**EMERGENCY USE AUTHORIZATION (EUA)**
**SUMMARY SARS-CoV-2 RT-PCR Assay**

**Stanford Health Care Clinical Virology Laboratory**

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

**(The SARS-CoV-2 RT-PCR assay will be performed at the Stanford Health Care Clinical Virology Laboratory, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a as described in the Laboratory Instructions for Use that was reviewed by the FDA under this EUA.)**

## INTENDED USE

The SARS-CoV-2 assay is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, nasal, and mid-turbinate nasal swabs in Viral Transport Medium and bronchoalveolar lavage fluid from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with nasal swab specimens that are self-collected at home or in a healthcare setting using the Vera COVID-19 Test Unsupervised Collection Kit, from individuals (18 years of age and older) suspected of COVID-19 by their healthcare provider.

Testing is limited to the Stanford Health Care Clinical Virology Laboratory, located at 3375 Hillview Avenue, Palo Alto, CA, 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.

Results are for the detection and 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 SARS-CoV-2 assay is only intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR assays and in

vitro diagnostic procedures. The assay is intended for use under the Food and Drug Administration's Emergency Use Authorization.

## DEVICE DESCRIPTION AND TEST PRINCIPLE

SARS-CoV-2 Assay:

The assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test. The SARS-CoV-2 primer and probe set is designed to detect RNA from the SARS-CoV-2 in respiratory specimens from patients as recommended for testing by public health authority guidelines.

SARS-CoV-2 nucleic acid from patient samples is extracted utilizing either the Qiagen EZ1 XL or QIAsymphony SP/AS extraction platforms and then reverse transcribed to complementary DNA (cDNA). The cDNA is then amplified during the PCR reaction. During amplification, the primers and probe bind to the SARS-CoV-2 target sequences. Subsequent extension of the PCR product hydrolyzes the probe and separates the probe's fluorescent reporter from the quencher molecule. As the PCR product is amplified the fluorescent signal increases and detection is measured by the Rotor-Gene Q real-time PCR thermal cycler.

The reaction mix also contains primers and probe specific to RNase P as an internal control. If negative for SARS-CoV-2 RNA, all clinical samples with successful nucleic acid extraction and the absence of inhibitors should exhibit amplification of the RNase P target.

Self-Collection Kit:

The Vera COVID-19 Test Unsupervised Collection Kit enables the self-collection of an anterior nasal swab sample that is transported in dry conditions in a collection tube to the Stanford Laboratory for processing with the SARS-CoV-2 assay when determined to be appropriate by a healthcare provider.

The Vera COVID-19 Test Unsupervised Collection Kit collects viral RNA from nasal swab specimens. It can also be used for the transportation and short-term room temperature storage of a sample. The Vera COVID-19 Test Unsupervised Collection Kit is a non-invasive alternative for collecting high quality and quantity viral RNA by/from individuals who are suspected of COVID-19 by their healthcare provider.

The Vera COVID-19 Test Unsupervised Collection Kit consists of a sterile packaged spun polyester swab, sterile collection tube, activation card, biohazard bag, instructions for use and a return shipping mailer with a prepaid return label.

The individual using the Vera COVID-19 Test Unsupervised Collection Kit to collect nasal swab specimens begins the initial specimen collection process by activating the collection kit using either the QR code on the activation card or visiting www.myverakit.com/activate and entering a human readable alphanumeric code also on the activation card. After washing and drying their hands, the nasal swab is removed from the wrapper and the soft tip inserted into one nostril until resistance is felt. The swab is

rubbed slowly, in a circular motion, around the inside of the nostril four times. Using the same swab, the same process is repeated in the other nostril.

After the nasal swab specimen is collected, the swab is inserted, tip first, into the collection tube and the cap securely fastened. The tube is placed in the biohazard bag, and the bag is closed with the adhesive seal. The biohazard bag is placed in the prepaid UN3733 return mailer and the mailer sealed closed. Each collection kit is intended to be returned via 48-hour shipping (or same day shipping via a courier for those collections completed on-site) at ambient conditions. Specimens received for testing at the Stanford Laboratory will undergo review and accessioning prior to acceptance for testing with the SARS-CoV-2 assay.

The Vera COVID-19 Test Unsupervised Collection 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. Separately, FedEx reviewed the Vera COVID-19 Test Unsupervised Collection Kit return shipping plans and determined the return shipping met their requirements.

## VERA COVID-19 TEST UNSUPERVISED COLLECTION KIT ORDERING, PROCESSING AND MEDICAL OVERSIGHT

The Vera COVID-19 Test Unsupervised Collection Kit and the Stanford SARS-CoV-2 Assay are only for patients who have been previously qualified by their healthcare provider as needing SARS-CoV-2 testing based on the provider's medical judgement regarding symptoms, exposure, and risk factors. After a healthcare provider qualifies a patient for testing using the self-collection kit, the healthcare provider will submit an order to Stanford following either on-site or at-home unsupervised collection workflows as described below.

### On-Site Unsupervised Collection Kit Workflow

1. At the healthcare provider's discretion, the patient or provider completes, via a Stanford-managed website, the eligibility questionnaire, which adheres to the CDC screening guidelines for COVID-19.
2. A healthcare provider at specific institutions authenticates the questionnaire information and determines patient suitability for the Vera COVID-19 Test Unsupervised Collection Kit.
3. The patient receives and activates their kit online, collecting their own anterior nasal sample following the instructions provided with the kit and returns the completed kit to the on-site collection bin.
4. All samples collected on-site are delivered by courier to the clinical laboratory within 56 hours for processing.
5. Specimens received at the clinical laboratory for testing with the SARS-CoV-2 assay undergo review and accessioning prior to acceptance for testing.

6. Test results are communicated back to the patient and the ordering provider following established healthcare practices. Results are returned electronically or by fax to the ordering provider.
7. If the ordering provider directs Stanford to do so, patients will also receive a notification via email or text message containing a link to a Stanford-managed website with a HIPAA-compliant portal to access their results post-testing.
8. Results are automatically shared with local Department of Public Health registries.

**At-Home Unsupervised Collection Kit Workflow**

1. At the healthcare provider's discretion, the patient completes, via a Stanford-managed website, the eligibility questionnaire which adheres to the CDC screening guidelines for COVID-19.
2. A healthcare provider at specific institutions authenticates the questionnaire information and determines patient suitability for the Vera COVID-19 Test Unsupervised Collection Kit.
3. If the patient is determined to be suitable to receive the unsupervised collection kit, a licensed healthcare provider places the order for the patient via Stanford's online HIPAA-compliant platform or by signed documentation from the ordering provider.
4. The patient will be asked to provide their shipping details through Stanford's online portal.
5. Stanford will ship the unsupervised collection kit to the patient's home via local courier, overnight or 2-day shipping common carrier (FedEx), depending on the patient location.
6. The patient receives and activates their kit online, collecting their own anterior nasal swab sample following the instructions provided with the kit.
7. The patient returns the completed kit to the clinical laboratory same day by local courier or overnight carrier (FedEx using a prepaid shipping envelope). Specimens are sent same day or overnight at ambient conditions and must be sent the same day they are collected.
8. Specimens received at the clinical laboratory for testing with the SARS-CoV-2 assay undergo review and accessioning prior to acceptance for testing.
9. Test results are communicated back to the patient and the ordering provider following established healthcare practices. Results are returned electronically or by fax to the ordering provider.
10. If the ordering provider directs Stanford to do so, patients will also receive a notification via email or text message containing a link to a Stanford-managed website with a HIPAA-compliant portal to access their results post-testing.
11. Results are automatically shared with local Department of Public Health registries.

**INSTRUMENTS USED WITH TEST**

The 2019 novel Coronavirus (SARS-CoV-2) Real-Time, RT-PCR test is to be used with the Qiagen Rotor-Gene Q thermocycler using Rotor-Gene Q Series Software 2.3.1 (Build 49). The following extraction platforms can be used: Qiagen EZ1 XL and QIAsymphony SP/AS.

**REAGENTS AND MATERIALS**

EZ1 Virus Mini Kit v2.0
Qiagen, Catalog # 955134 (48 isolations)
PMM # 92453

Contains:

- Reagent cartridges, Virus Mini v2.0
- Disposable Tip Holders
- Disposable Filter-Tips
- Sample Tubes (2 mL)
- Elution Tubes (1.5 mL)
- Carrier RNA (cRNA)
- AVE Buffer

QIAsymphony DSP Virus/Pathogen Midi Kit (96 extractions)
Qiagen Cat #937055
PMM#186996

Contains:

- Reagent Cartridge X2
- Enzyme rack X2
- Piercing Lid X2
- Buffer AVE (20 mL) X2
- Buffer AVE (2 mL) X2
- Reuse Seal Set X2
- Carrier RNA X2
- Handbook X1

Superscript III One Step RT-PCR (Life Technologies)
Cat. No. 11732-020 Size: 100 reactions
PMM# 207751
Cat. No. 11732-088 Size: 500 reactions
PMM# 207752

Molecular-Grade, Glass-Distilled $H_2O$
Teknova Catalog # W3335
PMM # 178379

Pooled Negative Nasopharyngeal Patient Samples
Prepared in the Virology Laboratory

SARS-CoV-2 E single-stranded DNA (ssDNA)
Prepared in the Virology Laboratory
Synthesized as 4nmol ultramers by Integrated DNA Technologies (IDT)

100X TE (Tris-EDTA) for Primer-Probes
Sigma Catalog # T9285-100 mL

PMM # 190656

## COMPONENTS INCLUDED WITH THE VERA COVID-19 TEST UNSUPERVISED COLLECTION KIT

| Name | Description | Quantity |
|---|---|---|
| Swab | Sterile packaged spun polyester anterior nares | 1 |
| Transport tube | Sterile BD Vacutainer™ no additive (13 x 75 mm; 3 ml or 13 x 100 mm; 6 ml) with dual identifier labelling including barcode | 1 |
| Specimen biohazard bag | UN3373 P650 Rigid Safety Bag (105 x 175 mm) | 1 |
| Return shipping mailer | UN3373 bag (132 x 213 mm) w/FedEx prepaid return label | 1 |
| Compartment bag | Trifold 5-pocket compartment bag (swab, tube, IFU, card, return shipping components) | 1 |
| Kit activation card | Activation card with QR and human readable codes | 1 |
| Instructions for use (IFU) | Instructions for unsupervised self-collection | 1 |

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

SARS-CoV-2 Positive Control:
A positive control is needed to assess the integrity of the PCR run. Synthesized single stranded DNA (ssDNA) of the SARS-CoV-2 E gene is used as positive control material. One positive control is included on each run.

Negative/Extraction Control:
A negative control is needed to monitor for any cross-contamination that occurs during the RT-PCR process. Pooled negative nasopharyngeal samples are used as a negative control. This also serves as an extraction control. One negative control is included on each run.

RNase P in patient samples (Extraction Control)
An internal control is needed to verify that nucleic acid is present in every sample and is used for every sample processed. Detection of human RNase P present in patient samples serves as the internal control.

NTCs (No template controls):
A negative (no template) control is needed to eliminate the possibility of sample contamination on the assay run. DNase and RNase free water is used as the NTC and is included on every run.

## INTERPRETATION OF RESULTS

### *1) SARS-CoV-2 RT-PCR test Controls – Positive, Negative, and Internal:*

Positive control: The positive control must be Detected, showing an exponential growth curve in the SARS-CoV-2 (Green) channel. The CT must be detected within the lot specific ranges.

Negative control: The negative SARS-CoV-2 control must be Not Detected, showing no fluorescent signal above the threshold in the SARS-CoV-2 (Green) channel. The CT value for RNase P (Yellow) channel must be detected within the expected lot specific ranges.

NTC: The No Template Control must be Not Detected, showing no fluorescent signal above the threshold in the SARS-CoV-2 (Green) and RNase P IC (Yellow) channels.

If one or more controls fail, consult with the Section Head, Supervisor or Medical Director. Failure of controls will result in a failed run and the entire run may need to be repeated from extraction as soon as possible. If it can be determined that an error was made in the PCR portion of the run, repeat the run from the eluates.

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

It is necessary to look at the data for a sample's SARS-CoV-2 RNA result as well as its corresponding RNase P Internal control (IC) result to render an interpretation. The presence or absence of a fluorescent growth curve and the CT value to determine the result for each sample should be assessed.

1. Positive Specimens:
   Samples in which the E gene SARS-CoV-2 RNA target is detected within the first 40 cycles of amplification are considered "Detected" (the CT value will be < 40).

   If the specimen is Detected (CT < 40) but the RNase P does not amplify within the expected range, the reaction is acceptable, and the specimen will be reported as SARS-CoV-2 RNA "Detected".

2. Negative Specimens:
   Samples in which there is no value for SARS-CoV-2 (E Gene) are considered Not Detected (the CT value will be blank). In order to accept these results as Not Detected, the RNase P Internal Control (IC) must be detected at a CT ≤ 35 cycles.

3. Indeterminate Results:
   If the E gene channel shows detection between CT 40-45 and the RNAse P is not detected, the PCR run is repeated from extraction. If the repeated testing yields an E gene CT <45, with or without RNase P, the run is reported as detected. If the E gene CT is not detected and RNase P Ct is ≤35, the medical director/designee must be notified.

4. Invalid Results:
   If SARS-CoV-2 RNA is Not Detected and the RNase P does not amplify within the expected range, the sample should be re-extracted.

   Upon re-extraction, if the SARS-CoV-2 RNA is Not Detected, and the RNase P does not amplify within the expected range, the specimen may be inadequate or may have inhibitors.

   Any scenarios not mentioned above or if any questionable curves are observed, must be submitted for immediate review by the Medical Director or Designee.

**Interpretation of Patient Results**

| | **Green Channel CT:** | **Yellow Channel CT:** | |
|---|---|---|---|
| **Patient Sample** | **E Gene** | **RNAse P IC** | **Conclusion** |
| Not Detected | No CT | ≤ 35 | Report as NDET. |
| 1st Invalid | No CT | > 35 or No CT | **Invalid, repeat from extraction.** |
| 2nd Invalid | No CT | > 35 or No CT | **Report as UNABLE.** |
| **Detected** | **<40** | **N/A** | **Report as DTD** |
| Indeterminate | 40-45 | N/A | Repeat from Extraction |
| Any scenarios not mentioned or questionable curve(s). | | | Notify Medical Director/Designee. |
| **After Indeterminate Result is Repeated** | | | |
| **Detected** | <45 | N/A | **Report as DTD** |
| Review | No CT | ≤ 35 | Notify Medical Director/Designee. |

**VERA COVID-19 TEST UNSUPERVISED COLLECTION KIT SAMPLE ACCESSIONING AND CONTROLS**

In order for the clinical laboratory to perform testing, the received samples shall meet the following criteria:

- Sample collection tube must be intact and not visibly damaged
- The tube barcode label must be present and readable by a barcode scanner
- The tube cap must be properly secured onto the tube
- Accession date is within 56 hours of the collection date/time

For dry swab samples sent by courier or overnight carrier, the clinical laboratory's LIMS will check that the sample is approved by a licensed healthcare provider, a consent form is present, and that the collection kit has been activated within the last 48 hours.

Stanford Laboratory's SARS-CoV-2 assay includes an RNase P human sample control to verify that nucleic acid is present in every sample and is used for every sample processed.

Detection of endogenous human RNase P present in patient samples serves as the internal control.

## PERFORMANCE EVALUATION

### 1) ***Analytical Sensitivity:***

*Limit of Detection (LoD):*
One SARS-CoV-2 positive clinical nasopharyngeal swab specimen was diluted in pooled viral transport medium from clinical nasopharyngeal swab specimens negative for SARS-CoV-2. Twenty 400 µL replicates were extracted on the QIAsymphony. 100% (20/20) of replicates were detected at 1000 copies/mL. The positive clinical specimen was quantitated via a standard curve generated using ssDNA obtained from IDT. The ssDNA standard curve was run in triplicate with concentrations ranging from 150 to 150,000,000 copies/mL.

The original clinical nasopharyngeal swab specimen was diluted in viral transport medium from negative pooled clinical NP swab specimens to make a 100,000 copies/mL stock. The dilutions were made according to the tables below and then tested with the SARS-CoV-2 assay:

| Concentration (copies/mL) | Number of Replicates Tested | Number of Replicates Detected | Mean Ct (E target) | Mean Ct (RNase P) |
|---|---|---|---|---|
| 10000 | 5 | 5 | 32.12 | 19.89 |
| 5000 | 5 | 5 | 32.85 | 19.74 |
| 2500 | 5 | 5 | 34.21 | 19.73 |
| 2000 | 20 | 20 | 34.21 | 19.89 |
| 1000 | 20 | 20 | 35.55 | 19.90 |
| 500 | 10 | 10 | 37.19 | 19.86 |

The LoD was confirmed to be 1000 copies/mL based on a positivity rate of ≥95% for 20 replicates.

### 2) ***Analytical Inclusivity:***

In silico evaluation of the SARS-CoV-2 E gene primers and probes were evaluated against all publicly available SARS-CoV-2 (taxid: 2697049) sequences present in GenBank as of November 11$^{th}$, 2020. Resulting primer and probe alignments demonstrated 100% match to all SARS-CoV-2 strains.

### 3) ***Cross-Reactivity:***

In silico evaluation of the SARS-CoV-2 E gene primers and probe was carried out with the following parameters:

- The program used was the BLASTN 2.10.0 with default parameters for short input sequences.
- The database used was the Nucleotide collection (nt) which was queried March 25th, 2020.
- SARS-CoV-2 (taxid:2697049), HCoV-SARS (taxid:694009), and Bat Betacoronavirus SARS related virus (taxid:1508227) sequences were excluded.

The organisms tested are outlined in the table below:

| Other high priority pathogens from the same genetic family | High priority organisms likely in circulating areas |
|---|---|
| **Human coronavirus 229E** | **Adenovirus (e.g. C1 Ad. 71)** |
| **Human coronavirus OC43** | **Human Metapneumovirus (hMPV)** |
| **Human coronavirus HKU1** | **Parainfluenza virus 1-4** |
| **Human coronavirus NL63** | **Influenza A & B** |
| **SARS-coronavirus** | **Enterovirus (e.g. EV68)** |
| **MERS-coronavirus** | **Respiratory syncytial virus** |
| | **Rhinovirus** |
| | ***Chlamydia pneumoniae*** |
| | ***Haemophilus influenzae*** |
| | ***Legionella pneumophila*** |
| | ***Mycobacterium tuberculosis*** |
| | ***Streptococcus pneumoniae*** |
| | ***Streptococcus pyogenes*** |
| | ***Bordetella pertussis*** |
| | ***Mycoplasma pneumoniae*** |
| | ***Pneumocystis jirovecii* (PJP)** |
| | **Pooled human nasal wash – *to represent diverse microbial flora in the human respiratory tract*** |
| | ***Candida albicans*** |
| | ***Pseudomonas aeruginosa*** |
| | ***Staphylococcus epidermis*** |
| | ***Staphylococcus salivarius*** |

The only sequences with substantial similarity (>80% homology) were pangolin and bat betacorona viruses that were not appropriately assigned a taxid. Given that these viruses are not known to circulate in humans, cross-reactivity with these zoonotic sequences are not expected to impact the clinical utility of this assay. Forward and Reverse primers and probe for the SARS-CoV-2 E gene demonstrated no substantial similarities with any of the recommended organisms tested.

Wet testing with clinical specimens was also conducted to assess potential cross-reactivity. No cross-reactivity was observed with NP swab specimens positive for seasonal coronaviruses (n=50) including three mixed infections; influenza A (n=1); rhinovirus/enterovirus (n=2). In addition, no cross-reactivity was observed with NP swab specimens positive for influenza A (no subtype; n=2), influenza A 2009 H1N1 (n=2), influenza B (n=2), respiratory syncytial virus (n=5), human metapneumovirus (n=4), parainfluenza virus 1 (n=2), and parainfluenza virus 4 (n=1), as well as two

mixed infections: respiratory syncytial virus/parainfluenza virus 3/rhinovirus/enterovirus and human metapneumovirus/rhinovirus/enterovirus.

### *4) Clinical Evaluation:*

The clinical evaluation was conducted by testing a total of 60 nasopharyngeal swab specimens in viral transport media (30 reactive and 30 non-reactive). These specimens were collected from individuals under investigation for COVID-19 in Northern California. All 60 specimens were tested with the SARS-CoV-2 E gene assay as well as a validated molecular comparator assay targeting the RNA-polymerase (RdRp) sequence in the *ORF1ab* gene to confirm results. Specimens were extracted using the QIAsymphony and EZ1 XL extraction platforms.

All 30 specimens positive by the comparator assay were also positive by the SARS-CoV-2 assay (100% PPA). All 30 specimens negative by the validated comparator assay were also negative by the SARS-CoV-2 assay (100% NPA). The table below shows the mean CT values for the SARS-CoV-2 E gene assay and the comparator test:

| Test | Number tested | Number positive | Mean Ct |
|---|---|---|---|
| **SARS-COV-2 E gene test** | 30 | 30 | 27.97 |
| **Validated comparator test** | 30 | 30 | 28.4 |

In addition, the first 5 positive and first 5 negative samples by the SARS-CoV-2 test were sent to the Santa Clara Department of Public Health Laboratory for confirmatory testing. All 10 patient specimens yielded concordant results.

### *5) Simulated Sample Stability/Shipping Studies*

**Shipping Stability:**

Shipping stability of dry spun polyester swabs (US Cotton) and foam tipped swabs (Puritan) has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and United Health Group. The Quantigen study demonstrated up to 56-hour stability for dry anterior nasal spun polyester swabs.

Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Stanford Laboratory, pursing an EUA for which a claimed specimen type is dry spun polyester swabs. Therefore, the stability of anterior nasal samples collected using dry spun polyester swabs were not evaluated in a separate sample stability study.

**Dry Swab Resuspension:**

The Vera COVID-19 Test Unsupervised Collection Kit leverages dry transport of the nasal swab specimen, as validated by Quantigen. Therefore, the swab must be rehydrated in advance of performing SARs-CoV-2 and RNase P testing using the following swab rehydration process:

1. Add 2 mL of PBS into the BD vacutainer tube containing the dry swab
2. Incubate the dry swab in PBS for at least 15 mins
3. Vortex for about 3-5 secs

To demonstrate that dry spun polyester swabs were an acceptable specimen type for testing with the SARS-CoV-2 assay, performance of the assay was evaluated using dry swabs resuspended using the process described above.

Contrived positive specimens at 2X, 5X and 10X LoD were prepared by spiking a SARS-CoV-2 clinical specimen into PBS followed by spiking the solution directly onto the spun polyester swabs. The swab solution was dried in a hood for approximately 30 minutes and then rehydrated following the swab rehydration process described above. Five technical replicates at 2X, 5X and 10X LoD concentrations were tested. In addition, results from 43 samples collected with nasopharyngeal swabs in viral transport media were compared to rehydrated spun polyester swabs. The 43 swabs tested were negative for SARS-CoV-2 in both swab types. Results are summarized in the table below. There was 100% agreement with expected results for positive contrived samples and all negative samples tested were non-reactive.

**Dry Swab Resuspension Study Results Stratified by Assay Target**

| Concentration | Swab Type | Replicates Tested (n) | (Green Channel) E-gene Detected | (Yellow Channel) RNase P Detected |
|---|---|---|---|---|
| 2X LoD (2.0 copies/µL) | Spun Polyester | 5 | 5/5 | 5/5 |
| 5X LoD (5.0 copies/µL) | Spun Polyester | 5 | 5/5 | 5/5 |
| 10X LoD (10.0 copies/µL) | Spun Polyester | 5 | 4/4* | 4/4* |
| Negative | Spun Polyester | 43 | 0/43 | 43/43 |

* IC failure for one sample

*6)* ***Human Usability Study***

A usability study was conducted to assess user comprehension of the Vera COVID-19 Test Unsupervised Collection Kit for both collection and packaging of the dry nasal swab for shipment.

A total of 43 adults between the ages of 24 and 75 years of age followed the Instructions for Use and completed the study, of which 14.0% were ≥51 years old, 14.0% were between 41 - 50 years, and 46.5% were between 31 - 40 years old, 23.3% were between 18-30; 62.8% of participants were female and 37.2% were male. Age was not available for one participant. Participants included individuals of both Hispanic (14.0%) and non-Hispanic (74.4%) ethnicity (11.6% declined to state). Racial composition of participants was diverse, including white (69.8%), Asian (14.0%), and African American (2.3%) participants (14.0% declined to state). Educational attainment levels were similarly varied, with middle school (2.3%), high school (16.3%), college (46.5%) and advanced degree (34.9%) graduates all represented.

Study participants were observed using the collection kit following the Instructions for Use in an open-air tent run by Stanford Health Care, under pre-existing general IRB protocols for laboratory methods. The participants were observed for technique, but were provided no input, as they self-collected a sample and prepared the Vera COVID-19 Test Unsupervised Collection Kit for shipment. After completing all instructions, participants were then asked to complete a post-kit survey on kit usability using a provided iPad, and the completed samples were inspected and sent for laboratory analysis. The primary endpoint for the study was successful collection of human material as confirmed by laboratory methods (human RNAse P detected using the control of the Stanford Lab SARS-CoV-2 Assay).

Of the samples processed by the Stanford Lab, human RNase P was detected in 100% of samples, indicating successful collection of human biological material that was extracted and amplified.

The kit Instructions for Use received a median rating of 4 out of a possible 5 with 5 being easy to follow. Based on physical inspections, 43/43 (100%) of participants correctly packaged their specimen for shipment, producing a correctly assembled return package of swab sample, dry tube, biohazard bag and shipping envelope. Participants were very satisfied with the overall self-collection experience (median rating of 5 out of a possible 5) with 36/39 (92%) of participants rating the experience as a 4 or a 5. No participants rated the Instructions for Use or overall self-collection experience as lower than a 3 rating.

Based on the usability study data and participant feedback, the Vera collection kit Instructions for Use were understandable, the kit was easy to use, and samples were successfully self-collected.

**Warnings:**

- This product has not been FDA cleared or approved;
- This product has been authorized by FDA under an EUA for use by the authorized laboratory: Stanford Health Care Clinical Virology Laboratory located at 3375 Hillview Avenue, Palo Alto, CA, that 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;

- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.