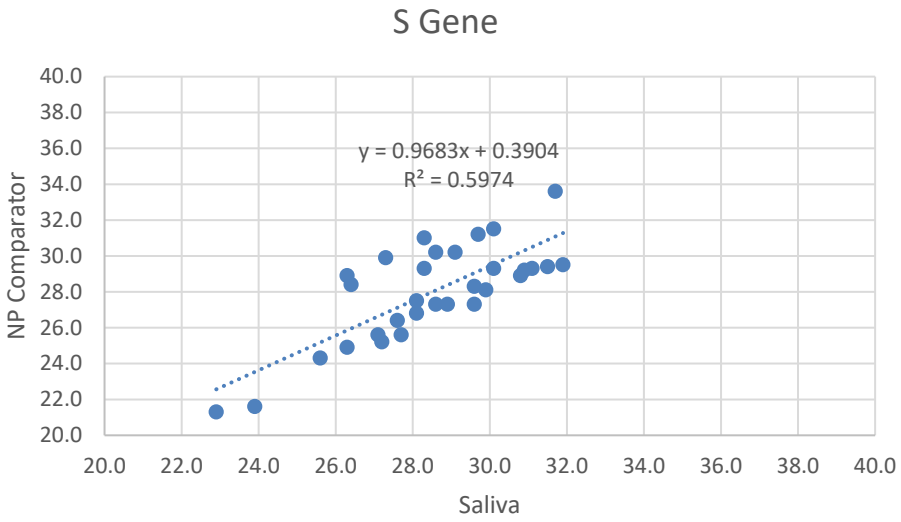

S Gene
Difference in Ct between the paired Saliva and NPS
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
-2.0
-3.0
-4.0
0.0
5.0
10.0
15.0
20.0
25.0
30.0
35.0
40.0
45.0
Mean Ct of the paired Saliva and NPS

**Figure 2. Regression Analysis for Individual Ct Values for the Paired NP and Saliva Specimens**






*Contrived Clinical Study:*

The performance of the P23 Labs TaqPath SARS-CoV-2 Assay was also evaluated in a contrived clinical study using leftover, negative clinical nasopharyngeal swab matrix and saliva (collected in the OM-505 collection device) spiked with the SeraCare material. Individual, unique NP swab specimens and saliva specimens were used for spiking. A total of 30 contrived positives prepared at 2X and 5X LoD and 40 contrived negative samples for both NP swabs and saliva were tested with the P23 Labs TaqPath SARS-CoV-2 Assay. A summary of the results of the study is provided in Table 15. All 40 (100%) contrived negative NP and saliva results were non-reactive and produced the expected results. Of the 30 contrived positive NP and saliva samples, all 30 produced positive results for all three assay targets (N, S, and ORF1ab). The results of the contrived clinical evaluation with nasopharyngeal swabs and saliva were considered acceptable.

**Table 15. Contrived Clinical Study Summary Results for NP and Saliva Samples**

| Type of Sample | Concentration (copies/µL) | Number of samples | Detection Rate (%) | | |
|---|---|---|---|---|---|
| | | | N Gene | ORF1ab | S Gene |
| Nasopharyngeal swab | 2X LoD (20 copies/µL) | 25 | 25/25 (100%) | 25/25 (100%) | 25/25 (100%) |
| | 5X LoD (50 copies/µL) | 5 | 5/5 (100%) | 5/5 (100%) | 5/5 (100%) |
| | Negative clinical samples | 40 | 0/40; UND | 0/40; UND | 0/40; UND |
| Saliva collected in OM-505 | 2X LoD (20 copies/µL) | 25 | 25/25 (100%) | 25/25 (100%) | 25/25 (100%) |
| | 5X LoD (50 copies/µL) | 5 | 5/5 (100%) | 5/5 (100%) | 5/5 (100%) |
| | Negative clinical samples | 40 | 0/40; UND | 0/40; UND | 0/40; UND |

To further support the use of unsupervised self-collected saliva using the OM-505 collection device within the P23 At-Home COVID-19 Test Collection Kit, a contrived clinical study was completed by spiking SARS-CoV-2 negative self-collected saliva with packaged SARS-CoV-2 RNA. Saliva specimens were collected using the self-collection instructions from volunteers that were either exposed to or were caring for a confirmed COVID-19 positive patient. The status of each collected saliva specimen was determined using the P23 TaqPath SARS-CoV-2 assay and all were reported to be negative. Of the 50 saliva specimens, 20 individual samples were spiked with SeraCare packaged viral RNA at 2X LoD, while the 30 remaining samples were unspiked (negative). Samples in the OM-505 device were held at ambient temperature for 24 hours prior to testing with the P23 Labs TaqPath SARS-CoV-2 Assay. Positive contrived specimens and negative specimens were blinded and randomized for testing. All spiked positives yielded 100% detection for all assay targets and RNase P (Table 16). All negative saliva samples were non-reactive for all SARS-CoV-2 assay targets but positive for the MS2 internal control and RNase P demonstrating that nucleic acid extraction and amplification were successful and that human biological material was collected for testing.

**Table 16. Contrived Study Using Unsupervised Collected Saliva in the OM-505 Collection Device**

| Concentration (copies/µL) | # of Samples Evaluated | Analysis | SARS-CoV-2 Assay Targets and RNase P Assay | | | | |
|---|---|---|---|---|---|---|---|
| | | | ORF1ab | N Gene | S Gene | MS2 (IC) | RNase P |
| 20 | 20 | Detection Rate | 20/20 (100) | 20/20 (100) | 20/2 (100) | 20/20 (100) | 20/20 (100) |
| | | Mean (SD) | 25.8 (2.87) | 26.6 (2.32) | 25.3 (3.32) | 25.0 (0.98) | 20.5 (0.27) |
| Negative | 30 | Detection Rate | UND | UND | UND | 30/30 (100) | 30/30 (100) |
| | | Mean (SD) | N/A | N/A | N/A | 24.5 (0.98) | 20.4 (0.23) |

UND; Undetermined (No detectable Ct value)
N/A; Not Applicable
Mean; mean Ct value

*Clinical Confirmation:*

The first 5 positive and first 5 negative nasopharyngeal specimens as determined by P23 Labs using the P23 Labs TaqPath SARS-CoV-2 Assay were also tested by the Arkansas State Health Department using the previously authorized CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. There was 100% (5/5) positive and negative agreement for the specimens tested. These results are acceptable and support use of the by P23 Labs TaqPath SARS-CoV-2 Assay for testing clinical specimens.

**5) Simulated Shipping Study for Saliva Collected with the OMNIgene·ORAL OM-505 Collection Device**

To support at home use of the OMNIgene·ORAL OM-505 collection device (included with the P23 At-Home COVID-19 Test Collection Kit), 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 and winter months. See Tables 17 and 18 for summer and winter thermal profiles evaluated in this study. Room temperature stability was evaluated by physically shipping samples via UPS from Little Rock, AR to Memphis, TN over 3 days (72 hours) and 5 days (120 hours) at ambient (room temperature) conditions.

Simulated sample stability and shipping studies were performed using both contrived positive saliva specimens at 2X and 5X LoD concentrations as well as previously reported clinical positive and negative patient specimens. After the samples underwent the thermal excursions, they were equilibrated to room temperature, extracted, and tested with the P23 Labs TaqPath SARS-CoV-2 Assay.

**Table 17. Summer Temperature Excursion**

| Temperature | Cycle Period | Cycle Period Hours | Total 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

**Table 18. Winter Temperature Excursion**

| Temperature | Cycle Period | Cycle Period Hours | Total Hours[1] |
|---|---|---|---|
| -10°C | 1 | 8 | 8 |
| 18°C | 2 | 4 | 12 |
| -10°C | 3 | 2 | 14 |
| 10°C | 4 | 36 | 50 |
| -10°C | 5 | 6 | 56 |

[1] Sum of cycle periods

*Shipping Study Using Contrived Saliva Samples:*

Contrived samples were prepared using pooled known negative patient sample matrix and spiking with quantified SeraCare material to establish low positives of 2X LoD (LoD previously established as 10 copies/µL) and high positive saliva samples of 5X LoD. For the spiked saliva, donated pathogen free saliva was pooled. Saliva was shown to be negative as each donor was asymptomatic and a prior NP swab was tested and shown to be negative. The donor saliva was screened by an outside laboratory using the P23 Labs TaqPath SARS-CoV-2 Assay 48 hours before use in the contrived study.

Testing included 25 contrived spiked saliva samples; 20 low positive and 5 high positive saliva samples collected in the OM-505 collection device. The contrived positive and negative saliva samples were either physically shipped at room temperature conditions or stored for the duration of each simulated shipping study as shown in Table 17 and 18. At the conclusion of each thermal profile, the samples were equilibrated to room temperature, extracted using the MagMAX kit, and retested with the P23 Labs TaqPath SARS-CoV-2 Assay. Results were compared to those reported upon initial testing when specimens were received at time 0 (day 0, room temperature).

Twenty out of 20 low positive samples (100%) and 5/5 high positive contrived samples (100%) were reported as positive after exposure to room temperature as well as the summer and winter 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 ambient temperature and extreme temperature conditions (no amplification of N, ORF1ab, or S genes).

A summary of the mean Ct values observed for each SARS-CoV-2 specific target gene is provided in Table 19.

**Table 19. Summary of Results From the Simulated Shipping Study Using Contrived Samples**

| Sample Group | Test Point | N | Mean Ct (Standard Deviation) | | | Positive (%) |
|---|---|---|---|---|---|---|
| | | | N Gene | ORF1ab | S Gene | |
| Negative | Day 0 (RT)[1] | 20 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Day 3 (RT)[2] | 20 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Day 5 (RT)[3] | 20 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Summer[4] | 20 | N/A | N/A | N/A | 0 (0) |
| | Winter[5] | 20 | N/A | N/A | N/A | 0 (0) |
| Low Positive 2X LoD 20 copies/µL | Day 0 (RT) | 20 | 22.9 (1.9) | 24.3 (2.8) | 26.1 (1.6) | 20/20 (100) |
| | Day 3 (RT) | 20 | 23.3 (1.6) | 25.5 (1.0) | 26.9 (2.1) | 20/20 (100) |
| | Day 5 (RT) | 20 | 26.9 (0.9) | 27.4 (1.8) | 28.1 (1.3) | 20/20 (100) |
| | Summer | 20 | 26.8 (1.8) | 27.8 (1.3) | 27.1 (1.9) | 20/20 (100) |
| | Winter | 20 | 26.3 (2.1) | 26.9 (0.6) | 26.9 (1.7) | 20/20 (100) |
| High Positive 5X LoD 50 copies/µL | Day 0 (RT) | 5 | 22.3 (1.1) | 23.9 (1.6) | 24.7 (2.0) | 5/5 (100) |
| | Day 3 (RT) | 5 | 24.1 (1.6) | 24.8 (1.2) | 25.3 (1.9) | 5/5 (100) |
| | Day 5 (RT) | 5 | 25.1 (0.9) | 25.9 (13) | 27.3 (1.3) | 5/5 (100) |
| | Summer | 5 | 25.9 (1.1) | 25.5 (1.8) | 24.3 (2.3) | 5/5 (100) |
| | Winter | 5 | 25.9 (1.8) | 25.4 (1.1) | 24.8 (1.4) | 5/5 (100) |

[1] Day 0 (RT) = within 2 hours of collection at room temperature shipping conditions
[2] Day 3 (RT) = 72 hours at room temperature shipping conditions
[3] Day 5 (RT) = 120 hours at room temperature shipping conditions
[4] Testing performed at the conclusion of the thermal excursions described in Table 17
[5] Testing performed at the conclusion of the thermal excursions described in Table 18
[6] Und = Undetermined value (no detectable Ct value)

*Shipping Study Using Confirmed Positive Clinical Saliva Samples:*

A total of 31 previously confirmed clinical SARS-CoV-2 positive saliva specimens were evaluated in the simulated shipping study. The clinical samples were either physically shipped at room temperature conditions or stored for the duration of each simulated temperature excursion, followed by equilibration to room temperature, extracted using the MagMAX kit, and tested with the P23 Labs TaqPath SARS-CoV-2 Assay.

Results of the simulated shipping studies when using previously confirmed clinical positive and negative saliva specimens showed that 31/31 positive samples were positive by the P23 Labs SARS-CoV-2 Assay (See Table 20). The mean and standard deviation of the Ct values for each gene target were similar before and after simulated shipping scenario (within ~3

Cts), with no evidence of significant degradation of the SARS-CoV-2 RNA. Eleven out of 11 negative clinical saliva specimens were negative by the P23 Labs TaqPath SARS-CoV-2 Assay (no amplification of N, ORF1ab, or S genes).

**Table 20. Summary of Results From the Simulated Shipping Study Using Clinical Saliva Samples**

| Saliva Sample Group | Test Point | N | Mean Ct (Standard Deviation) | | | Positive (%) |
|---|---|---|---|---|---|---|
| | | | N Gene | ORF1ab | S Gene | |
| Negative | Day 0 (RT)[1] | 11 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Day 3 (RT)[2] | 11 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Day 5 (RT)[3] | 11 | Und[6] | Und[6] | Und[6] | 0 (0) |
| | Summer[4] | 11 | N/A | N/A | N/A | 0 (0) |
| | Winter[5] | 11 | N/A | N/A | N/A | 0 (0) |
| Positive | Day 0 (RT)[1] | 31 | 25.3 (0.8) | 23.6 (1.5) | 26.1 (1.2) | 31/31 (100) |
| | Day 3 (RT)[2] | 31 | 26.9 (1.1) | 24.4 (0.9) | 28.1 (1.3) | 31/31 (100) |
| | Day 5 (RT)[3] | 31 | 27.3 (1.9) | 24.9 (1.8) | 27.7 (1.6) | 31/31 (100) |
| | Summer[4] | 31 | 28.9 (1.8) | 25.9 (1.1) | 27.1 (2.3) | 31/31 (100) |
| | Winter[5] | 31 | 25.9 (1.3) | 27.3 (1.5) | 27.1 (0.9) | 31/31 (100) |

[1] Day 0 (RT) = within 2 hours of collection at room temperature shipping conditions
[2] Day 3 (RT) = 72 hours at room temperature shipping conditions
[3] Day 5 (RT) = 120 hours at room temperature shipping conditions
[4] Testing performed at the conclusion of the thermal excursions described in Table 17
[5] Testing performed at the conclusion of the thermal excursions described in Table 18
[6] Und = Undetermined value (no detectable Ct value)

These results demonstrate that SARS-CoV-2 RNA positive saliva specimens are stable in the OMNIgene·ORAL OM-505 collection device when exposed to a broad range of temperature conditions. P23 Labs TaqPath SARS-CoV-2 Assay performance was equivalent when using saliva collected in OM-505 and spiked with SARS-CoV-2 RNA versus patient self-collected saliva in OM-505 under HCP supervision (i.e., contrived specimens versus clinical samples). These data support the use of the OMNIgene·ORAL OM-505 for transport and storage of specimens following collection of saliva with or without HCP supervision in the home or healthcare setting. Saliva specimens in the OMNIgene·ORAL OM-505 must be tested within 72 hours of collection.

## LIMITATIONS:

- Testing of saliva specimens is limited to patients with symptoms of COVID-19.
- Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.
- Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.
- The clinical performance has not been established in 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 SARSCoV-2 and their prevalence, which change over time.

**WARNINGS:**

- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories designated by P23 Labs, LLC. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests;
- 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 is revoked sooner.