EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
The Nano Test for COVID-19
(Nanobiosym Precision Testing Services)

For *In Vitro* Diagnostic Use
For prescription use only
For Use Under Emergency Use Authorization (EUA) Only
For use by individuals age 18 years or older

The Nano Test for COVID-19 will be performed at Nanobiosym Precision Testing Services, located at 245 First Street, Suite 175, Cambridge, MA 02142, 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, as described in the Laboratory Standard Operating Procedures that were reviewed by the FDA under this EUA.

INTENDED USE

The Nano Test for COVID-19 is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected at home by individuals age 18 years or older (self-collected) using The Nano-Saliva Collection Kit, when suspected of COVID-19 by their healthcare provider. Saliva specimens collected using The Nano-Saliva Collection Kit can be transported at ambient temperature for testing.

Testing is limited to Nanobiosym Precision Testing Services, located at 245 First Street, Suite 175, Cambridge, MA, 02142, 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva 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 test 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.

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

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Nano Test for COVID-19 uses an unmodified EUA authorized molecular test, New Coronavirus Nucleic Acid Detection Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens self-collected at home using The Nano-Saliva Collection Kit, for single sample testing without pooling. The SARS-CoV-2 primers are designed to detect RNA from SARS-CoV-2 in saliva specimens from individuals 18 years old or older as recommended for testing by a healthcare provider.

Saliva specimens must be self-collected using The Nano-Saliva Collection Kit which contains the Spectrum Solutions, LLC SDNA-1000 Saliva Collection Device.

Specimens received at the clinical laboratory for testing will undergo review and accessioning prior to acceptance for testing.

1) The New Coronavirus Nucleic Acid Detection Kit

The New Coronavirus Nucleic Acid Detection Kit is a real-time RT-PCR *in vitro* diagnostic test intended for the qualitative detection of nucleic acid from SARS-CoV-2 including in saliva samples collected using the SalivaSecure Saliva Collection Kit either by a healthcare provider (HCP) or self-collected under the supervision of an HCP in a healthcare setting from individuals suspected of COVID-19.

The New Coronavirus Nucleic Acid Detection kit uses TaqMan based real-time PCR technique to conduct *in vitro* reverse transcription of SARS-CoV-2 RNA, DNA amplification and fluorescence detection. The assay targets specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene and Open Reading Frame 1ab (ORF1ab) gene. The TaqMan probes for the two amplicons are labeled with FAM and ROX fluorescent dyes respectively to generate target-specific signal. The assay includes an RNA internal control (IC, bacteriophage MS2) to monitor the processes from nucleic acid extraction to fluorescence detection. The IC probe is labeled with VIC fluorescent dye to differentiate its fluorescent signal from SARS-CoV-2 targets. The assay also uses a dUTP/UNG carryover prevention system to avoid contamination of PCR products and subsequent false positive results.

Components of the New Coronavirus Nucleic Acid Detection Kit

- Kit, Cat # 2019-nCoV-PCR-AUS, 48 tests/kit

Component Name	Storage Conditions
nCoV Reagent A	-25 to -15°C
nCoV Reagent B	-25 to -15°C
nCoV Enzyme Mix	-25 to -15°C
nCoV Internal Control	-25 to -15°C
nCoV Positive Control	-25 to -15°C
nCoV Negative Control	-25 to -15°C

- chemagic Viral DNA/RNA 300 Kit special H96 and chemagic 360 with chemagic Rod Head Set 96 (software version 6.3.0.3)
- Applied Biosystem QuantStudio 5 Real-Time PCR System: 384-well block, Design and Analysis Software v1.5.1

2) The Nano-Saliva Collection Kit

The Nano-Saliva Collection Kit is a prescription use only product for individuals aged 18 years or older suspected of COVID-19 by their healthcare provider. The Nano-Saliva Collection Kit includes the Spectrum Solutions, LLC SDNA-1000 Saliva Collection Device, The Nano-Saliva Collection Kit IFU, Shipping Instructions, and a Welcome Card with a link to a secure (HIPAA compliant) online portal where each user can register their kit.

Table 1. The Nano-Saliva Collection Kit Components

Name	Description	Quantity	Material Supplier
SDNA-1000 Full blister pack (unopened)	Saliva collection device with instructions for saliva collection from Spectrum	1	Spectrum Solutions, LLC
Outbound box	7 ½" x 5 ¾" x 1 ½" white	1	Stephen Gould Corporation
The Nano-Saliva Collection Kit Welcome Card	Card containing QR Code for Kit Registration	1	Nanobiosym
The Nano-Saliva Collection Kit IFU	Nanobiosym step-by-step instructions for proper collection and packaging of sample	1	Nanobiosym

Shipping Instructions	Nanobiosym step-by-step instructions for return shipping to Nanobiosym Precision Testing Services, LLC	1	Nanobiosym
Biohazard Bag (i.e., "Bio-bag")	Biohazard bag (95kPa Specimen transport bag) containing absorbent material	1	Vonco Corporation
Return Shipping bag	Opaque bag for return shipment of sample, including return address label	1	UPS or FedEx

Table 2. Components of the Spectrum SDNA-1000 Blister Pack

Name	Description	Quantity	Material Supplier
2019163	SDNA Fill Cap Assembly 1.5ml	1	Spectrum Solutions
201593	SDNA Blank Thermo Form Tray	1	Premier Plastics
2019077	IFU Insert – SDNA-1000	1	CCL
201570	Tyvek – SDNA-1000	1	Oliver Healthcare
2019094	SDNA Tube 6ml	1	Spectrum Solutions
2019076	Barcode Label SDNA-1000	1	Kala
2017115	DNA Funnel – CD	1	Spectrum Solutions

Sample collection and transport

When the patient is ready to collect their saliva specimen, they register their kit using the secure online portal link provided on the Welcome Card. In this secure online (HIPAA compliant) portal, the individual will be asked to answer additional health related questions. Individuals who qualify for testing are allowed to complete registration of their collection kit and begin the (unsupervised) saliva collection process. In addition to the IFU for sample collection and shipping provided in The Nano-Saliva Collection Kit, patients will also have access to an instructional video on the Nanobiosym Precision Testing Services website. The instructional video demonstrates how to fill the sample tube, seal the tube, label the sample, and package the sample for return shipping.

The individual using The Nano-Saliva Collection Kit to collect a saliva sample performs the following steps:

1. Fill the tube with saliva to the level of the wavy black line. Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. Do not overfill.

2. Replace the funnel with the fluid cap. Remove the funnel from the tube. Screw on the enclosed cap TIGHTLY to release the solution that will stabilize the DNA/RNA in your saliva.
3. Firmly screw cap down to release solution and seal tube. You will know it works when the blue solution from the cap is released into the tube. Firmly tighten cap to assure the cap and tube is completely sealed.
4. Shake the tube gently for at least five seconds. This will ensure your sample mixes thoroughly with the stabilizing solution.
5. Write your initials and date of birth (mm/dd/yy) with a black marker on the white space on the tube.
6. Place the saliva tube inside bio-bag and seal bag closed. Do not remove absorbent pad from the bag.
7. Place sealed bio-bag into shipping bag and seal closed. Please follow the steps below to return the sample to us.

Return via UPS Next Day Air or FedEx Priority Overnight: *Either* a FedEx pre-paid return shipping label *or* a UPS pre-paid return shipping label and corresponding shipping instructions will be provided in each kit. Note the sample must be shipped (on the same day it was collected) to arrive to the Nanobiosym Precision Testing Services Lab before 10:30 am EST.

Nanobiosym Precision Testing Services,
245 First St., Suite 175, Cambridge, MA, 02142

Medical Oversight and Process

A. Group Orders

Nanobiosym Precision Testing Services will supply The Nano-Saliva Collection Kit to entities who participate in our testing program. Such entities include businesses, government agencies, colleges, companies, doctor's offices, retail pharmacies, and other institutions for distribution to individuals (18 years of age or greater) as ordered under prescription by a physician or other qualified healthcare provider. Group orders may be initiated through the Nanobiosym-testing.com website or by contract with Nanobiosym Precision Testing Services. Nanobiosym Precision Testing Services will ship group orders to the ordering entity for distribution to individuals 18 years of age or greater under prescription or, if requested on the order of a physician, will send kits to individuals (who are 18 years of age or greater) directly. **Under no circumstance will a collection kit be provided to an individual without a prescription**.

B. Individual Online Orders

To place an order an individual must verify that he/she is 18 years or older for self-use and complete an online COVID-19 questionnaire provided by an authorized provider (either in person or via telemedicine). The healthcare provider will authorize the test order only after the patient is determined to be eligible for the at-home self-collection with The Nano-Saliva Collection Kit and

downstream testing with The Nano Test for COVID-19 based on the online questionnaire that aligns with current CDC guidelines.

Individuals may also request The Nano-Saliva Collection Kit by either speaking with a healthcare provider or requesting a test through an online questionnaire on the Nanobiosym-testing.com website. The questionnaire is reviewed by a physician to ascertain patient symptoms or reasons for testing. This prescription from a healthcare provider enables an individual to receive The Nano-Saliva Collection Kit. Our network of authorized providers determine test eligibility based on online questionnaire responses. A qualified healthcare provider will provide a prescription for qualifying individuals. **Test collection kits will not be sent to patients without a prescription.**

Using the prescription from an authorized provider, individuals will be able to receive the collection kit(s) by mail or pick them up at certain designated locations including certain participating doctor's offices, pharmacies, and other select designated and participating retail locations. **These home collection kits will not be dispensed to the patient before the prescription for the test is written.**

Accessioning of Saliva Samples at Nanobiosym Precision Testing Services

Saliva specimens collected using The Nano-Saliva Collection Kit must be checked for the following criteria upon receipt at Nanobiosym Precision Testing Services (NBS-PTS) prior to processing.

A. Acceptance criteria:

- Containers and tubes are not compromised or broken.
- Saliva sample is not very viscous and does not have a lot of particulate matter.
- Saliva sample is present at the fill line indicated on the saliva collection device.
- Saliva samples collected in The Nano-Saliva Collection Kit is usually blue (sometimes green) in color.
- Saliva samples collected in The Nano-Saliva Collection Kit reach NBS-PTS within 48 hours of being shipped and 56 hours from being collected.
- The patient IDs on the specimen and the requisition form matches.
- The proper specimen containers or tubes were used in collection for the tests ordered as per the in-house or reference laboratory test procedure.
- There are no missing specimens or missing orders.
- There is no missing information on the order.

B. Rejection criteria:

- If the patient information on the Test Requisition Form and the specimen tube do not match, are missing or incorrect, the specimen has to be quarantined and a supervisor decides whether to reject or accept the specimen for testing.
- At least 2 forms of the following types of identification must be included on each specimen tube in order for the sample to be processed:
  - Barcode
  - Patient's name
  - Patient's initial
  - Patient's date of birth
- If the specimen container or tube is broken or leaking,
- If the specimen volume is below the fill line.
- If the specimen was not shipped at ambient room temperature.
- If the specimen was in transit for >48 hours or >56 hours from sample collection.
- If patient is less than 18 years of age.
- If the sample is not blue or green.

All patients will receive notice of test result availability by text message or email. Patients will be able to access results online using a mobile and web-based application. The healthcare provider will have electronic access to test results and will contact patients as appropriate. Individuals with positive and/or invalid results will be contacted via phone by a healthcare provider (HCP). The HCP will inform individuals of their results, provide education, and a recommended course of care or appropriate follow-up action.

Note patients who receive negative results will be reported as "SARS-CoV-2 Not Detected (Neither of the SARS-CoV-2 targets were detected in the specimen.)" and are encouraged to follow CDC guidelines for COVID-19 prevention actions. The lab report will include a footnote that states "Negative results do not preclude infection with SARS-CoV-2 and should not be used as the sole basis for patient management. False negative results may result from improperly collected specimens, target levels in the specimen below the lower limit of detection of the assay, presence of inhibiting substances, or mutational changes in the genomic target(s). Interpretation of negative results requires correlation with subject clinical and exposure history, possibly including additional laboratory findings and other epidemiological considerations."

Results are reported by Nanobiosym Precision Testing Services to public health agencies as required.

INSTRUMENTS USED WITH THE TEST

The Nano Test for COVID-19 is the unmodified New Coronavirus Nucleic Acid Detection Kit and uses the Revvity Chemagic 360 automated nucleic acid extraction instrument (v6.1.0.5) and the Applied Biosystems QuantStudio 5 Real-Time PCR instrument equipped with Design & Analysis Software (v1.5.1) for data analysis as authorized.

CONTROLS TO BE USED WITH THE TEST

The test control materials are provided with the New Coronavirus Nucleic Acid Detection Kit are described in the Table below.

Table 3. Controls supplied with the New Coronavirus Nucleic Acid Detection Kit

Control Type	Composition	Purpose	Frequency of Use
Negative	TE Buffer	To monitor cross-contamination during RNA extraction and RT-PCR	Once per each batch of specimen,
Positive	SARS-CoV-2 RNA fragments capsulated in MS2 bacteriophage	To monitor the integrity of RNA extraction process and RT-PCR reagents	Once per each batch of specimen
Internal	MS2 bacteriophage	To monitor the integrity of RNA extraction process and RT-PCR reaction for each specimen	Added to each specimen and to the positive and negative controls prior to RNA extraction

INTERPRETATION OF RESULTS

1) Examination and Interpretation of Controls:

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

If the results obtained with the Positive, Negative and Internal Controls do not meet the criteria shown in the Table below, the results from the entire batch of samples are considered invalid and the testing must be repeated by extracting the RNA from the residual sample.

Table 4. Expected Ct Values for the Test Controls to obtain the Valid Results

Control	N-gene (FAM) Ct Value	ORF1ab (ROX) Ct Value	Internal Control (VIC) Ct Value
Negative	No Ct or Ct > 42	No Ct or Ct > 42	Ct ≤ 40
Positive	Ct ≤ 37	Ct ≤ 37	No Requirement

1) Negative Control: both ORF1ab and N of SARS-CoV-2 must be not detected, and the Ct value of internal control should be ≤ 40.
2) Positive Control: both ORF1ab and N of SARS-CoV-2 must be detected, and their Ct values should fall within the ranges described in the above tables, the Ct value of internal control does not have to be ≤40 for positive control.

2) Examination and Interpretation of Patient Sample Results:

Assessment of The Nano Test for COVID-19 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 from testing of patient samples must be interpreted according to the criteria described in **Table 5**.

Table 5. Results Interpretation for Patient Samples

N-gene (FAM) Ct Value	ORF1ab (ROX) Ct Value	Internal Control (VIC) Ct Value	Result Interpretation
No Ct or Ct > 42	No Ct or Ct > 42	Ct ≤ 40	SARS-CoV-2 not detected
Ct ≤ 42	Ct ≤ 42	N/A	SARS-CoV-2 detected
No Ct or Ct > 42	Ct ≤ 42	N/A	SARS-CoV-2 detected
Ct ≤ 42	No Ct or Ct > 42	N/A	SARS-CoV-2 detected
No Ct or Ct > 42	No Ct or Ct > 42	No Ct or Ct > 40	Invalid; Re-test*

N/A = Not Applicable or No requirements on the Ct values.
*Re-testing is 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 same as the original, then report result as "inconclusive".

PERFORMANCE EVALUATION

The analytical and clinical performance of the New Coronavirus Nucleic Acid Detection Kit with saliva specimens has been demonstrated by Revvity, Inc. in an Emergency Use Authorization. The Nano Test for COVID-19 runs the New Coronavirus Nucleic Acid Detection Kit on the Applied Biosystem QuantStudio 5 Real-Time PCR System per Revvity's Instructions for Use (IFU) without modifications for single sample testing without pooling. Revvity has granted Nanobiosym's The Nano Test for COVID-19 right of reference to data in support of using New Coronavirus Nucleic Acid Detection Kit in The Nano Test for COVID-19. The details of the

performance of the New Coronavirus Nucleic Acid Detection Kit can be found here: In Vitro Diagnostics EUAs.

1) Limit of Detection (Analytical Sensitivity):

The Nano Test for COVID-19 was further validated by a side-by-side Limit of Detection (LoD) study with The Nano-Saliva Collection Kit and the SalivaSecure collection kit (SDX-56338) authorized for use with the New Coronavirus Nucleic Acid Detection Kit.

The preliminary LoD of each saliva collection kit was evaluated using heat-inactivated SARS-CoV-2 (BEI NR-52286, Isolate USA-WA1/2020, Heat Inactivated; stock titer $7.9x10^5$ $TCID_{50}$/mL). A preliminary LoD was established by testing 3 replicates of 10-fold dilutions of BEI NR-52286 spiked into pooled saliva (collected from individuals that were tested to be negative for SARS-CoV-2) collected in The Nano-Saliva Collection Kit and the SalivaSecure collection kit, starting at 5000 copies/mL. The preliminary LoD was estimated to be 50 copies/mL (Tables 6 and 7 for each collection kit).

Table 6. Estimation of LoD Using The Nano-Saliva Collection Kit

Copies/Reaction	Copies/mL	Internal Control (VIC) Average Ct Value	N-gene (FAM) Average Ct Value	ORF1ab (ROX) Average Ct Value	Call Rate
250	5000	31.23	31.07	32.17	3/3
25	500	31.30	34.50	36.20	3/3
2.5	50	31.43	37.37	39.50	3/3
0.25	5	31.70	36.80	Undetermined	1/3
0.025	0.5	31.93	38.00	Undetermined	1/3
0.0025	0.05	31.77	Undetermined	Undetermined	0/3

Table 7. Estimation of LOD Using SalivaSecure SDX-56338 Saliva Collection Kit

Copies/Reaction	Copies/mL	Internal Control (VIC) Average Ct Value	N-gene (FAM) Average Ct Value	ORF1ab (ROX) Average Ct Value	Call Rate
250	5000	29.60	32.40	32.97	3/3
25	500	29.57	35.87	35.97	3/3
2.5	50	29.77	37.83	39.25	3/3
0.25	5	30.13	Undetermined	Undetermined	0/3

0.025	0.5	30.90	Undetermined	40.40	1/3
0.0025	0.05	31.00	Undetermined	Undetermined	0/3

Confirmation of the LoD:

The preliminary LoD was confirmed by testing an additional 20 independent replicates at three target levels around the estimated LoD as shown in Table 8. The confirmed LoD, defined as the lowest level at which ≥ 95% of replicates were reported positive, was 150 copies/mL or 7.5 copies/reaction for both The Nano-Saliva Collection Kit and the PerkinElmer, SalivaSecure SDX-56338 Saliva Collection Kit.

Table 8. Confirmation of LoD for The Nano-Saliva Collection Kit (A) and SalivaSecure SDX-56338 Saliva Collection Kit (B)

Collection Device	Copies/Reaction	Copies/mL	Internal Control (VIC) Average Ct Value	N-gene (FAM) Average Ct Value	ORF1ab (ROX) Average Ct Value	Call Rate
A	7.5	150	31.15	35.15	37.20	20/20
B	7.5	150	29.00	35.42	37.23	20/20
A	2.5	50	30.57	37.65	38.19	18/20
B	2.5	50	28.52	37.36	38.31	18/20
A	0.83	16.67	30.96	38.59	38.00	11/20
B	0.83	16.67	29.73	34.02	33.40	9/20

2) Sample Stability:

The shipping stability of saliva collected from Spectrum SDNA-1000 collection kit has been demonstrated by Infinity BiologiX LLC (IBX). IBX has granted a right of reference to Nanobiosym's The Nano Test for COVID-19 to leverage performance data from shipping stability studies. IBX performed the winter and summer simulated shipping studies that support a 48-hour shipping stability (56 hours from sample collection) for saliva samples collected in the SDNA-1000 saliva collection device. Therefore, the stability of saliva collected using The Nano-Saliva Collection Kit were not evaluated in a separate sample stability study.

3) Human Usability Study:

To support specimen home collection with The Nano-Saliva Collection Kit, a Human Usability Study was conducted to evaluate the entire workflow including online registration, sample collection, labeling the sample, packaging of the sample, and mailing to the laboratory with a pre-prepared address label.

Testing included 30 adult participants (18 years of age or older) representing varying education levels ranging from high school education to doctorate level degrees and took place in a simulated home environment. The participant's race, age, and gender distribution are described below:

Table 9A. Age Group Distribution

Age	Count
18-35	7
35-50	9
Over 50	14

Table 9B. Gender Distribution

Gender	Count
Male	18
Female	11
Prefer not to Disclose	1

Table 9C. Race Distribution

Race	Count
Black	1
White	23
Hispanic/Other/Prefer Not to Disclose	6

Each participant collected the saliva sample while under observation by a Nanobiosym staff member, who recorded any difficulties the participant experienced with the sample collection process. The participants were provided the 1) Welcome Flash Card and 2) Instructions for Use (IFU) from Nanobiosym and the 3) IFU from Spectrum in the unopened Spectrum Blister pack. Participants also had access to an instructional video which demonstrates sample collection workflow. None of the participants in the usability study elected to watch the instructional video but used only the written instructions provided. After the entire process was completed, the user was given a questionnaire to indicate the ease of use of the kit and sample collection. The parameters evaluated in The Nano-Saliva Collection Kit usability study are listed in the table below along with the percentage of participants who performed each step correctly and without difficulty.

Table 10. Parameters Evaluated and Performed Correctly

Parameters Evaluated	**Percent Performed Correctly (# of correctly completed tasks/total # of participants)**
Online Registration of date and time of collection	100% 30/30
Open sealed saliva collection kit	100% 30/30
Label tube with and align with existing barcode	93% 28/30
Fill the tube with saliva	100% 30/30
Remove funnel	100% 30/30
Firmly screw cap to release blue liquid	100% 30/30
Shake for 5 seconds	97% 29/30
Place sample collection tube in biohazard bag	100% 30/30
Place biohazard bag in shipping bag	100% 30/30
Label and prepare for shipping	100% 30/30

Thirty out of the 30 samples were received at Nanobiosym Precision Testing Services within 48 hours of saliva collection. All samples received by the laboratory met acceptance criteria and were tested. Twenty-nine out of 30 samples yielded valid test results. One sample out of 30 gave an invalid result due to the viscosity of the sample. The laboratory staff also noticed that some of the caps on the tubes were extremely tight, which led to difficulties in opening them to process.

Upon review of the study results, The Nano-Saliva Collection Kit IFU was updated to address identified difficulties for the user:

- Components of The Nano-Saliva Collection Kit were added.
- Graphics were revised for clarity and accuracy.
- The text size was increased.
- Language was added to discard Spectrum SNDA-1000 IFU prior to saliva collection.

In summary, results from the Usability study support that The Nano-Saliva Collection Kit can appropriately be used for collection of saliva specimens from individuals aged 18 years and older (self-collected).

4) Post Authorization 30 Day Report

Upon authorization, within 30 days of the receipt of the first home collected sample, Nanobiosym will submit to the FDA a summary of any testing, performed with The Nano-Saliva Collection Kit including how many kits were prescribed and distributed for unsupervised collection, how many kits were returned, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the collection device.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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 SARS-CoV-2 and their prevalence, which change over time.
- Laboratories are required to report all negative and positive results to the appropriate public health authorities.
- Primers and probes for The Nano Test for COVID-19 target highly conserved regions within the genome of SARS-CoV-2. Mutations rarely occur in these highly conserved regions, but if a mutation did occur in these regions, SARS-CoV-2 RNA could become undetectable.
- Reliable results depend on proper sample collection, storage, and handling procedures.
- 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.
- Performance with specimens collected from individuals 18 years and older by an adult in the home has not been evaluated.

WARNINGS

- For use under Emergency Use Authorization (EUA) only.
- For *in vitro* diagnostic use.
- For prescription use only.
- For use by individuals age 18 years or older.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory.
- 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.