EMERGENCY USE AUTHORIZATION (EUA) SUMMARY

Verily COVID-19 RT-PCR Test for use with the

Verily COVID-19 Nasal Swab Kit

(Verily Life Sciences)

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

(The Verily COVID-19 RT-PCR Test will be performed at the Verily Life Sciences laboratory, located at 249 E Grand Avenue, South San Francisco, CA 94080, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests, as described in the Laboratory Standard Operating Procedure that was reviewed by the FDA under this EUA.)

INTENDED USE

The Verily COVID-19 RT-PCR Test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens) collected from individuals suspected of COVID-19 by their healthcare provider (HCP).

This test is also for individually tested nasal swab specimens that are self-collected at home (which includes in a community-based setting) without the supervision of a HCP by individuals 18 years or older using the Verily COVID-19 Nasal Swab Kit when determined to be appropriate by a HCP based on results of a COVID-19 medical questionnaire.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 12 individual upper respiratory specimens (such as nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs specimens) that are collected by a HCP using individual vials containing transport media, from individuals suspected of COVID-19 by their HCP. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive, inconclusive, or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to Verily Life Sciences laboratory, located at 249 E Grand Avenue, South San Francisco, CA 94080, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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 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.

The Verily COVID-19 RT-PCR Test is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Verily COVID-19 RT-PCR Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

a. Verily COVID-19 Nasal Swab Kit

The Verily COVID-19 Nasal Swab Kit for home collected specimens collects virus from nasal swab specimens; it can also be used for the transportation and short-term room temperature storage of a sample. The Verily Nasal Swab Kit is a non-invasive alternative for self-collecting virus by/from individuals who are suspected of COVID-19 by their healthcare provider for use in the Verily RT-PCR COVID. Self-collection can be done, either at home or on-site (e.g., workplace or school). The kit consists of the following components:

- Sterile polyester swab or sterile polyurethane foam swab with polypropylene shaft
- Sterile sample collection tube filled with 3 mL saline (0.9 % sodium chloride)
- Barcode sheet
- Instructional insert and tube holder
- Specimen biohazard bag & absorption sheet
- Shipping Box – Cardboard box
- FedEx return shipping envelope with prepaid return label

For the on-site self-collection kit the FedEx shipping envelope is not provided.

The Verily COVID-19 Nasal Swab Kit will include instructions, a pre-printed test requisition form, nasal swab, transport tube containing appropriate fluid (i.e., 0.9% saline), pre-printed tube label, zip-lock bag (with biohazard symbol) containing an absorbent pad, shipping box, and FedEx UN3373 shipping bag with pre-printed FedEx Shipping Label attached.

Users with approved tests pending have written and video instructions on the sample collection and return process available on the Verily website and sent to them by email, text message or other direct communication. Written instructions are also included in the kit to direct the home users how to appropriately collect the nasal swab specimen, place the specimen into the transport tube, properly package the specimen, and mail the specimen back to the laboratory using the pre-labeled FedEx return bag. Each Verily COVID-19 Nasal Swab Kit is intended to be returned via FedEx service at ambient conditions on the same day of collection.

Medical Oversight:
Medical oversight of the process is provided by the healthcare provider who is ordering the test. Verily Life Sciences will only distribute self-collection kits to patients suspected of respiratory viral infection consistent with COVID-19 when home collection is determined to be appropriate by a healthcare provider.

Specimen Transport:
The Verily COVID-19 Nasal Swab Kit was reviewed for adherence to the Department of Transportation's shipping requirements for hazardous materials. The kit was found to be acceptable and appropriate for shipping within the United States.

Inspection of Specimens:
Verily Life Sciences submitted an SOP for receipt and accessioning of samples collected with the Verily COVID-19 Nasal Swab Kit at Verily Life Sciences Laboratory. This protocol is summarized below. Home collected specimens received at the laboratory will undergo review for the following items prior to processing:

- Proper return of sample packaging: confirm that sample is present, test requisition is present, the sample tube is not broken or leaking,
- Verification that the tube barcode label is present and readable by a barcode scanner
- Verification of Patient Information: ensure the patient information on the sample container matches the information on test requisition
- Sample Acceptability: ensure swab is inserted the correct way, sample has sufficient sample volume, acceptable sample temperature, sample was received within 2 days from patient shipping date, and sample was received within acceptable stability window after collection

b. Verily COVID-19 RT-PCR Test

The Verily COVID-19 RT-PCR Test uses a modified version of the ThermoFisher Scientific TaqPath COVID-19 Combo Kit that was FDA authorized for emergency use (EUA) on March 13, 2020. The Verily Pooled COVID-19 Test is a real-time reverse transcription polymerase chain reaction (RT-PCR) test. The test detects three specific regions of the SARS-CoV-2 genome including the ORF1ab region, the N (nucleocapsid) gene, and the S (spike protein) gene. The assay also includes one primer and probe set to

detect the MS2 phage internal control in both the negative extraction control and clinical samples.

Samples self-collected without the supervision of a healthcare provider (i.e., those collected with the Verily COVID-19 Nasal Swab Kit) must be tested with the unpooled workflow and with RNase P.

Samples collected by a healthcare provider may be tested with the Verily COVID-19 RT-PCR Test using a matrix [2D]-pooling strategy for which samples are pooled in a 96-well plate across the rows (12-plex) and the columns (8-plex) as indicated in **Figure 1**; Pools are created prior to extraction using the Tecan Fluent GX automated liquid handler with the Tecan FluentControl v2.6 software. Each sample will be tested as part of the 8-plex pool and as part of the 12-plex pool and thereby identifies the individual positive sample/s or in some cases narrows the positive samples down to a few candidate samples. Positive samples and candidates are then retested individually.

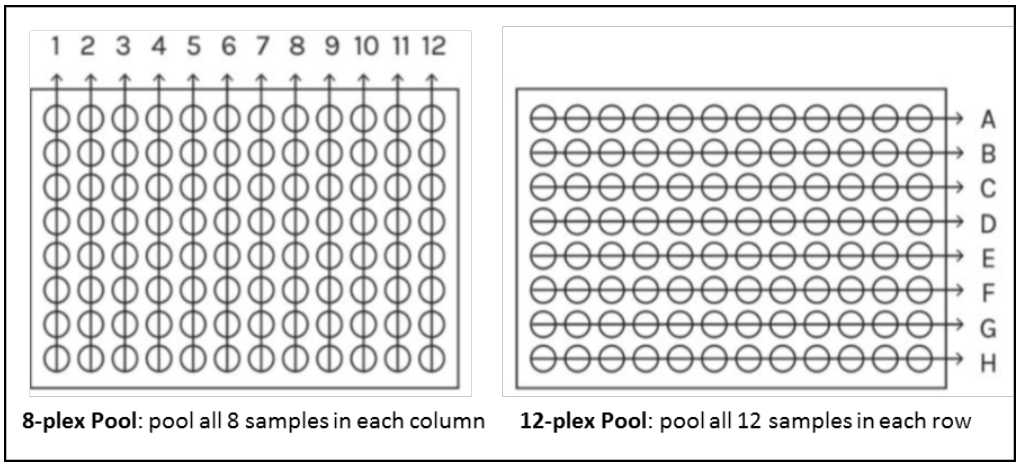

Figure 1: 2D Pooling Matrix

The Verily COVID-19 RT-PCR Test includes procedural modifications that compensate for sample dilution during the pooled testing. RNA is isolated from upper respiratory specimens including nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens using the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit performed on the KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head (reagents are added in a different order to increase sensitivity). RNA is reverse transcribed to cDNA using the TaqPath 1-Step Multiplex Master Mix and subsequently amplified using the 7500 Dx Fast Real-Time PCR with SDS Software v1.4.1 or QuantStudio 5 Real-Time PCR Instrument 384-well block with QuantStudio Design and Analysis Desktop Software v1.5.1 (increased template volume for higher sensitivity).

During the amplification process, the probe anneals to the three specific target sequences located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5’ nuclease activity of Taq polymerase degrades the bound probe, causing the reporter dye (VIC, ABY, and FAM for the N gene, S gene, and ORF1ab targets, respectively) to separate from the quencher dye, generating a fluorescent signal.

INSTRUMENTS USED WITH TEST

The Verily COVID-19 RT-PCR Test is to be used with the following instrumentation:

- Pools are created prior to extraction using the Tecan Fluent GX automated liquid handler with the Tecan FluentControl v2.6 software
- RNA Extraction is performed with the MagMAX Viral/Pathogen Nucleic Acid Isolation on the KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head
- RT-PCR is performed using one of the following realtime fluorescence PCR instruments:
    - 7500 Dx Fast Real-Time PCR with Sequence Detection System (SDS) Software v1.4.1
    - QuantStudio 5 Real-Time PCR Instrument 384-well block with QuantStudio Design and Analysis Desktop Software v1.5.1

EQUIPMENT, REAGENTS AND MATERIALS

The following equipment/reagents/materials are required to run this test in additional to common laboratory reagents and the consumables for the extraction and PCR process:

- Optional: Verily COVID-19 Nasal Swab Kit for self-collection
- Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument
- Applied Biosystems QuantStudio 5 Real-Time PCR Instrument, 384-well Block
- Automated Liquid Handlers
- Centrifuge, with a rotor that accommodates standard and deepwell microplates
- KingFisher Flex 96 Deep-Well Heating Block
- KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head
- MicroAmp Adhesive Film Applicator
- Pipette Controller
- Single and multichannel adjustable pipettors (0.1 µL to 1,000 µL)
- Ethanol, Absolute, Molecular Biology Grade
- MagMAX Viral/Pathogen Nucleic Acid Isolation Kit
- TaqPath 1-Step Multiplex Master Mix (No ROX)
- TaqPath COVID-19 Control Kit
- TaqPath RT-PCR COVID-19 Kit
- COVID-19 Real Time PCR Assay Multiplex (ORF1ab, N gene, S gene, MS2)

HOME COLLECTION KIT ORDERING AND PROCESSING

Contracting organizations first request that participant complete a detailed consent form prior to testing. The consent form is accessed through the Verily website (www.healthy.verily.com). Upon completion of the consent form, individuals who request the Verily COVID-19 Nasal Swab Kit for home collecting nasal swabs are

completing an eligibility questionnaire (also housed on the Verily website), or through an equivalent process (processes for the on-site collection where the provider fills out either the online questionnaire or an identical paper copy with the patient) that collects this information for the ordering physician and adheres to the CDC COVID-19 screening guidelines. Equivalent processes are processes for the on-site collection where the provider fills out either the online questionnaire, or an identical paper copy thereof with the patient. The Verily COVID-19 Nasal Swab Kit can only be provided to the individual after completion of the questionnaire and subsequent consultation with the ordering physician. The Verily platform is integrated with PWNHealth (www.pwnhealth.com), a national Physician Network.

The screener collects necessary information on exposure, symptoms, and risk for reporting to relevant authorities. Individuals who are experiencing severe symptoms to the point of requiring medical attention are not eligible for testing but are advised to seek immediate medical assistance.

While all laboratory processes are run by Verily, the medical interactions are handled by the physician. This includes clinician review and approval of each test ordered and clinical contact with patients after testing is completed. Test results from the Verily COVID-19 RT-PCR Test (including those that used the Verily COVID-19 Nasal Swab Kit) are communicated back to patients via electronic communication to the ordering physician, who will communicate results to the patient as appropriate. Test results can also be securely viewed by the patients via Verily's website (www.healthy.verily.com) or a comparable service that integrates with the laboratory or physician network

CONTROLS TO BE USED WITH THE COVID-19 RT-PCR

Table 1. Assay Controls Run with Each Test

Control Type	Purpose	Frequency of Testing
Negative Control	To monitor for cross-contamination during RNA extraction and RT-PCR	Once per extraction plate
Positive Control	To monitor the integrity of the RT-PCR reagents and process	Once per run of RT-PCR
Internal (MS2 Phage) Control	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 (NTC)	To monitor for contamination of extraction and assay reagents	Once per run of RT-PCR

- **Negative Control:** The negative control monitors for any potential cross-contamination that could occur during the nucleic acid extraction process or RT-PCR assay. Molecular grade, nuclease free water is used in place of sample

nucleic acid for this control. This control is added to each KingFisher extraction run and carried through RT-PCR.

- **Positive Control:** The TaqPath COVID-19 Control (1 x 10^4 copies/µL) is used as positive control and serves as an amplification control for the ORF1ab, N gene, and S gene amplicon sequences. This control is included in every PCR run and only included in the RT-PCR reaction. The positive control is used to verify proper assay set-up and SARS-CoV-2 reagent integrity. The positive control will be used to confirm near the test LoD.
- **Internal (MS2 Phage) Control:** The internal MS2 phage control serves as an internal process control for nucleic acid extraction to ensure that clinical samples and controls contain sufficient and acceptable quality RNA to be used in the RT-PCR reactions.
- **No Template Control (NTC):** The no template control is molecular-grade, nuclease-free water and is used to monitor non-specific amplification, cross-contamination during PCR setup, and nucleic acid contamination of PCR reagents. This control is included once in each RT-PCR run.

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. Result interpretation for patient samples was established based on a cutoff of Ct ≤37 for SARS-CoV-2 target.

a. Control Result Interpretation

Assess all test controls prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Any target with a Ct≤37 is positive and any target with a Ct>37 is negative. Refer to **Table 2** for a summary of control results.

Table 2. Expected Results of Controls

Control	Ct Value			
	N Gene	**S Gene**	**ORF1ab**	**MS2 Phage**
Negative Extraction Control	Undetermined[1]	Undetermined[1]	Undetermined[1]	≤37
Positive Control	≤37	≤37	≤37	Undetermined[2]
No Template Control	Undetermined[1]	Undetermined[1]	Undetermined[1]	Undetermined[2]
MS2 Internal Control	Any	Any	Any	≤37

[1] Undetermined (Not detectable Ct; negative)

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

- **Negative Extraction Control:** The negative extraction control is processed with each batch of samples. The negative control should only show an amplification curve for MS2 with a Ct≤37 but must be negative for all SARS-CoV-2 targets (Ct undetermined).
- **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.
- **No Template Control:** The negative control must be negative for all targets (undetermined; no detectable Ct value) for the test result to be valid.
- **MS2 Internal Control:** MS2 in a patient result 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 the SARS-CoV-2 is present in the specimen, amplification of the target RNA may be reduced or abrogate MS2 amplification. In this case, the amplified SARS-CoV-2 targets indicate proper RNA extraction and amplification. Therefore, MS2 may or may not be detectable in a valid positive test on patient specimens.

b. Examination and Interpretation of Patient Specimen Results

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.

The results of all samples from a given pooled sample plate will only be reported after all positive and/or inconclusive wells on the pooled sample plate have been deconvoluted per the 2D pooling matrix to identify any positive samples through individual testing - including any necessary follow-up testing per Table 3 and 4 below.

Pool Interpretation and Deconvolution:

As described below, the interpretation of the sample pools in the 2D pooling and the extent of the Deconvolution Testing depends on the results of the column-pooled vs. row-pooled samples as well as on the occurrence of individual invalid pools vs. entirely invalid plates. Refer to **Table 3** for guidance on interpretation of pooled sample results.

- Pooled sample wells for which all three SARS-CoV-2 specific targets (ORF1ab, N, and S) are negative (undetermined) and the MS2 control is also negative (undetermined), the result of the pool is invalid. Re-run all samples included in the invalid pool individually using the unpooled workflow starting from extraction.
- Pooled sample wells for which all three SARS-CoV-2 specific targets (ORF1ab, N, and S) are negative (undetermined) and the MS2 control is positive (Ct≤37),

SARS-CoV-2 is not detected in the pooled samples and the following actions occur:

- For pooled sample plates with positive and/or inconclusive wells, a negative result is reported for all samples in the pool once deconvolution of all pools on the plate is complete.
- For pooled sample plates that are entirely negative, no deconvolution is needed, and the negative result is reported for all samples on the plate.

- Pooled sample wells for which only one of the SARS-CoV-2 specific targets (ORF1ab, N, or S) is positive (Ct≤37), and the MS2 control is positive (Ct≤37) or negative (undetermined), SARS-CoV-2 are SARS-CoV-2 inconclusive pools. All samples within that pool, in combination with other pools derived from the plate, will be retested individually to identify any positive, inconclusive and/or negative samples.
- For pooled sample wells with two or more positive (Ct≤37) SARS-CoV-2 specific target (ORF1ab, N, and S), and the MS2 control is positive (Ct≤37) or negative (undetermined), SARS-CoV-2 is detected in the pool. All samples within that pool, in combination with other pools derived from the plate, will be retested individually to identify any positive, inconclusive and/or negative samples.

Deconvolution Testing: Retest samples indicated by the pool or plate individually using the Verily COVID-19 RT-PCR Test to confirm any positive and/or inconclusive samples. Detailed deconvolution is described in **Figure 2**. If the pooled sample plate contains positive or inconclusive wells that cannot be confirmed, re-testing is performed as outlined below. Sample results for the entire plate are only reported after all deconvolution testing is complete.

Table 3. Interpretation of Pooled Sample Results

ORF1ab	N gene	S gene	MS2	Status	Pool Result	Deconvolution
NEG[1]	NEG[1]	NEG[1]	NEG[1]	Invalid	NA	Individually assay samples in the invalid pool.
NEG[1]	NEG[1]	NEG[1]	POS Ct ≤37	Valid	SARS-CoV-2 Negative Pool	Deconvolution Testing not required for samples in this pool. Report as negative.
Only one SARS-CoV-2 target = POS (Ct≤37)			POS or NEG[1]	Valid	SARS-CoV-2 Inconclusive Pool	Deconvolution Testing by individually assaying samples indicated by the inconclusive pool
Two or more SARS-CoV-2 targets = POS Ct≤37			POS or NEG[1]	Valid	SARS-CoV-2 Positive Pool	Deconvolution Testing by individually assaying samples indicated by the

				positive pool

[1] NEG (Ct not detectable or >37, negative)

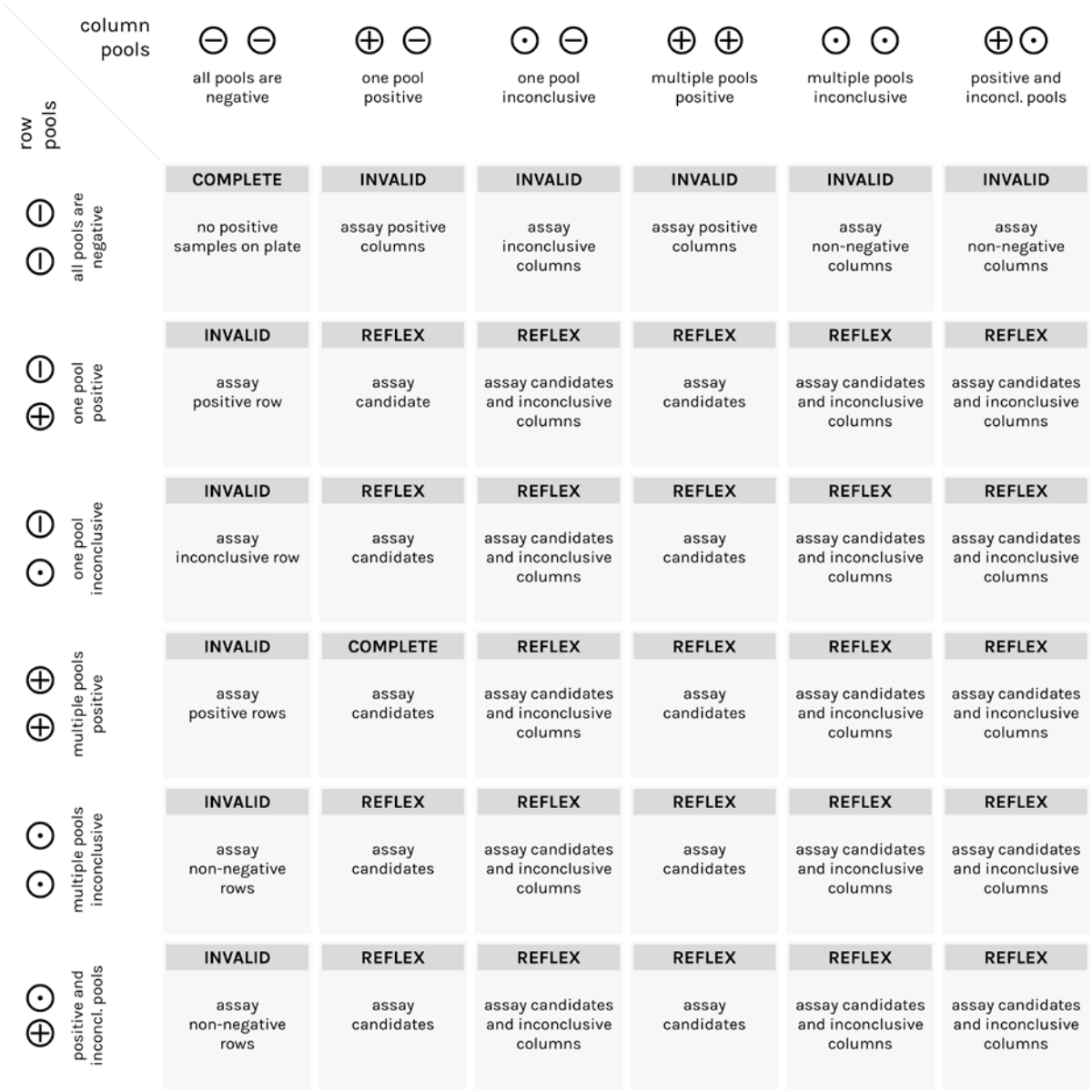

Figure 2: Deconvolution of Pooled Testing (Interpretation Automated by Software)

Individual Sample Interpretation and Result Reporting:

Sample results for the entire plate are only reported after all deconvolution is completed and if all positive, and/or inconclusive wells are confirmed. Individual samples are reported as described in **Table 4** below.

Table 4. Interpretation of Sample Result and Individual Sample Reporting

ORF1ab	N gene	S gene	MS2	Status	Sample Result	Action
NEG[1]	NEG[1]	NEG[1]	NEG[1]	Invalid	NA	Samples that have tested invalid are retested once individually. If retest result is invalid, a new sample is requested.
NEG[1]	NEG[1]	NEG[1]	POS Ct≤37	Valid	SARS-CoV-2 Not Detected	All samples from a negative pool and all samples testing negative during Deconvolution Testing, are individually reported as negative.
Only one SARS-CoV-2 target = POS Ct≤37			POS or NEG[1]	Valid	SARS-CoV-2 Inconclusive	All samples that report an inconclusive result in individual testing will be retested once and if they are retested as inconclusive, they will be reported as inconclusive with the recommendation to obtain a new sample.
Two or more SARS-CoV-2 targets = POS Ct≤37			POS or NEG[1]	Valid	SARS-CoV-2 Detected	All samples that test positive after deconvolution of the pools are reported as positive

[1] NEG (Not detectable Ct or >Ct 37)

PERFORMANCE EVALUATION

A. Verily COVID-19 RT-PCR Test

1) *Limit of Detection (LoD) - Analytical Sensitivity:*

a. Tentative LoD Study:

The LoD of the Verily COVID-19 RT-PCR Test was determined using quantified, SARS-CoV-2 viral genomic RNA material obtained from American Type Culture Collection (ATCC, VR-1986D). After initial range titration the preliminary LoD was determined by testing a range of SARS-CoV-2 concentrations, between 90 GCE/mL and 50 GCE/mL, in 10 copy increments. Samples were prepared by spiking SARS-CoV-2 viral genomic RNA into pooled clinical negative, nasopharyngeal swab matrix, and were tested in triplicate. These replicates were individually processed according to the laboratory SOP and tested on both, the Applied Biosystems 7500 Fast Dx and QuantStudio 5 real-time PCR instruments.

For both instruments, the initial LoD determination of the unpooled Verily COVID-19 RT-PCR Test was 60 GCE/mL.

b. Confirmation of the LoD:

The LoD was verified by testing 20 additional extraction replicates consisting of pooled clinical negative, nasopharyngeal swab matrix spiked with SARS-CoV-2 viral genomic RNA at 60 GCE/mL. Samples were spiked with SARS-CoV-2 viral genomic RNA and replicates tested on both instruments according to the laboratory SOP. The LoD of the Verily COVID-19 RT-PCR Test (unpooled workflow) was confirmed at **60 GCE/mL** (**Table 5**).

Table 5. Confirmatory LoD Results for the Verily COVID-19 RT-PCR Test at 60 GCE/mL

Rep.	7500 Dx					QuantStudio 5				
	MS2	N Gene	S Gene	ORF1ab	Final Result*	MS2	N Gene	S Gene	ORF1ab	Final Result*
1	24.0	34.2	UND	UND	INC	23.6	33.8	UND	34.8	POS
2	24.0	32.9	UND	33.1	POS	24.0	33.5	37.0	34.6	POS
3	24.1	32.5	32.0	33.8	POS	24.4	33.7	34.4	UND	POS
4	24.1	32.2	32.0	32.1	POS	24.0	33.4	36.9	36.7	POS
5	24.1	32.7	34.2	32.7	POS	24.0	34.6	36.5	38.4	POS
6	24.3	33.0	33.6	32.7	POS	24.1	34.1	36.2	34.5	POS
7	24.1	32.1	UND	32.0	POS	24.1	33.5	37.0	35.2	POS
8	24.4	32.4	31.8	31.8	POS	24.1	33.4	35.0	36.6	POS

9	24.2	32.5	32.6	31.6	POS	23.0	32.8	36.2	34.2	POS
10	24.1	32.4	33.1	33.0	POS	23.9	32.9	34.8	35.5	POS
11	24.2	32.3	UND	33.7	POS	24.1	33.8	35.0	37.5	POS
12	24.2	31.7	34.7	32.3	POS	23.9	33.4	37.4	34.4	POS
13	24.2	33.1	33.0	32.9	POS	24.1	33.3	39.1	39.5	INC
14	24.3	31.9	UND	34.2	POS	24.0	34.0	36.6	36.0	POS
15	24.2	32.3	UND	33.1	POS	24.1	34.3	33.6	33.8	POS
16	24.3	32.2	33.9	33.1	POS	23.9	33.2	33.8	35.1	POS
17	24.0	31.8	32.1	32.5	POS	23.3	33.6	33.2	34.4	POS
18	24.2	32.3	33.6	31.6	POS	23.8	33.6	34.0	36.1	POS
19	24.2	32.5	34.2	31.8	POS	23.8	32.9	36.6	35.1	POS
20	24.3	32.2	UND	32.0	POS	23.8	33.2	37.3	36.2	POS
Mean	**24.2**	**32.5**	**33.1**	**32.6**	n/a	**23.9**	**33.5**	**35.8**	**35.7**	n/a
Positive/ Valid	**20/20**	**20/20**	**14/20**	**19/20**	**19/19**	**20/20**	**20/20**	**16/20**	**17/20**	**19/19**
Hitrate	**100%**	**100%**	**70%**	**95%**	**100%**	**100%**	**100%**	**80%**	**85%**	**100%**

*** Final result based on interpretation table (Table 4)**
UND: Undetermined Ct (no detectable Ct in any SARS-CoV-2 targets);
INC: Inconclusive (one target positive); and **POS**: Positive (two or more target positive)

2) Analytical Inclusivity/Specificity:

a. Inclusivity

The Verily COVID -19 RT-PCR Test utilizes the primers and probes included in the ThermoFisher TaqPath COVID-19 Combo Kit. In silico testing of the SARS-CoV-2 assay was previously performed by ThermoFisher as part of their EUA authorization (EUA authorized March 13, 2020) and this information has been provided in the FDA authorized EUA granted to this manufacturer. ThermoFisher provided a Right-to-Reference letter to Verily allowing the reference to their EUA data package.

b. Cross-reactivity

In silico testing of the SARS-CoV-2 assay was previously performed by ThermoFisher as part of their EUA authorization (EUA authorized March 13, 2020) and this information has been provided in the FDA authorized EUA granted to this manufacturer. ThermoFisher provided a Right-to-Reference letter to Verily allowing the reference to their EUA data package.

3) Clinical Evaluation:

a. Detection Study of Unpooled Workflow

The *Detection Study* establishes accurate detection of positive and negative nasopharyngeal swabs when samples are tested individually with the Verily COVID-19 RT-PCR Test (unpooled workflow). The performance of the Verily COVID-19 RT-PCR Test (unpooled workflow) was evaluated using:

- 35 unique positive patient clinical samples
- 30 unique negative patient clinical samples

All clinical samples were tested for SARS-Cov-2 with the ThermoFisher TaqPath COVID-19 Combo Kit (EUA authorized March 13, 2020) as the comparator using the standard EUA authorized workflow on both, the Applied Biosystems 7500 Fast Dx and QuantStudio 5 real-time PCR instruments. Note that one sample was positive on the 7500 Fast Dx, but inconclusive on the QuantStudio 5 tested with the comparator. Samples were tested randomized and blinded using the Verily COVID-19 RT-PCR (unpooled workflow). Testing was performed on both, the Applied Biosystems 7500 Fast Dx and QuantStudio 5 real-time PCR instruments.

All 30 clinically negative samples tested negative in the Verily COVID-19 RT-PCR unpooled workflow on both PCR instruments.
All 35 positive samples tested positive in the Verily COVID-19 RT-PCR unpooled workflow on both PCR instruments including the sample that was previously tested as *inconclusive* with the comparator on the QS5 (**Table 6**). Ct correlation plots between the comparator and the Verily COVID-19 RT-PCR unpooled workflow for the 35 positive samples on both 7500 Fast Dx and QuantStudio 5 are shown in **Figure 3**. Results from the unpooled detection study are summarized in **Tables 6-7**.

Table 6. Clinical Validation Verily COVID-19 RT-PCR Test results using the unpooled workflow compared to an EUA authorized comparator test.

		EUA authorized Comparator (matched instrument)			
		Positive	**Inconclusive**	**Negative**	**Total**
Verily Unpooled ABI 7500	**Positive**	35	0	0	35
	Inconclusive	0	0	0	0
	Negative	0	0	30	30
	Total	35	0	30	65
	PPA: 35/35 = 100% (95% CI: 90.1–100%)				
	NPA: 30/30 = 100% (95% CI: 88.7–100%)				

Verily Unpooled QS5	**Positive**	34	1*	0	35
	Inconclusive	0	0	0	0
	Negative	0	0	30	30
	Total	**34**	1	30	65
	PPA: 34/34 = 100% (95% CI: 89.9–100%)				
	NPA: 30/30 100% (95% CI: 88.7–100%)				
* Because this sample was positive for one target but negative for the other two targets, it was excluded from the performance calculation.					

In total, 35 unique positive samples were tested through the unpooled workflow of the Verily COVID-19 RT-PCR Test. The percent positive agreement (PPA) of the Verily COVID-19 RT-PCR Test when compared to the EUA authorized comparator was 100% (95% CI: 90.1-100% for ABI 7500 and 89.9-100% for QS5) and the NPA was 100% (95% CI: 88.7-100%) on both instruments.

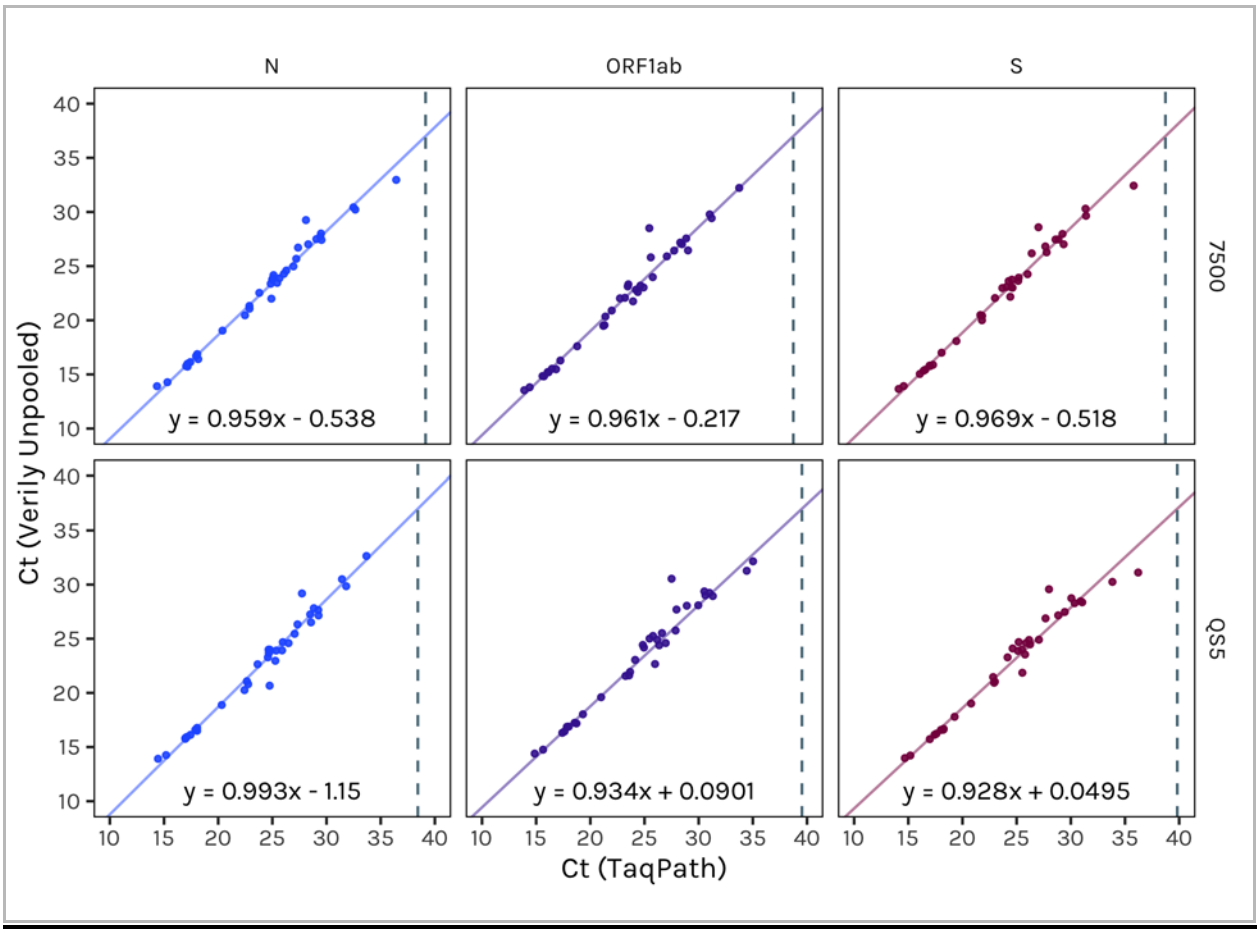

Figure 3. Clinical remnant samples analyzed by Comparator and Verily COVID-19 RT-PCR unpooled workflow on the 7500 Fast Dx and QuantStudio 5. The diagonal line is the Passing-Bablok regression line; the vertical dashed line shows the equivalent Comparator Ct when the regression equation (displayed on chart) is solved for a Ct of 37.

Table 7. Passing-Bablok regression of Verily COVID-19 RT-PCR Test (unpooled) vs. Comparator

Instrument	Gene	Slope (95% CI)	Intercept (95% CI)	Equation	eqn solved for y=37	Ct shift
7500	N	0.959 (0.927, 0.997)	-0.538 (-1.429, 0.071)	y = 0.959x - 0.538	39.14	-2.14
	ORF1ab	0.961 (0.934, 0.984)	-0.217 (-0.811, 0.288)	y = 0.961x - 0.217	38.73	-1.73
	S	0.969 (0.927, 1.005)	-0.518 (-1.28, 0.342)	y = 0.969x - 0.518	38.73	-1.73
QS5	N	0.993 (0.949, 1.028)	-1.15 (-1.957, -0.235)	y = 0.993x - 1.15	38.43	-1.43
	ORF1ab	0.934 (0.899, 1.004)	0.09 (-1.299, 0.9)	y = 0.934x + 0.0901	39.53	-2.53
	S	0.928 (0.874, 0.997)	0.049 (-1.334, 1.185)	y = 0.928x + 0.0495	39.83	-2.83

b. Detection Study of Pooled Workflow

Study Design:

The *Detection Study* of the pooled workflow establishes accurate detection of positive and negative nasopharyngeal (NP) swab samples when samples are tested with the Verily COVID-19 RT-PCR Test using the pooled workflow with pools containing 8 and 12 samples. The performance of the Verily COVID-19 RT-PCR pooled workflow was evaluated using:

- 40 negative 12-plex pools (12 negative NP swab samples)
    - Due to sample limitations, 65 negative samples were used to construct the 40 combination-unique pools.
- 49 8-plex pools containing 1 positive NP swab sample and 7 negative NP swab samples
    - Initial 40 pools: 40 positive samples and 49 negative samples were used. Due to sample limitations, seven negative pools (seven unique samples each) were constructed and used to dilute up to six positive samples each.
    - Additional 9 pools: nine positive samples and 72 negative samples were used. No negative samples were shared between pools.
- 49 12-plex pools containing 1 positive NP swab sample and 11 negative NP swab samples

- Initial 40 pools: 40 positive samples and 44 negative samples were used. Due to sample limitations, four negative pools (11 unique samples each) were constructed and used to dilute 10 positive samples each.
- Additional 9 pools: nine positive samples and 72 negative samples were used. Due to sample limitations, 27 negative samples were used in up to three pools, but each pool was combination-unique.

All clinical samples were tested for COVID-19 individually with the ThermoFisher TaqPath COVID-19 Combo Kit using the standard (unpooled) workflow. Forty nine (49) positive samples of the following Ct ranges were included:

- Samples with a Comparator Ct <18: n=10
- Samples with a Comparator 18 < Ct < 26: n=16
- Samples with a Comparator 26 < Ct < 33: n=17
- Samples with a Comparator 33 < Ct ≤ 37: n=6

Pools were then created by one operator and a second operator performed the testing blinded to the sample composition in the pool according to the Laboratory SOP. The testing was performed on both, the Applied Biosystems 7500 Fast Dx and QuantStudio 5 real-time PCR instruments using the same extracted RNA.

Note: One pool included a low positive sample that was erroneously called positive when individually tested with the ThermoFisher TaqPath COVID-19 Combo kit. The TaqPath test's COVID-19 Interpretive Software called it positive despite having Ct values >37 for two target genes when analyzed with the QuantStudio's analysis software. When analyzed with the pooled workflow of the Verily COVID-19 RT-PCR Test, this sample tested positive in the 8-plex pool on the ABI 7500 and inconclusive in the 8-plex pool on the QS5. Consequently, the Verily COVID-19 RT-PCR Test pooled workflow would have still identified this sample as positive through the deconvolution testing independent of the instrument.

Results:

All 40 12-plex pools without any positive samples tested negative.

All 49 8-plex pools that included one ThermoFisher TaqPath-COVID-19 Combo Kit positive NP swab sample per pool tested positive by the Verily COVID-19 RT-PCR Test pooled workflow, except for one pool that tested positive on the ABI 7500 and inconclusive on the QS5 instrument. This pool contained the low positive sample described in the Note above and had an inconclusive result on the QS5 in both, the 8-plex and the 12-plex pool. Overall performance on both instruments is summarized in **Tables 8 and 9** below. Ct correlation analysis for 8-plex pools for the 7500 Fast Dx and QuantStudio 5 are presented in **Figure 4 and Table 11;** Ct Correlation for the 12-plex pools are presented in **Figure 5 and Table 11**.

Table 8. Overall performance of Verily COVID-19 RT-PCR pooled workflow (run on ABI 7500) vs. TaqPath (standard workflow)

		Comparator (Individually Tested)		
		Positive	Inconclusive	Negative
Verily COVID-19 Test 8-plex pools	Positive	49	0	0
	Inconclusive	0	0	0
	Negative	0	0	0
	PPA (95% CI)	**100% (92.73-100%)**		
	NPA (95% CI)	**negative samples were tested only in 12-plex pools**		
Verily COVID-19 Test 12-plex pools	Positive	48	0	0
	Inconclusive	0	0	0
	Negative	1*	0	40
	PPA (95% CI)	**97.96% (89.31-99.90%)**		
	NPA (95% CI)	**100% (91.24-100%)**		

* This positive sample would have been identified during reflex testing based on the matrix design as it was detected in the 8-plex pool.

Table 9. Overall performance of Verily COVID-19 RT-PCR pooled workflow (run on ABI QS5) vs. ThermoFisher TaqPath COVID-19 Combo Kit (standard workflow)

		Comparator (Individually Tested)		
		Positive	Inconclusive	Negative
Verily COVID-19 Test 8-plex pools	Positive	48	0	0
	Inconclusive	1*	0	0
	Negative	0	0	0
	PPA[1] (95% CI)	**100% (92.73-100%)**		
	NPA (95% CI)	**negative samples were tested only in 12-plex pools**		
Verily COVID-19 Test 12-plex pools	Positive	48	0	0
	Inconclusive	0	0	0
	Negative	1*	0	40
	PPA (95% CI)	**97.96% (89.31-99.90%)**		
	NPA (95% CI)	**100% (91.24-100%)**		

* This positive sample would have been identified during reflex testing based on the matrix design.
[1] Includes non-negative samples.

All 12-plex pools that included one ThermoFisher TaqPath COVID-19 Combo Kit positive NP swab sample and 11 negative NP swab samples tested positive by the Verily COVID-19 RT-PCR Test, except for the pool that contained the low positive

sample described above. The 12-plex pool containing the low positive sample described in the Note above tested negative on the ABI 7500 and inconclusive on the QS5 instrument. This pool had an inconclusive result on the QS5 for both, the 8-plex and the 12-plex pool.

In total, 49 unique positive samples in pools and 40 unique negative sample pools were tested through the pooled workflow of the Verily COVID-19 RT-PCR Test. For 8-sample pools this assay has a positive percent agreement (sensitivity) of 100% (95% CI: 92.73% to 100%). For 12-sample pools, this assay has a positive percent agreement (sensitivity) of 97.96 (95% CI: 89.31% to 99.90%) and a negative percent agreement (specificity) of 100% (95% CI: 91.24% to 100%).

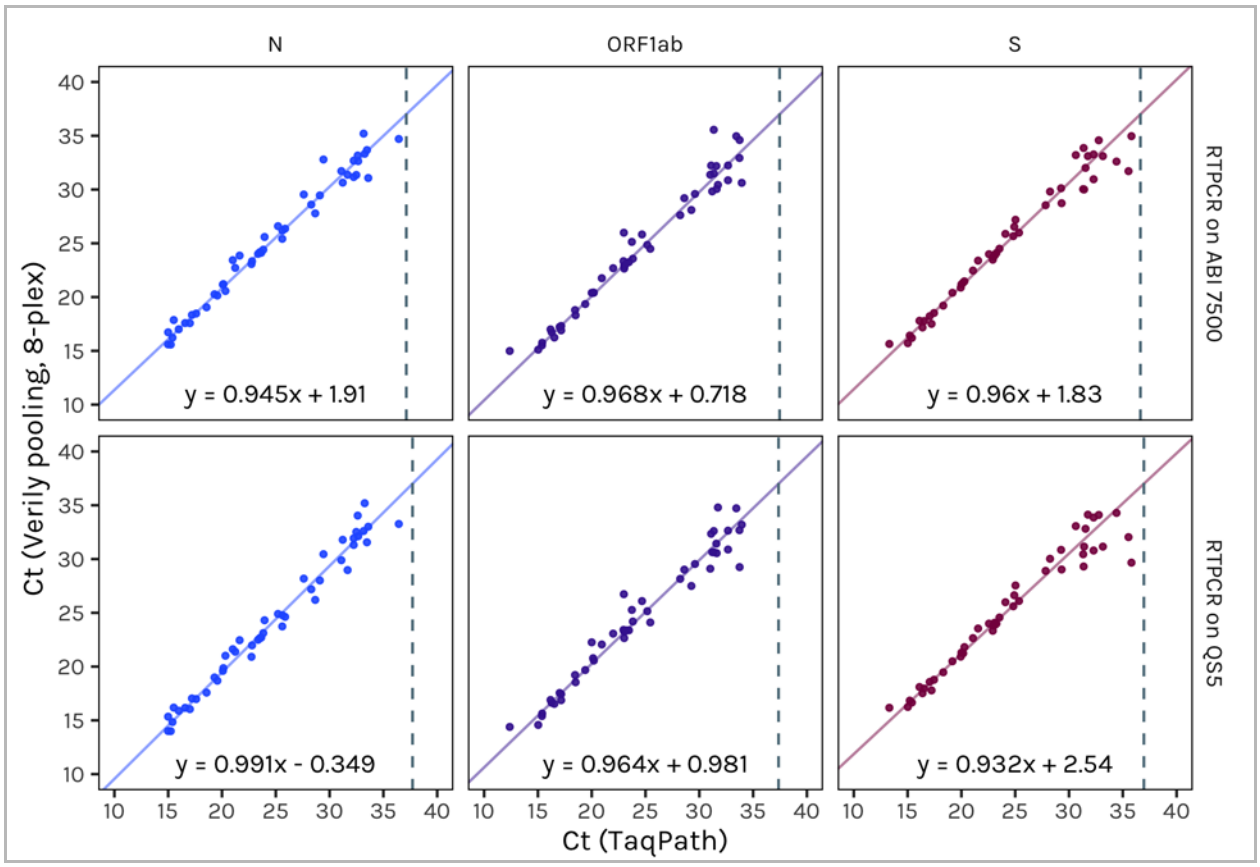

Figure 4. 8-plex pools of one positive nasopharyngeal sample and seven negative nasopharyngeal samples analyzed by the ThermoFisher TaqPath Combo Kit and Verily COVID-19 RT-PCR pooling methods on the 7500 Fast Dx and QuantStudio 5. The diagonal line is the Passing-Bablok regression line, the vertical dashed line shows the equivalent TaqPath Ct when the regression equation (displayed on chart) is solved for a pooled Ct of 37. One sample was called positive by Comparator when tested unpooled, though it had had a Ct > 37 for two genes and should have been called negative. This sample was excluded from the analysis because the comparator assigned a wrong result.

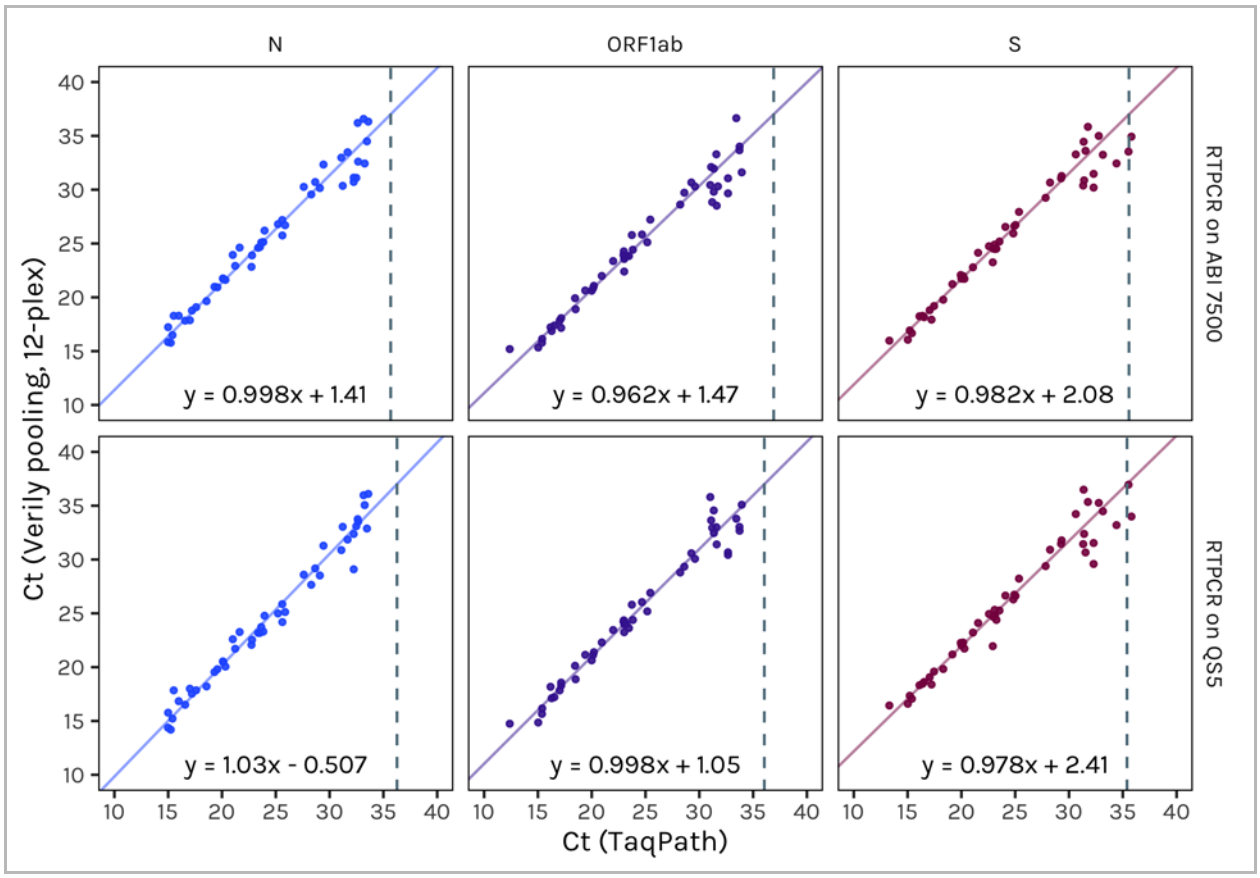

Figure 5. 12-plex pools of one positive nasopharyngeal sample and 11 negative nasopharyngeal samples analyzed by the ThermoFisher TaqPath COVID-19 Combo kit and Verily COVID-19 RT-PCR pooling methods on the 7500 Fast Dx and QuantStudio 5. The diagonal line is the Passing-Bablok regression line, the vertical dashed line shows the equivalent TaqPath Ct when the regression equation (displayed on chart) is solved for a pooled Ct of 37. One sample was called positive by the comparator when tested unpooled, though it had had a Ct > 37 for two genes and was excluded from the analysis because the Comparator assigned a wrong result.

Table 10. Summary of Passing-Bablok regression of Ct values for samples tested with the Verily COVID-19 RT-PCR test pooled workflow and the unpooled ThermoFisher TaqPath COVID-19 Combo kit workflow

Pool Size	Instrument	Gene	Slope (95% CI)	Intercept (95% CI)	Equation	eqn solved for y=37	Ct shift
8-plex	7500	N	0.945 (0.897, 0.979)	1.909 (1.1, 2.971)	y = 0.945x + 1.91	37.13	0.13
		S	0.96 (0.898, 1.012)	1.834 (0.701, 3.13)	y = 0.96x + 1.83	36.64	-0.36
		ORF1ab	0.968 (0.909, 1.027)	0.718 (-0.396, 2.006)	y = 0.968x + 0.718	37.46	0.46
	QS5	N	0.991 (0.927, 1.039)	-0.349 (-1.436, 0.985)	y = 0.991x - 0.349	37.71	0.71
		S	0.932 (0.859, 0.999)	2.542 (1.303, 4.068)	y = 0.932x + 2.54	36.96	-0.04
		ORF1ab	0.964 (0.91, 1.018)	0.981 (-0.085, 2.215)	y = 0.964x + 0.981	37.36	0.36
12-plex	7500	N	0.998 (0.917, 1.065)	1.409 (0.014, 3.171)	y = 0.998x + 1.41	35.68	-1.32
		S	0.982 (0.895, 1.042)	2.079 (0.772, 3.803)	y = 0.982x + 2.08	35.57	-1.43
		ORF1ab	0.962 (0.891, 1.018)	1.474 (0.358, 2.887)	y = 0.962x + 1.47	36.91	-0.09
	QS5	N	1.034 (0.976, 1.096)	-0.507 (-1.928, 0.712)	y = 1.03x - 0.507	36.26	-0.74
		S	0.978 (0.919, 1.038)	2.405 (1.257, 3.522)	y = 0.978x + 2.41	35.39	-1.61
		ORF1ab	0.998 (0.93, 1.05)	1.047 (-0.16, 2.509)	y = 0.998x + 1.05	36.04	-0.96

c. Sample Position Study:

The *Sample Position Study* validates the correct identification of those individual 2D pools that require deconvolution and reflex testing of individual samples in order to identify positive samples. All clinical samples were tested individually for COVID-19 with the ThermoFisher TaqPath COVID-19 Combo Kit (EUA authorized March 13, 2020). Plates were set up by one operator and then transferred to a blinded second operator for testing so that the position of the positive samples on the plate was unknown to the operator. After the extraction, sample pools were created by pooling down a column of a 96 well plate (8-plex) and across a row of a 96 well plate (12-plex). See **Figure 1** for more details of the pooling process. When pooling down a column (8-plex), 50 µL of each sample are combined. When pooling across a row (12-plex) 33 µL of each sample are combined. The deconvolution performance of the Verily COVID-19 RT-PCR Test was evaluated by running four representative plate scenarios consisting of previously tested positive and negative clinical samples; testing was performed on both, the Applied Biosystems 7500 Fast Dx and QuantStudio 5 real-time PCR instruments using the same extracted RNA:

- Two positive samples in two different rows or columns (Plate 1, (**Figure 6**)
  The known positive sample well positions for Plate 1 were H1 and F6.
- Zero positive samples in a plate (Plate 2, **Figure 7**)
- Two positive samples in the same row or column (Plate 3; **Figure 8**)
  The known positive sample well positions for Plate 3 were E1 and E9
- One positive sample in a plate (Plate 4; **Figure 9**)
  The known positive well position for Plate 4 was G8

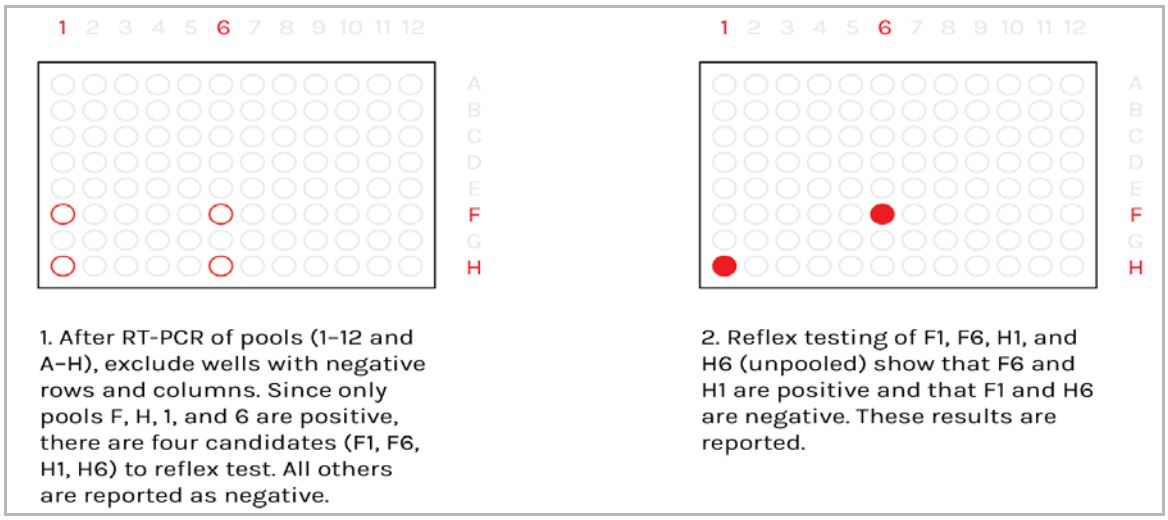

Figure 6. Plate 1 contains two positive samples in two different rows or columns.

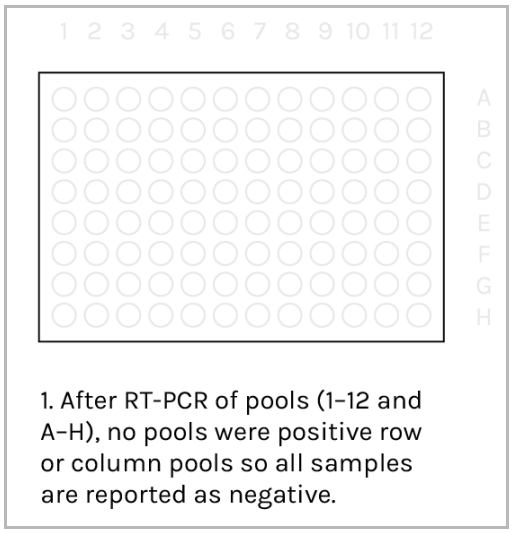

Figure 7. Plate 2 contains zero positive samples in a plate.

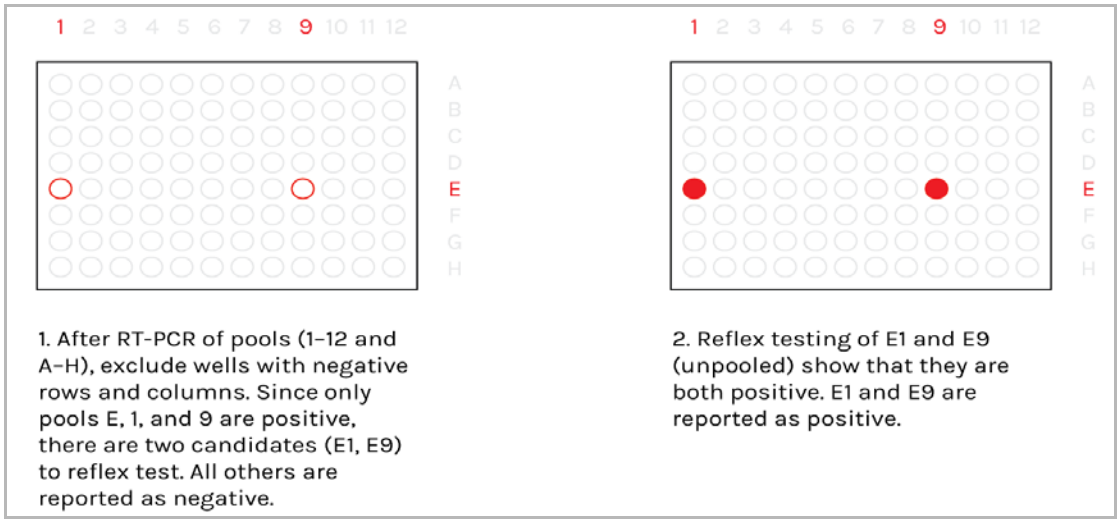

Figure 8. Plate 3 contains two positive samples in the same row.

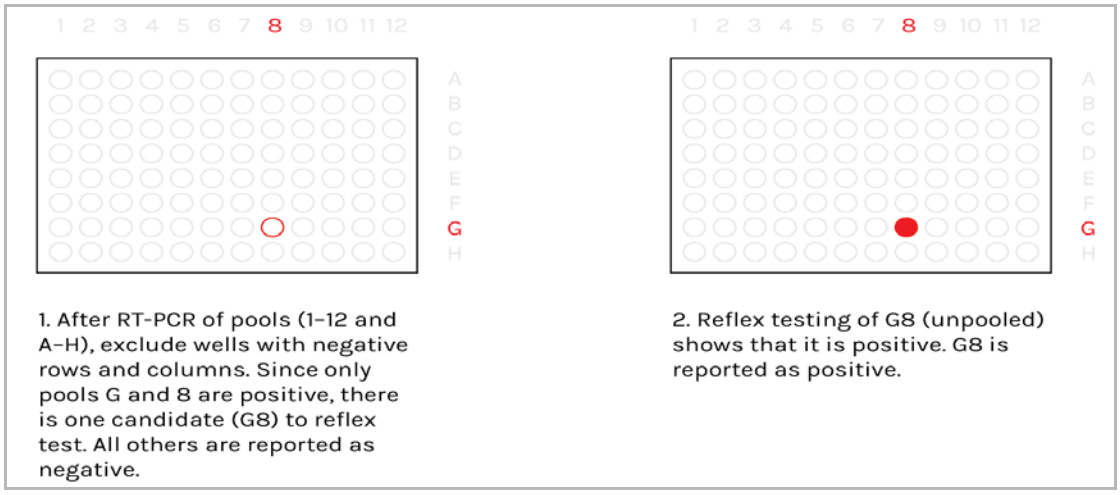

Figure 9. Plate 4 contains one positive sample in a plate.

Results are summarized in **Tables 11 and 12**.

Table 11. Sample Position Study: Sample Detection Pool Summary Results

Plate Number	Pool	7500 Dx Ct				QuantStudio 5 Ct			
		MS2	S gene	N gene	ORF1ab	MS2	S gene	N gene	ORF1ab
Plate 1	F	24.2	24.1	24.1	23.8	24.6	24.2	24.1	23.8
	H	24.2	21.9	22.0	21.8	24.2	22.1	22.0	21.8
	1	23.9	21.3	21.2	21.0	24.2	21.3	21.1	21.0
	6	24.2	23.5	23.5	23.3	24.1	23.5	23.4	23.2
	other pools[2]	24.2	UND[1]	UND[1]	UND[1]	24.4	UND[1]	UND[1]	UND[1]
Plate 2	all pools[2]	24.6	UND[1]	UND[1]	UND[1]	24.7	UND[1]	UND[1]	UND[1]
Plate 3	E	24.8	25.8	25.9	25.7	25.1	25.9	25.8	25.7
	1	24.8	27.4	28.6	27.3	25.1	27.5	28.3	27.3
	9	24.5	25.8	25.6	25.6	24.8	25.8	25.5	25.5
	other pools[2]	24.6	UND[1]	UND[1]	UND[1]	24.7	UND[1]	UND[1]	UND[1]
Plate 4	G	24.5	28.1	28.4	27.9	24.8	28.2	28.3	28.0
	8	24.2	26.5	26.6	25.3	24.5	26.6	26.6	25.4
	other pools[2]	24.4	UND[1]	UND[1]	UND[1]	24.6	UND[1]	UND[1]	UND[1]

[1] UND: Undetermined Ct (Not detectable Ct)
[2] Ct values in this row are means

Table 12. Sample Position Study: Sample Detection Reflex Summary Results

Plate Number	Known Positive Samples	Detected Positive Positions	7500 Dx Ct				QuantStudio 5 Ct			
			MS2	S gene	N gene	ORF1ab	MS2	S gene	N gene	ORF1ab
Plate 1	H1, F6	H1	25.1	13.1	15.0	13.5	25.0	13.7	15.9	15.6
		F6	24.6	14.6	16.3	15.0	24.3	15.4	17.4	17.5
Plate 2	None	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plate 3	E1, E9	E1	24.3	18.2	22.5	19.7	24.3	19.1	23.2	22.4
		E9	23.8	17.2	18.9	17.5	24.0	17.9	19.8	19.7
Plate 4	G8	G8	24.2	19.4	21.5	20.2	24.2	20.2	22.5	22.0

4) Monitoring Plan:

A. Determine if pooling is appropriate
- At positivity rates less than 10%, the matrix pooling workflow employed by the Verily COVID-19 RT-PCR Test improves efficiency relative to the unpooled workflow.
- The historical positivity rate of individual samples P(individual) tested by the Verily lab is <1% (0.29%).

B. During application of pooling strategy
- The two-week moving (rolling) average of the positivity rate of samples through the pooling workflow P(pools) will be monitored.
- If P(pools) is >5% then a study to reassess pooling (Part D) will be performed.
- Every two weeks 20 diluted positive samples at 3x LoD of the TaqPath Combo Test (i.e., 750 copies/mL) will be tested through the pooling workflow (both, 8 plex and 12 plex, randomly tested with Patient samples including deconvolution). Operators will be blinded to the identity of these positive samples. If less than 19 (95%) of the diluted positive samples are detected, then a re-assessment of pooling will occur (Part D).

C. Initial assessment of pooling
- Patient samples will be individually tested until at least 20 positives have been obtained or a total of 2000 patient samples have been tested individually. If after testing 2000 patient samples individually, 20 positives have not been obtained, then the most recent consecutively collected historical positives, identified through individual testing, will be used to supplement positive samples for a total of 20 total positives.
- If the P(individual) is >10% then pooling will be ceased until P(individual) decreases to ≤10%.
- If P(individual) is ≤10% then pooling can commence if the PPA requirements outlined below are achieved.
- The twenty individual samples with positive results, when tested individually, will each be pooled with 11 randomly selected negative samples. The resulting 20 pools, each consisting of 1 positive sample and 11 negative samples will be tested.
- If the PPA is ≥85% between the positive samples when assayed pooled and individually, then pooling will resume.
- If the PPA is <85% between positive samples when assayed pooled and individually, then samples will continue to be tested individually until at least 50 positive samples are obtained.
- After obtaining at least 50 positive samples, when tested individually, each positive sample will be pooled with 11 randomly selected negative samples. The resulting 50 pools, each consisting of 1 positive sample and 11 negative samples will be tested.

- If the PPA is ≥85% (positive samples tested pooled compared to their individual testing results) pooling will commence. If the PPA is <85%, pooling will not commence.

D. Re-assessment of pooling

- Pooling will be reassessed when triggered by Part B and performed as in Part C, except: that patient samples will be individually tested until at least 10 positives have been obtained or a total of 1000 patient samples have been tested individually. If after testing 1000 patient samples individually, 10 positives have not been obtained then the most recent consecutively collected historical positives, identified through individual testing, will be used to supplement positive samples for a total of 10 total positives. If the PPA is <85% (i.e., more than one sample is missed), individual testing will continue until another 10 positive samples are collected. PPA will be calculated for the combined total of 20 samples. If the PPA is <85% (i.e., more than two samples are missed), individual testing will continue until 50 positives are obtained. If after obtaining 50 samples the PPA is <85% pooled testing will be ceased.

B. Verily COVID-19 Nasal Swab Kit for Home Collection

1) LoD confirmation in saline

The limit of detection of the Verily COVID-19 RT-PCR Test was evaluated using a matrix of negative anterior nares swabs collected in 3 mL 0.9% saline, to match the site and transport solution used by this device. The previously established LoD of 60 GCE/mL was confirmed by testing 20 extraction replicates consisting of pooled clinical negative anterior nares swabs collected in 0.9% saline spiked with SARS-CoV-2 viral genomic RNA at 60 GCE/mL. Samples were processed on the ABI 7500. The LoD of the Verily COVID-19 RT-PCR Test (unpooled workflow) was confirmed at 60 GCE/mL with saline matrix (Table 13).

Table 13. Confirmatory LoD in saline collected nasal swab matrix

Replicate	MS2	N Gene	S Gene	ORF1ab	Final Result
Mean	**21.8**	**31.8**	**33.7**	**31.4**	n/a
Positive/Valid	**20/20**	**20/20**	**20/20**	**20/20**	**20/20**
Hitrate	**100%**	**100%**	**100%**	**100%**	**100%**

2) Stability of samples collected with the Verily COVID-19 Nasal Swab Kit

The Verily COVID-19 Nasal Swab Kit uses foam or wrapped polyester nasal swabs transported in 0.9% saline expected to be received back for processing within 48 hours of collection. These claims fall within the stability studies conducted by Quantigen Biosciences, with support from The Gates Foundation and UnitedHealth Group. No additional studies were conducted.

3) Usability Study

A usability study was performed to demonstrate that the Verily COVID-19 Nasal Swab Kit could be used safely and effectively by the intended users, for the intended uses, and in the intended use environments. A total of 35 participants were selected to represent the general adult population, including a mix of ages and education levels. All participants were over age 18.

Exclusion criteria included having prior medical or laboratory training, having prior experience with self-collection, having contact with people with known cases of COVID-19, having COVID-19 symptoms, and being an employee of Verily.

Overall, the results indicated that users could successfully complete safety-critical tasks associated with use of the kit. 35/35 participants successfully completed safety critical tasks associated with collecting a nasal swab. Samples for 35 participants were received in the lab. One sample was found to be low on saline solution (this was determined to have been an error in manufacturing) and another was found to have the wrong date on the label sheet (as a result of a participant error). As a result, 34/35 samples were analyzed in the lab and all 34 were found to have detectable levels of RNAse P which was run in duplicates to determine sufficient material was collected by the participants (See Table 14).

Table 14. RNase P Ct values from samples collected during the usability study

Sample Number	RNase P (reaction 1)	RNase P (reaction 2)	Positive RNase P call
Ct Range	**21.6-32.0***	**21.2-32.4***	**34/34**
Ct Mean	**25.1**	**24.9**	
Ct Median	**25.0**	**24.9**	

* Only one sample of the 34 included samples in the study was detected with an RNase P value of 32 All other values were ≤ 26.9 Ct.

4) Testing of RNase P control for unobserved self-collection

RNase P testing is not part of the Verily COVID-19 RT-PCR test. Therefore, self-collected samples will be individual tested with the Verily COVID-19 RT-PCR test (unpooled workflow) and with a separately run RNase P test until such time, that the post-authorization study described in the Conditions of Authorization is completed and demonstrates that the invalid rate of self-collected specimens due to a negative RNase P result is ≤ 0.1%.

WARNINGS:

- For in vitro diagnostic use.
- Rx only.
- For use under Emergency Use Authorization (EUA).
- Members of the infectious disease laboratory will be trained to perform this assay and competency will be assessed and documented per CAP regulations.
- The Verily COVID -19 Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by Verily Life Sciences, located at 249 E Grand Avenue, South San Francisco, CA 94080;
- The Verily COVID -19 Test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of the Verily COVID -19 Test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Specimens should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious sample.
- Do not use reagents after the expiry date
- Dispose of waste in compliance with local, state, and federal regulations.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

LIMITATIONS:

- The pooling performance of this SARS-CoV-2 assay was clinically validated using nasopharyngeal swab specimens. While nasal, oropharyngeal and mid-turbinate swabs are also considered acceptable specimen types for use with the Verily COVID-19 RT-PCR Test, clinical performance with pools including these specimen types has not been established.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.

- Results from the Verily Pooled COVID -19 Test should be used as an adjunct to clinical observations and other information available to the physician. The result is only for clinical reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.
- Although the detected target sequences of this kit are in conserved regions of the SARS-CoV-2 genome, rare mutations may lead to negative results.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined.