EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
Genetrack SARS-CoV-2 Molecular Assay
(Genetrack Biolabs, Inc.)

For in vitro diagnostic use
Rx only
For use under Emergency Use Authorization (EUA) Only

(The Genetrack SARS-CoV-2 Molecular Assay will be performed at Genetrack Biolabs Inc., located at 100 - 2806 Kingsway Vancouver BC V5R 5T5 Canada, 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 procedures that were reviewed by the FDA under this EUA).

INTENDED USE

The Genetrack SARS-CoV-2 Molecular Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of SARS-CoV-2 RNA in anterior nasal swab specimens self-collected at home using the Vo' COVID-19 Test Home Collection Kit by individuals suspected of COVID-19 when home collection is determined to be appropriate by their healthcare provider. Specimens collected using the Vo' COVID-19 Test Home Collection Kit are transported at ambient temperature for testing at Genetrack Biolabs, Inc.

Testing is limited to Genetrack Biolabs Inc., located at 100 - 2806 Kingsway Vancouver BC V5R 5T5 Canada which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

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

Testing with the Genetrack SARS-CoV-2 Molecular Assay 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 Vo' COVID-19 Test Home Collection Kit and the Genetrack SARS-CoV-2 Molecular Assay are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) Device Description

The Vo' COVID-19 Test Home Collection Kit is composed of sample collection and shipping instructions, a nasal swab, molecular transport buffer in a collection tube, specimen biohazard bag, adsorbent sheet, a shipping container, and pre-filled courier waybill. Instructions are included in the kit to direct the home users on how to appropriately collect the nasal swab specimen and place it in the transport tube, how to properly package the specimen, and how to mail the specimen back to the laboratory using the predetermined courier that has been approved by Genetrack for the geographical region in which the patient collects the sample. Each COVID-19 Collection Kit is intended to be returned within 48 hours at ambient conditions on the same day or the following day of sample collection in accordance with the standards as put forth by the CDC and WHO for the transport of suspected COVID-19 samples and any other transport authority.

The Genetrack SARS-CoV-2 Molecular Assay is a real-time reverse transcription polymerase chain reaction (rRT -PCR) test. The SARS-CoV-2 primer and probe sets are designed to detect RNA from SARS-CoV-2 in anterior nasal swabs self-collected at home by individuals qualified by their healthcare provider as needing SARS-CoV-2 testing based on an online questionnaire.

The Vo' COVID-19 Test Home Collection Kit contains the following materials:

Table 1. Materials Included with the Vo' COVID-19 Test Home Collection Kit

Component	Manufacturer	Catalog #
Genetrack Molecular Transport Buffer Solution	Genetrack	#A101
Copan FLOQSwab OR	Copan	#502CS01
Specimen Collection Swab OR	Jiangsu Benoy Lab Instrument	#BN0751
Flocked Sampling Swab	Huachenyang (Shenzhen) Technology	#CY-98000
5 mL Collection vial OR	VWR	#10018-774
3 mL Collection vial OR	Simport	#T310-3A
5 mL Collection vial	Jiangsu Benoy Lab Instrument	#BN0537

Component	Manufacturer	Catalog #
Shipping Box		
Barcode Label (Sample Identification Number, affixed to Collection Tube)		
Adsorbent Sheet	VWR	#89170-926
Biohazard Bag	Fisher Scientific	#01-800-06
Shipping Instructions		
Self-Collection Instructions		

The Vo' COVID-19 Test Home Collection Kit was reviewed for adherence to the Department of Transportation's shipping requirements. The Genetrack Molecular Transport Buffer solution contains concentrations of ethanol that would inactivate the SARS-CoV-2 virus. The kit was found to be acceptable and appropriate for shipping within the United States.

Reagents and materials required for use of the Genetrack SARS-CoV-2 Molecular Assay are described in the table below.

Table 2. Reagents Required to Perform Genetrack SARS-CoV-2 Molecular Assay

Component	Manufacturer	Catalog #
MagMAX Viral/Pathogen Nucleic Acid Isolation Kit	Thermo Fisher	A42352 or A48310
TaqPath1-Step Multiplex Master Mix (No ROX)	Thermo Fisher	A28522 or A28523
2019-nCoV CDC EUA Kit; Includes N1, N2, RNase P assay primers and probes.	IDT	10006606 or 10006770
COVID-19_N_Positive Control	IDT	10006625
Synthetic SARS-CoV-2 RNA Control 2 (MN908947.3)	Twist Bioscience	102024

INSTRUMENTS USED WITH THE TEST
The Genetrack SARS-CoV-2 Molecular Assay is to be used with the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit for RNA extraction and the Applied Biosystems QuantStudio 6 Pro Real-Time PCR System equipped with software v2.4.1.

2) Home Collection Kit Ordering, Processing, and Testing

As part of the registration process, individuals must complete a health survey. The Vo' COVID-19 Test Home Collection Kit will only be dispensed to patients meeting the inclusion criteria based on the information provided through the Vo' website COVID-19 questionnaire (www.vo-test.com/survey) and reviewed by a licensed physician that will determine test eligibility.

Negative results will be delivered either via email, text, or through the website portal. Positive results will be delivered by phone call, informing patients of their results and providing education and a recommended course of care; in the event a patient cannot be reached after 3 call attempts, a letter will be sent.

Anterior nasal swabs are self-collected using the provided flocked nasal swab, placed in 1.5 mL of Genetrack Molecular Transport Buffer Solution (transport solution) to be transported to Genetrack at a temperature between 4° C to 30° C within 48 hours. The Genetrack Molecular Transport Buffer does not contain Guanidinium Thiocyanate.

Upon receipt at the Genetrack Biolabs facility, nucleic acids are isolated and purified using MagMAX Viral/Pathogen Nucleic Acid Isolation Kit manually. The input sample volume is 400µL, the elution volume is 60µL. The purified nucleic acid is reverse transcribed using TaqPath 1-Step Multiplex Master Mix (No ROX) with 5µL of the extracted sample into cDNA which is then subsequently amplified using the Applied Biosystems QuantStudio 6 Pro Real-Time PCR System.

The Genetrack SARS-CoV-2 Molecular Assay is run in a singleplex format (three individual assays) using 2019-nCoV CDC qPCR Probe primer/probe mix (IDT Technologies). The test uses two primer and probe sets to detect two regions in the SARS- CoV-2 nucleocapsid (N1 and N2) gene and one primer and probe set to detect human RNase P (RP). In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by Applied Biosystems QuantStudio 6 Pro Real-Time PCR System.

PATIENT INCLUSION/EXCLUSION CRITERIA

Exclusion criteria for testing:

- Individuals with severe symptoms (will be directed to seek immediate care)

Inclusion criteria for testing:

- Individuals with signs or symptoms of COVID-19
- Individuals with no symptoms but recently had contact with someone known or suspected to have COVID-19
- Individuals with no symptoms and no known contact with someone known or suspected to have COVID-19 but still may be tested for early identification in special settings
- Individuals that have had confirmed COVID-19 but no longer have symptoms

INSPECTION OF SPECIMENS

Specimens received through the Vo' COVID-19 Test Home Collection Kit shall be checked for the following criteria before entering the work flow:

- Packaging damaged
- No swab
- Swab not placed in Molecular Transport Buffer
- No or low quantity of Molecular Transport Buffer
- Unexpected substance in Collection Tube (inconsistent with mucus)
- Sample not registered or identifying information inconsistent
- Missing Sample Identification Code (barcode)
- Collection time greater than 48 hours after collection time

3) Test Results and Interpretation

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

Controls that will be provided with the test kit include:

1. A Negative Extraction Control is used to monitor reagent contamination or sample cross-contamination during RNA extraction and in the assay run. It is included with every assay plate. This control is molecular grade, nuclease-free water.

2. A Positive Amplification Control (2019-nCoV_N_Positive Control) is used to verify that the PCR amplification is performing as intended and is included with every assay plate starting at master mix addition of 50 GCE (genomic copy equivalents). The positive template control does not include the RNase P target sequence and should be negative for that marker.

3. A Positive Extraction Control (Twist Bioscience 102024) is used to ensure expected RNA-specific extraction efficiency and to ensure that no inhibitors of the downstream assay are carried over and is included with every extraction batch at the starting concentration of 1 GCE/µl per sample.

4. An Internal Sample Control targeting RNase P is used to verify that nucleic acid is tested for every sample processed. This also serves as general nucleic acid extraction control to ensure that a sample with a negative test result contains nucleic acid for testing.

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. Appropriate control results are described below.

1. Negative Extraction Control (no template control) – This control must NOT have a detectable Ct in the N1, N2, or RNase P reactions. If this control has a detectable Ct in any of the reaction wells, this indicates contamination of the PCR run and any other positive reactions on the same sample plate shall be considered invalid and must be repeated.

2. Positive Amplification Control – this control must have a detectable Ct in the N1 and N2 reactions. The control's Ct value should fall within 40.00 cycles (< 40.00 Ct) for both gene targets. If it does not, all negative samples on the same plate shall be considered invalid and must be repeated.

3. Positive Extraction Control –this control must have a detectable Ct in the N1 and N2 reactions. The control's Ct value should fall within 40.00 cycles (< 40.00 Ct) for both genes. If it does not, all negative samples on the same plate shall be considered invalid and must be repeated.

4. Internal Sample Control– All clinical samples should exhibit fluorescence growth curves in the RNase P reaction that cross the threshold line within 40.00 cycles (< 40.00 Ct), thus indicating the presence of the human RNase P (RP) gene. Failure to detect RP in any clinical specimens may indicate:
    a. Improper extraction of nucleic acid from clinical materials resulting in loss of RNA and/or RNA degradation.
    b. Absence of sufficient human cellular material due to poor collection or loss of specimen integrity.
    c. Improper assay set up and execution.
    d. Reagent or equipment malfunction.

    If the RP assay does not produce a positive result for human clinical specimens, interpret as follows:

    a. If N1 and N2 are positive (< 40.00 Ct) even in the absence of a positive RP, the result should be considered valid. It is possible that some samples may fail to exhibit RNase P growth curves due to low cell numbers in the original clinical sample. A negative RP signal does not preclude the presence of SARS-CoV-2 RNA in a clinical specimen.

    b. If all SARS-CoV-2 markers AND RNase P are negative for the specimen, the result should be considered invalid for the specimen. If residual specimen is available, repeat the extraction procedure and repeat the test. If all markers remain negative after re-test, report the results as invalid and a new specimen should be collected if possible.

The Genetrack SARS-CoV-2 Molecular Assay will use the result interpretation displayed in the table below:

Table 3. Result Interpretation Algorithm for the Genetrack SARS-CoV-2 Molecular Assay

SARS-CoV-2 N1	SARS-CoV-2 N2	RP	Result Interpretation	Report	Actions
+ (Ct ≤ 40)	+ (Ct ≤ 40)	± (Any Ct value)	SARS-CoV-2 detected	Positive SARS-CoV-2	Report results.
+ (Ct ≤ 40)	- (Ct > 40)	± (Any Ct value)	Inconclusive Result	Inconclusive	This is an inconclusive result and could represent a low positive. Repeat testing and, if indicated, consider collecting a new specimen.
- (Ct > 40)	+ (Ct ≤ 40)	± (Any Ct value)	Inconclusive Result	Inconclusive	This is an inconclusive result and could represent a low positive. Repeat testing and, if indicated, consider collecting a new specimen.
- (Ct > 40)	- (Ct > 40)	+ (Ct ≤ 40)	SARS-CoV-2 not detected	Not Detected	Report results. Consider recommending for clinical follow-up if the patient is symptomatic.
- (Ct > 40)	- (Ct > 40)	- (Ct > 40)	Invalid Result	Invalid	Repeat extraction and rRT-PCR. If the result remains invalid, consider collecting a new specimen from the patient.

PERFORMANCE EVALUATION

1) Analytical Sensitivity

The LoD of the Genetrack SARS-CoV-2 Molecular Assay test was determined using synthetic viral RNA (MN908947.3 GeneBank ID) obtained from Twist Bioscience (102024). A preliminary LoD was determined by testing serial dilutions of RNA (0.05 - 2.5 genomic copies/µL) spiked into nasal swab matrix in triplicate. Nasal swab matrix was collected in the Genetrack Molecular Transport Buffer. Spiked samples were tested with the Genetrack SARS-CoV-2 Molecular Assay following extraction with the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit. The lowest concentration of SARS-CoV-2 RNA that yielded a detection rate of ≥95% was 1 genomic copy/µl.

Table 4. LoD Estimation for the Genetrack SARS-CoV-2 Molecular Assay

Effective Concentration (Genomic Copies/µL)	% Positive	Mean Ct	
		N1	N2
2.5	100% (3/3)	31.97	33.81
		32.05	33.9
		31.85	33.63
2	100% (3/3)	32.57	34.82
		33.08	34.99
		32.63	34.2
1	100% (3/3)	34.76	35.88
		34.4	35.26
		35.44	36.59
0.5	33.3% (1/3)	Und	Und
		37.91	39.03
		38.13	Und
0.1	0% (0/3)	39.14	Und
		Und	Und
		Und	Und
0.05	0% (0/3)	Und	Und

Effective Concentration (Genomic Copies/µL)	% Positive	Mean Ct	
		N1	N2
		Und	Und
		Und	Und

The LoD was verified by testing 20 additional extraction replicates consisting of a nasal swab matrix spiked at the preliminary LoD concentration of 1 copies/µl. Samples were spiked with RNA prior to extraction with the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit. 100% of replicates containing 1 genomic copy/µL were positive successfully confirming the estimated LoD.

Table 5. LoD Confirmation Study for Genetrack SARS-CoV-2 Molecular Assay

Effective Concentration (Genomic Copies/µL)	Replicate	Mean Ct		Interpretation	% Positive
		N1	N2		
1	1	34.22	35.51	Positive	100%
	2	34.92	35.98	Positive	
	3	35.52	36.83	Positive	
	4	34.12	36.66	Positive	
	5	34.55	35.37	Positive	
	6	34.98	36.98	Positive	
	7	34.22	37.22	Positive	
	8	34.98	37.99	Positive	
	9	34.76	37.82	Positive	
	10	35.12	35.88	Positive	
	11	34.01	36.23	Positive	
	12	35.29	36.99	Positive	
	13	35.67	35.54	Positive	
	14	34.88	37.04	Positive	
	15	34.67	37.12	Positive	

Effective Concentration (Genomic Copies/µL)	Replicate	Mean Ct		Interpretation	% Positive
		N1	N2		
	16	35.59	37.81	Positive	
	17	34.32	36.45	Positive	
	18	34.18	35.58	Positive	
	19	35.68	35.98	Positive	
	20	35.78	37.38	Positive	

2) Inclusivity

The Genetrack SARS-CoV-2 Molecular Assay is a modification of the previously authorized CDC assay. Inclusivity of target primer and probe sequences has already been evaluated by FDA under the original EUA and therefore additional analysis is not required.

3) Analytical Specificity (Cross-reactivity)

The Genetrack SARS-CoV-2 Molecular Assay is a modification of the previously authorized CDC assay. Cross-reactivity of target primer and probe sequences has already been evaluated by FDA under the original EUA and therefore additional analysis is not required.

4) Clinical Validation of the Genetrack SARS-CoV-2 Molecular Assay

A total of 60 nasopharyngeal swab specimens in viral transport media, including 30 negative and 30 positive samples, were evaluated with both Genetrack SARS-CoV-2 Molecular Assay and a comparator EUA RT-PCR assay. All samples had RP Ct values less than 40, and the N1 and N2 viral targets were not detected in any of the confirmed negatives (100% agreement). All assay targets were detected in 30/30 confirmed positive samples (100% agreement). Results are summarized in the table below.

		EUA Authorized Comparator Assay			
		Positive	Inconclusive	Negative	Total
Genetrack SARS-CoV-2	Positive	30	0	0	30
	Inconclusive	0	0	0	0
	Negative	0	0	30	30
	Total	30	0	30	60
Positive Agreement			100% (30/30) [88.6%-100%]		
Negative Agreement			100% (30/30) [88.6%-100%]		

5) Sample Stability Studies for Vo' COVID-19 Test Home Collection Kit

Two separate shipping stability studies were performed using both contrived positive samples and negative samples to demonstrate stability of the SARS-CoV-2 analyte in both summer and winter conditions. Positive samples were prepared by spiking remnant positive patient sample into negative clinical matrix. Testing included the following 30 contrived spiked samples: 20 low positive (2x LoD) and 10 high positive (5x LoD) samples as well as 10 negative samples. The contrived positive and negative samples were stored for the duration of the simulated shipping studies as shown in Table 6 and Table 7. Samples were tested at time 0 and at the conclusion of the thermal profiles. Before extraction, the samples were equilibrated to room temperature and tested with the Genetrack SARS-CoV-2 Molecular Assay. As shown in Table 8, all negative samples remained negative and all positive samples remained positive. Furthermore, the mean Ct shift for both N1 and N2 assay targets in samples across both stability studies was < 0.5 cycles, indicating acceptable specimen stability under simulated shipping conditions.

Table 6. Summer temperature excursion

Temperature	Cycle	Cycle Time (time at temperature)	Total Experimental Time Elapsed
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56

Table 7. Winter temperature excursion

Temperature	Cycle	Cycle Time (time at temperature)	Total Experimental Time Elapsed
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56

Table 8. Summary of Results from the Simulated Shipping Studies

Sample Group	Test Point	Number	Mean Ct (St Dev)			Positive (%)
			N1	N2	RNase P	
Negative	Time 0	10	und	und	23.8±0.1	0 (0)
	Summer	10	und	und	24.3±0.3	0 (0)
	Winter	10	und	und	23.7±0.1	0 (0)
Low Positive 2X LoD	Time 0	20	34.0±0.3	37.3±0.4	23.7±0.1	20/20 (100)
	Summer	20	34.3±0.4	37.5±0.6	24.1±0.2	20/20 (100)
	Winter	20	34.3±0.3	37.6±0.4	23.8±0.1	20/20 (100)
High Positive 5X LoD	Time 0	10	31.4±0.2	33.8±0.1	23.7±0.1	10/10 (100)
	Summer	10	31.3±0.4	33.9±0.4	24.1±0.3	10/10 (100)
	Winter	10	31.4±0.2	34.0±0.1	23.7±0.1	10/10 (100)

6) Human Usability Study For the Vo' COVID-19 Test Home Collection Kit

A usability study was performed to evaluated whether patients could follow the instructions provided with the Vo' COVID-19 Test Home Collection Kit and appropriately collect, package, and ship a self-collected nasal swab specimen to Gentrack Biolabs. Briefly, 30 subjects were provided with assembled Vo' COVID-19 Test Home Collection Kit and were asked to collect samples using the kit under observation, and with no further instructions or intervention and to place the kit in a box (representing courier drop-box). Participants in the study were organized to represent the US population including individuals representing varying education levels and age ranges. No individuals under the age of 18 were included in this study. Individuals with prior medical or laboratory training as well as prior experience with self-collection were excluded from the study. Specific demographics of the study population are included in the table below.

Table 9. Demographics of Usability Study Population

Age	Participants
18-44 years old	14
45-64	9
65 or older	7
Gender	**Participants**
Male	14
Female	16
Education Level	**Participants**
< High School Diploma	1
High School Diploma	13
Bachelor's Degree	11
Master's Degree	4
Ph.D. Degree	1

The same subjects were requested to collect another specimen 3 days later under the same conditions. A total of 60 self-collected nasal specimens, 2 from each participant, on different days. Subsequent to the first sample collection, participants were requested to complete a simple questionnaire indicating the ease of use of the Kit.

The observers noted that no grossly aberrant collection was observed with any of the 30 subjects. 28 of 30 subjects 'Strongly Agreed' that the Kit instructions were easy to understand. 2 of 30 subjects 'Agreed' that the Kit instructions were easy to understand. 30 of 30 subjects 'Strongly Agreed' that the Procedure was easy to perform.

A separate evaluation was performed to evaluate the ability of participants to register the test on the sponsor's website. All the participants were able to register the kit successfully.

One of each participant sample was spiked with 2x LoD Twist Bioscience (102024) RNA *in vitro* transcript for SARS-COV-2 N1 and N2 targets. The remaining duplicate patient sample remained unspiked. All positive and negative samples agreed with the expected results and all evaluated samples had successful RNase P amplification indicating successful sampling of human biological material.

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction method used was MagMAX Viral/Pathogen Nucleic Acid Isolation Kit and the assay was Genetrack SARS-CoV-2 Molecular Assay on the Applied Biosystems QuantStudio 6 Pro Real-Time PCR System equipped with software v2.4.1. The results are summarized in the following Table.

Table 10. Summary of LoD Confirmation Result Using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provide d by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Anterior Nares Swab	$1.8x10^3$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL: RNA NAAT detectable units/mL
N/A: Not Applicable
ND: Not Detected

WARNINGS

- This product has not been FDA cleared or approved;
- This product has been authorized by FDA under an EUA for use by Genetrack Biolabs located at 100 - 2806 Kingsway Vancouver BC V5R 5T5 Canada;
- This test 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.