baebies FINDER 1.5

FINDER® SARS-CoV-2 Test

Instructions for Use

The FINDER SARS-CoV-2 Test is intended to be used only with the FINDER 1.5 Instrument. The FINDER 1.5 Instrument and FINDER SARS-COV-2 Test are distributed together as a system. Validation of the instrument and test system has been completed at Baebies but has not been reviewed by FDA. Review under the EUA program is pending. Distributed in accordance with the guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.2.

For in vitro diagnostic use only. Rx only. Caution: Federal law restricts this device to sale by or on the order of a physician.

IVD

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1. Intended Use

1.1. FINDER® SARS-CoV-2 Intended Use

FINDER SARS-CoV-2 Test is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in nasopharyngeal swab (NP) and nasal swab (NS) specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet 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 NP and NS 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 positive results to the appropriate public health authorities.

The FINDER SARS-CoV-2 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.

Validation of the instrument and test system has been completed at Baebies but has not been reviewed by FDA. Review under the EUA program is pending. Distributed in accordance with the guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.2.

2. Summary and Explanation of the Test

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases worldwide, resulting in more than 55 million cases and 1.3 million deaths as of 11/17/2020[1]. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

FINDER SARS-CoV-2 Test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The FINDER SARS-CoV-2 Test contains primers and probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in NP and NS specimens.

3. Test Principle

The FINDER SARS-CoV-2 Test is a real-time RT-PCR test intended for the qualitative detection of RNA from SARS-CoV-2 in NP and NS specimens from individuals suspected of COVID-19 by their healthcare provider. The FINDER SARS-CoV-2 Test is performed on the FINDER 1.5 Instrument, which automates and integrates portions of sample preparation, nucleic acid extraction and amplification, and detection using real-time PCR assays.

SARS-CoV-2 RNA from an NP or NS swab specimen collected in viral transport medium (VTM) is bound to magnetic beads by mixing FINDER Proteinase K solution with FINDER Lysis Buffer and FINDER Binding Buffer. After incubating at room temperature for 10 minutes, the reaction mixture is loaded into the sample reservoir on the FINDER SARS-CoV-2 Test cartridge, and the assay is initiated on the instrument. The FINDER SARS-CoV-2 Cartridge performs all the steps required to complete sample preparation (includes sample concentration, clean up and elution), reverse transcription, DNA amplification, detection, and provides results within 17 minutes. The cartridge contains reagents

[1] Dong E, Du H, Gardner L. An interactive web-based dashboard to track COVID-19 in real time. Lancet Inf Dis. 20(5):533-534. doi: 10.1016/S1473-3099(20)30120-1

necessary to detect RNA from the CDC N1 region of SARS-CoV-2 and to detect RPP30 as the internal control.

4. FINDER SARS-CoV-2 Test

4.1. Contents

Each FINDER SARS-CoV-2 Test cartridge includes necessary reagents to analyze one patient sample for SARS-CoV-2. Tubes of FINDER Lysis Buffer and FINDER Binding Buffer are provided per sample; FINDER Proteinase K is provided in a dropper bottle with sufficient solution to prepare up to 10 samples. The FINDER SARS-CoV-2 Test Components are listed in Table 1.

Table 1: FINDER SARS-CoV-2 Test Components

Item	Component	Quantity per FINDER SARS-CoV-2 Test
FINDER SARS-CoV-2 Test cartridge	N1 reagent (dried)	1 per Cartridge
	RPP30 reagent (dried)	1 per Cartridge
	Diluent	0.27mL
	Filler fluid	1.7 mL
FINDER SARS-CoV-2 Test reagents	FINDER Lysis Buffer	80 µL
	FINDER Binding Buffer	120 µL
	FINDER Proteinase K	0.5 mL in multiuse dropper bottle – 1 drop (~15 µL per test)

4.2. Warnings and Precautions

⚠ **CAUTION:** For *in vitro* diagnostic use.

⚠ **CAUTION:** The FINDER SARS-CoV-2 Test has been validated but FDA's independent review of this validation is pending.

⚠ **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **CAUTION:** Before using the FINDER SARS-CoV-2 Test, the operator should read the FINDER SARS-CoV-2 Test Instructions for Use and the FINDER 1.5 Instrument User Guide. This device should only be used by adequately trained personnel.

⚠ **CAUTION:** Any deviation from the test procedure may affect the results in an adverse manner.

⚠ **CAUTION:** Performance characteristics of the test have been established using the sample type indicated in the intended use. Performance using other sample types has not been evaluated.

⚠ **CAUTION:** The FINDER SARS-CoV-2 Test can only be used with the FINDER 1.5 Instrument.

⚠ **WARNING Biohazard:** Use appropriate Personal Protective Equipment (PPE) when handling patient samples or used cartridges, in addition to observing your organization's approved procedures and following good clinical or laboratory practices.

⚠ **CAUTION:** Due to the sensitivity of the assay, contamination of the sample preparation and instrument areas with previous positive samples may cause false positive results. Follow cleaning procedures in the FINDER SARS-CoV-2 Test Instructions for Use and the FINDER 1.5 Instrument User Guide to reduce the potential for sample contamination.

⚠ **CAUTION:** Maintain a clean, dust-free work area since dust or other particulates may potentially interfere with optical detection.

⚠ **WARNING:** DO NOT use bleach or any other disinfectants that contain bleach to clean the instrument or the area used for sample preparation, as toxic gases may be formed.

⚠ **CAUTION:** Never use a dropped cartridge as it may compromise the performance of the system and can lead to contamination of the FINDER 1.5 Instrument.

⚠ **CAUTION:** Inspect the cartridge foil pouch prior to opening and inspect the cartridge after removal from the pouch. Do not use a cartridge that has been damaged or has a damaged pouch.

⚠ **WARNING Biohazard:** Used cartridges may contain viral samples and must be disposed of within the facility's standard biohazard waste stream.

⚠ **WARNING Biohazard:** Disposal of all waste should be in accordance with the local regulations. Ensure that all FINDER SARS-CoV-2 Test cartridges are incinerated after usage and treated as biohazard waste. Do not attempt to autoclave the used cartridge.

⚠ **CAUTION:** Do not reuse the FINDER SARS-CoV-2 Test cartridge, FINDER Lysis Buffer, or FINDER Binding Buffer.

4.3. Instructions for Kit Handling

FINDER SARS-CoV-2 Cartridges, Lysis Buffer and Binding Buffer vials are single-use and are intended to be used to complete a single FINDER SARS-CoV-2 Test. These components should be used immediately after opening and any solution remaining after use should be discarded.

The Proteinase K solution is provided in a multi-use dropper bottle; each bottle may be used to complete up to 10 FINDER SARS-CoV-2 Tests.

No user reconstitution or mixing of any reagents within the cartridge is necessary for the use of the FINDER SARS-CoV-2 Test cartridge. The self-contained, dried-down reagents are reconstituted with a diluent included in the cartridge as part of the test protocol performed by the FINDER 1.5 Instrument.

4.4. Storage Instructions

Store all FINDER SARS-CoV-2 Test components refrigerated at 2-8°C. Test components should not be frozen.

FINDER SARS-CoV-2 Test cartridges must be stored within their boxes and sealed foil pouches until use. Do not expose opened or unopened cartridges to direct sunlight. The box containing the kit is labeled with the expiration date of all included components; all components have the same expiration date. The

expiration date of the unopened cartridge is also printed on the outer label on the foil pouch and is also encoded in the barcode printed on the cartridge label. Other associated reagents (Lysis Buffer, Binding Buffer, and Proteinase K) are each individually labeled with their unopened expiration date.

Once removed from the refrigerator, the FINDER Proteinase K vial may be stored for use at room temperature for up to 60 hours. Following 60 hours at room temperature, the remaining solution should be discarded.

4.5. Indications of Instability or Deterioration

The FINDER SARS-CoV-2 Test is shipped in a box with cold packs and temperature indicators. If the temperature indicators show there has been exposure below 2°C or above 25°C, the cartridge shipment should not be used and the manufacturer should be notified. A milky white or violet bulb will appear on the ColdMark® indicator if exposed to temperatures below 2°C. Red dye will appear on the WarmMark® indicator if exposed to temperatures above 25°C.

Inspect the foil pouch before opening and inspect the cartridge after removal from the foil pouch for physical damage. Do not use a cartridge that has been damaged or has a damaged pouch, as it may compromise the performance of the system.

5. FINDER 1.5 Instrument

The FINDER SARS-CoV-2 Test can only be used with the FINDER 1.5 Instrument. Refer to the FINDER 1.5 Instrument User Guide for information on the proper use of the instrument.

6. Specimen Collection and Handling

6.1 Specimen Type and Collection

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

Follow the swab and VTM tube manufacturer instructions for guidance on sample collection technique. For optimal performance collect NP and NS specimens with standard collection techniques using flocked or polyester tipped swabs. Immediately place the swab into a tube containing 3 mL of VTM.

Ensure the sample tube is labeled appropriately with a patient-associated barcode or using a manual labeling process consistent with the facility requirements.

6.2 Specimen Transport and Storage

NP and NS swabs in VTM should be tested as soon as possible after collection. Specimens should be stored in accordance with the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. NP and NS swab specimens collected in 3mL VTM should be stored at 2-8^{0}C for up to 72 hours or stored at -70^{0}C for long-term storage. Transportation of collected specimens must comply with all applicable federal, state, and local regulations for the transport of potentially infectious agents.

7. Procedure

7.1. Materials Required

7.1.1. Materials provided

1. FINDER SARS-CoV-2 Test cartridge
2. FINDER Lysis Buffer
3. FINDER Binding Buffer
4. FINDER Proteinase K
5. FINDER SARS-CoV-2 Test Instructions for Use

7.1.2. Materials required but not provided with the FINDER SARS-CoV-2 Test:

1. FINDER 1.5 Instrument (Baebies P/N: 100-000030)
2. 100 µL fixed volume pipette – 2 each (VWR P/N: 83009-768, or equivalent)
3. Dualfilter T.I.P.S. 2-100 µL (Baebies P/N: 999-000020)
4. Negative control specimens (ZeptoMetrix P/N: NATSARS(COV2)-NEG) – Contact Baebies for a list of qualified control lots
5. Positive control specimens (ZeptoMetrix P/N: NATSARS(COV2)-ERC) – Contact Baebies for a list of qualified control lots
6. 1.5 mL microcentrifuge tube
7. Adjustable pipette
8. Sample tubes containing 3 mL of VTM
9. Laboratory timer (VWR P/N: 62344-641, or equivalent)
10. FINDER Cleaning Accessory (Baebies P/N: 4076)
11. RNase Displace (VWR P/N: 10611-534, or equivalent)
12. 70% isopropyl alcohol (VWR P/N: 89108-162, or equivalent)
13. Printer, optional (Baebies P/N: 100-000014)

7.2. Test Procedure

The test procedure is summarized in Table 2 and is described in detail in the following sections. Any deviation from the test procedure may adversely affect the results.

Before beginning the test, the sample preparation area and test area should be cleaned to reduce the risk of cross-contamination.

WARNING: Bleach should not be used in the sample preparation area as a reaction between bleach and the assay reagents can create toxic fumes.

Paper towels and cotton wipes should not be used in the sample preparation or instrument workspaces. Cleaning should be conducted using non-cotton, lint-free laboratory task wipes (Kimwipes, or equivalent).

RNAse Displace should be used to clean the deck of the instrument between runs as well as the sample preparation area. Any remaining residue after cleaning may be removed by wiping with 70% isopropanol.

Table 2: Test Procedure Summary

Step	Description
Add Proteinase K to Lysis Buffer	Dispense one (1) drop of Proteinase K into the Lysis Buffer tube.
Add Sample	Add 100 µL of sample to the Lysis Buffer tube and aspirate mix 10 times by pipetting
Add Binding Buffer	Aspirate mix Binding Buffer 10 times by pipetting. Add 100 µL of Binding Buffer to the Lysis Buffer Tube. Aspirate mix contents of Lysis Buffer Tube 10 times by pipetting and allow to incubate for 10 minutes at room temperature
Prepare Instrument for Test	Switch ON the instrument and login using a barcode ID or manual entry. Press 'New Run' and select the test to be performed.
Insert Cartridge	Remove cartridge from pouch. Scan the cartridge barcode on the instrument barcode reader. Insert cartridge into the instrument deck, then initialize cartridge.
Load Sample	Scan or enter the sample identifier. Aspirate mix contents of Lysis Buffer tube 10 times by pipetting. Transfer 100 µL of solution from the Lysis Buffer tube to the cartridge. Close the sample lid on the cartridge and initialize test. Close the cap on the Lysis buffer tube and save until results are verified.
View Results	Once the test is complete, view results. Refer to the FINDER 1.5 Instrument User Guide for test failures, flags, or troubleshooting. Remove the cartridge from the FINDER 1.5 Instrument and dispose in a biohazard waste receptacle.

Step 1: Add Proteinase K to Lysis Buffer

Before beginning sample preparation, remove all required components (Proteinase K, Lysis Buffer, Binding Buffer, and FINDER SARS-CoV-2 Test cartridge) from the refrigerator. Allow all components to equilibrate to room temperature before use; this requires approximately 5 minutes. Once components are at room temperature, they must be used within 60 hours, and discarded afterwards. Components that have been removed from the refrigerator cannot be placed back into the refrigerator.

After all components have reached room temperature; remove the caps from the Proteinase K dropper bottle and the Lysis Buffer tube; place the Lysis Buffer tube into a tube rack. When each bottle of Proteinase K is first opened for use, invert the dropper bottle and prime the dispenser tip by dispensing a single drop of the solution into the waste. Apply steady, gentle pressure while squeezing the bottle to ensure a consistent drop size. Next, add a single drop of the Proteinase K solution to the Lysis Buffer tube. The Proteinase K bottle must only be primed prior to first use.

The Proteinase K solution is provided in a multi-use dropper bottle that is intended to be used across 10 individual samples. When the bottle is opened, it should be labeled with the date and time of opening. The Proteinase K solution may be used for up to 60 hours after removing from the refrigerator. The bottle should be discarded after it has been used to prepare 10 samples or after 60 hours.

⚠ **WARNING:** Failure to add Proteinase K to the Lysis Buffer tube can cause false results.

Step 2: Add Sample

Acquire the sample to be tested and place it in a tube rack. If the sample has been stored refrigerated or frozen, allow the sample to equilibrate to room temperature before continuing.

Open the cap on the sample tube. Affix a filtered pipette tip capable of transferring 100 µL of solution on to a 100 µL fixed volume pipette. Depress the pipette plunger and submerge the pipette tip into the sample; release the plunger to aspirate the sample into the tip. Submerge the pipette tip into the solution in the Lysis Buffer tube and press the pipette plunger to dispense the sample. Aspirate mix the solution 10 times (by pressing and releasing the plunger while the pipette tip is still submerged). Discard the pipette tip into the hazardous waste stream. Replace the cap on the sample tube.

Step 3: Add Binding Buffer

Affix a filtered pipette tip capable of transferring 100 µL of solution on to a 100 µL fixed volume pipette. Remove the cap from the Binding Buffer vial. Aspirate mix the Binding Buffer 10 times; this will fully suspend the beads. Depress and release the plunger to aspirate buffer into the tip. Submerge the tip into the solution in the Lysis Buffer tube and press the plunger to dispense binding buffer. Aspirate mix the solution in the Lysis Buffer tube 10 times. Discard the pipette tip into the hazardous waste stream. Replace the cap on the lysis buffer tube and discard the Binding Buffer vial.

⚠ **WARNING:** Failure to aspirate mix the binding buffer prior to transferring the binding buffer to the solution in the lysis buffer can cause invalid results.

Incubate sample mixture at room temperature for ten (10) minutes; track elapsed time using a laboratory timer. The Lysis Buffer tube contains 300 µL of prepared sample. This prepared sample is stable for up to 180 minutes (3 hours) at room temperature and may be loaded on another cartridge within 180 minutes for confirmation or in the case of an invalid result.

Discard used gloves and wear clean gloves before proceeding to the next step.

Step 4: Prepare Instrument for Test

Ensure that the instrument is powered on and the VIEWER application is open on the tablet. Select “SCAN ID TO UNLOCK”. Scan a user barcode by placing the barcode into the red crosshairs generated by the barcode scanner on the instrument; alternately, the user ID can be entered manually.

Following user entry, the Completed Test Run screen will appear, which shows a list of prior runs. To test a sample, select “NEW RUN”. Ensure that the “SARS-CoV-2” test is selected, and press “NEXT”.

*Note: The **New Run** button will be red and the text will read “ERROR” or “WARNING” if the instrument is not fully operational. See the Troubleshooting section of the FINDER 1.5 Instrument User Guide for instructions to resolve issues that may prevent a run from being performed.*

Step 5: Insert Cartridge

Tear open a cartridge pouch at the notches and, grasping the cartridge by the grips, remove the cartridge from the foil pouch. When prompted by the software, hold the cartridge barcode in front of the instrument barcode reader to scan.

Keeping the cartridge parallel with the deck, insert and push the cartridge into the deck . The cartridge will offer some slight resistance when pushed; continue pushing until the cartridge “clicks” into place.

After the cartridge has been inserted, press “INITIALIZE” on the display. This process will take approximately one minute; this is an important quality step to ensure that the cartridge is ready to run the

assay. Following successful initialization, the sample must be loaded and the assay must be started within 15 minutes.

Step 6: Load Sample

Press the “SCAN” button to enter the sample identifier. After pressing the button, the barcode scanner will be activated; if a bar code is available that includes the sample identifier, it can be scanned at this time. If the sample does not contain a barcode, press and hold the “SCAN” button for approximately three (3) seconds to enter the sample identifier manually.

Note: The barcode scanner will timeout if no barcode is presented. This timeout period is configurable; see the “Barcode Scanner” section of the FINDER 1.5 Instrument User Guide for more information. If the scanner does timeout, press “SCAN” again to reactivate the timer.

Uncap the Lysis Buffer tube containing the reaction mixture from Step 3. Affix a filtered pipette tip capable of transferring 100 µL of solution into a 100 µL fixed volume pipette. Aspirate mix the solution in the Lysis Buffer tube 10 times. Press and release the plunger a final time to aspirate sample into the tip.

Insert the tip into the sample port on the cartridge until the tip reaches the bottom of the port. The pipette should be held at an approximately 30 degree angle away from the body of the instrument. Transfer the sample into the cartridge by fully pressing the plunger down. Discard the pipette tip into a biohazard waste receptacle.

Close the cartridge sample cap by pushing it down firmly with one finger. A “click” may be felt.

⚠ **CAUTION:** Failure to close the sample cap may lead to contamination of the FINDER 1.5 Instrument during cartridge removal. Always be sure to securely close the cartridge sample lid prior to the test starting.

Press the “START” button on the tablet to begin the run.

Step 7: View Results

Refer to section 8.1 – “Results and Reporting” for information regarding the interpretation of test results. Refer to FINDER 1.5 Instrument User Guide for test failures, flags, or troubleshooting.

Remove the cartridge from the instrument by pulling on the cartridge grip. Dispose of the used cartridge in a biohazard waste receptacle.

In the event of a NEGATIVE CARTRIDGE CONTROL or SYSTEM ERROR result, the prepared sample from Step 3 may be loaded onto a new cartridge within 180 minutes of initial sample preparation..

⚠ **CAUTION:** DO NOT attempt to autoclave the consumed cartridge.

⚠ **CAUTION:** Always remove the cartridge from the instrument at the conclusion of a test. Failure to remove the cartridge after an extended period of time can lead to oil leaks and contamination of the FINDER 1.5 Instrument.

7.3. Quality Control

7.3.1. Internal Controls

Each FINDER SARS-CoV-2 Test includes an internal control reaction, which utilizes primers and probes for the human RPP30 gene. Amplification of the RPP30 control indicates that the reaction steps completed successfully on the cartridge.

More information may be found in section 8, “Results and Reporting”.

7.3.2. External Controls

The performance of the FINDER 1.5 system can be verified by analyzing external quality control specimens. It is recommended that positive and negative quality control specimens should be tested when:

- A new lot of FINDER SARS-CoV-2 Test kits is received
- Qualifying performance of a new operator
- Otherwise required by federal, state, or local regulations, accrediting groups, or the site Quality Control (QC) procedures

The concentration of the positive quality control specimen should be diluted to below 5 times the limit of detection (LoD) of the FINDER SARS-CoV-2 Test prior to testing. Instructions for making a positive quality control at ~5x LoD are provided below:

1. Add 350µL of VTM into a clean, RNAse, DNAse-free 1.5mL microcentrifuge tube.
2. Mix Zeptometrix NATSARS(COV2)-NEG and NATSARS(COV2)-ERC by inverting 7-10 times.
3. Mix the Zeptometrix NATSARS(COV2)-NEG control 5 times using a pipette.
4. Add 100uL of NEG control to the VTM tube.
5. Mix the Zeptometrix NATSARS(COV2)-POS control 5 times using a pipette.
6. Add 50uL of POS control to the VTM tube.
7. Mix using a pipette 5 times.
8. Use 100uL of this control as specimen for the FINDER SARS-CoV-2 Test.

Quality control specimens should be tested using the same workflow as clinical specimens. In the case of a failed negative or positive external QC, the sample should be re-tested. If three consecutive QCs fail, contact FINDER Technical Support.

8. Results and Reporting

Following completion of the assay, the FINDER 1.5 Instrument automatically calculates and displays the results of the sample on the user interface within 17 minutes.

The results and their interpretation are listed in Table 3. Results can be printed if required.

Table 3 - FINDER SARS-CoV-2 Results and Interpretation

Result	Interpretation
SARS-CoV-2 Detected	• SARS-CoV-2 RNA detected. • Internal control result not considered. • Cycle threshold (Ct) value is displayed.
SARS-CoV-2 Not Detected	• SARS-CoV-2 RNA not detected. • Internal control result is in valid range. • No Ct value is displayed.
[5000] Internal control failure	• Both SARS-CoV-2 RNA and RPP30 internal control not detected. • Repeat test using new Cartridge. • Use 100µL of prepared sample (from Step 3) from Lysis Tube for 1st retest. • If retest fails prepare sample again from primary specimen tube and repeat using new Cartridge.
Cartridge Protocol Failure [all other codes]	• Suspected cartridge failure. • Repeat test using new Cartridge. • Use 100µL of prepared sample from Lysis Tube for 1st retest. • If retest fails prepare sample again from primary specimen tube and repeat using new Cartridge.

Refer to the Flags and Troubleshooting sections of the FINDER 1.5 Instrument User Guide for details on additional flags.

9. Limitations of the Procedure

- This test is intended for use as an *in vitro* diagnostic; use is limited to laboratories that are certified under CLIA to perform high complexity tests. A statement such as “the test has been validated but FDA’s independent review of this validation is pending” should be included in test reports to healthcare providers.
- The performance of the FINDER SARS-CoV-2 Test was evaluated only using the procedures provided in these Instructions for Use. Modifications to these procedures may alter the performance of the test.
- The performance of the FINDER SARS-CoV-2 Test has only been established in NP and NS swab specimens collected in VTM. Specimens other than NP or NS swab in VTM may give inaccurate results.
- False negative results may occur if the quantity of virus in the sample is below the device’s limit of detection.
- A false negative result may occur if a specimen is improperly collected, transported or handled.
- As with any molecular test, mutations within the target regions of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- The clinical performance has not been evaluated with all circulating SARS-CoV-2 variants but is expected to be reflective of variants in circulation during clinical evaluation. Performance may vary based on the prevalence of variants in circulation at the time of test, including newly emerging strains of SARS-CoV-2.
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors, and/or stage of infection.

- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The FINDER SARS-CoV-2 Test is a qualitative test and does not quantify the amount of viral RNA present in the sample.
- Concentrations of interfering substances higher than the maximum concentrations listed in Table 4 could potentially interfere with assay operation.
- Only the substances listed in Table 4 were evaluated for potential interference.

10. Analytical Performance Characteristics

10.1. Analytical Sensitivity (Limit of Detection)

The specimens used to determine the limit of detection (LoD) were negative NP swab media with non-infectious viral particles for SARS-CoV-2 (Zeptometrix P/N NATSARS(COV2)-ERC) spiked in at 1,000 copies/mL. 20 replicates at the expected LoD were tested; 20/20 replicates tested positive.

The limit of detection of the FINDER SARS-CoV-2 Test was determined to be 1,000 copies/mL.

10.2. Analytical Sensitivity (Inclusivity)

An *in silico* analysis was completed to provide the reactivity (inclusivity) of the FINDER SARS-CoV-2 assay primers and probes for all variants of the SARS-CoV-2 virus identified through March 08, 2021. A total of 54,712 sequences from the NCBI database, as well as sets of 8,352 and 3,068 complete genomes of the SARS-CoV-2 UK Variant (VUI202012/01), 9,890 sequences of the SARS-CoV-2 CA variant (452R.V1), 2,956 sequences of the SARS-CoV-2 SA variant (501Y.V2), and 607 sequences of the SARS-CoV-2 Brazil variant (501Y.V3), which were downloaded from the GISAID repository. The forward primer was a perfect match to 98.59% of all sequences across both databases. The reverse primer matched to 99.57% of all sequences across both databases. The probe matched to 98.22% of all sequences across both databases.

10.3. Analytical Specificity (Cross-Reactivity)

The nCoV N1 primer and probe utilized within the FINDER SARS-CoV-2 Test with the FINDER 1.5 Instrument are identical in sequence to those reported in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. The CDC reported an *in silico* analysis of primer and probe sequences within their IFU (CDC-006-0019, Rev 02), which has been reproduced below for reference:

> *BLASTn analysis queries of the 2019-nCoV rRT-PCR assay primers and probes were performed against public domain nucleotide sequences. The data-base search parameters were as follows: 1) The nucleotide collection consists of GenBank+EMBL+DDBJ+PDB+RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb; 2) The database is non-redundant. Identical sequences have been merged into one entry, while preserving the accession, GI, title and taxonomy information for each entry; 3) Database was updated on 10/03/2019; 4) The search parameters automatically adjust for short input sequences and the expected threshold is 1000; 5) The match and mismatch scores are 1 and -3, respectively; 6) The penalty to create and extend a gap in an alignment is 5 and 2, respectively.*
>
> *2019-nCoV_N1 Assay:*
>
> *Probe sequence of 2019-nCoV rRT-PCR assay N1 showed high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. However, forward and reverse primers showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. Combining primers and probe, there is no significant homologies with human genome, other coronaviruses or human microflora that would predict potential false positive rRT-PCR results.*
>
> *In summary, the 2019-nCoV rRT-PCR assay N1, designed for the specific detection of 2019-nCoV, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.*

In silico analyses of the internal control gene (RPP30) primer and probe sequences were performed as described below:

BLASTn queries of the 2019-nCoV CDC EUA rRT-PCR RPP30 amplicon sequence were performed against public domain nucleotide sequences. The search parameters were as follows:

1. RPP30 amplicon sequence: agatttggacctgcgagcgggttctgacctgaaggctctgcgcggacttgtggagacagccgctc;
2. Analyzed against 27 microorganisms (organisms listed on table titled *Recommended List of Organisms to be Analyzed in silico and by Wet Testing* on pages 12 and 13 of the U.S. FDA's *Molecular Diagnostics Template for Commercial Manufacturers*, dated July 28, 2020);
3. Automatically adjusted for short input sequences;
4. Expect threshold of 1000;
5. Word size of 15 bp;
6. Match and mismatch scores of 1 and -3, respectively;
7. Penalty to create and extend a gap in an alignment of 5 and 2, respectively.

No significant similarity was found between 24 of the respiratory microorganisms and the RPP30 amplicon sequence. The probe sequence showed some sequence homology with the MERS genome; however, the forward and reverse primers showed no similarity. The forward primer sequence showed sequence homology with the Influenza A genome; however, the reverse primer and probe sequences showed no similarity. The forward primer sequence and the probe showed some sequence homology with the Pseudomonas aeruginosa genome; however, these regions were distinct within the genome, and the reverse primer showed no similarity.

In summary, no significant combined homologies were found between the RPP30 primers and probes and other coronaviruses or respiratory microorganisms that would predict false positive results of RPP30 amplification in the FINDER SARS-CoV-2 Test.

10.4. Interfering Substances

Testing was completed to identify substances that could potentially interfere with the FINDER SARS-CoV-2 Test. If interference was observed at the tested concentration, an additional titration study was performed to determine the highest interferent level at which the test can achieve the stated performance.

A minimum of 3 replicates using positive and negative samples were used for testing. Positive samples were created by using negative NP swab media with non-infectious viral particles for SARS-CoV-2 (Zeptometrix P/N NATSARS(COV2)-ERC) spiked in at 5,000 copies/mL. Negative samples consisted of negative NP swab media.

The highest levels of the following potentially interfering substances that were found to not interfere with the FINDER SARS-CoV-2 Test are described in the Table 4.

Table 4 - Maximum Non-interfering Concentrations

Substance	Maximum non-interfering concentration	
	Positive sample	Negative sample
Mucin: bovine submaxillary gland, type I-S	1.5 mg/mL	1.5 mg/mL
Blood	0.5% (v/v)	5% (v/v)
Afrin Pump Mist – positive samples	0.1% (v/v)	5% (v/v)
Allergy Relief Nasal Spray (Fluticasone)	0.5% (v/v)	0.5% (v/v)
Zicam Intense Sinus Relief	5% (v/v)	5% (v/v)
Cepacol	5% (v/v)	5% (v/v)
Mupirocin	5 mg/mL	5 mg/mL
Oseltamivir	7.5 mg/mL	7.5 mg/mL
Tobramycin	4 µg/mL	4 µg/mL
Zanamivir	5 mg/mL	5 mg/mL

Additional potential interfering substances proposed in the table below were evaluated in negative and positive specimens (at 3000 copies/mL). Negative specimens were pooled nasal specimens collected in 3mL. Positive specimens were prepared using Zeptometrix controls at 3000 copies/mL. The results are in Table 5 below.

Table 5 - Maximum Non-interfering Concentrations

Substance	Maximum non-interfering concentration	
	Positive sample	Negative sample
Triamcinolone acetonide (Nasal allergy spray – Nasacort)	0.25% (v/v)	0.25% (v/v)
NaCL, Phenylcarbinol, Nemalkonium Chloride (Saline nasal spray – NeilMed, Nasogel)	1.25% (v/v)	1.25% (v/v)
Crest/Listerine Mouth Wash (Eucalyptol, menthol, Methyl Salicylate, Thymol)	5% (v/v)	5% (v/v)
Phenol, Glycerin (Chloroseptic sore throat spray)	5% (v/v)	5% (v/v)
Acetaminophen, Doxylamine succinate, Dextromethorphan HBr (Nyquil/Cough drops/Robitussin)	2.5% (v/v)	2.5% (v/v)
Petroleum Jelly (Vaseline)	2.5% (w/v)	2.5% (w/v)
Nicotine, Tar, Carbon Monoxide, Formaldehyde, Ammonia, Hydrogen Cyanide, Arsenic, and DDT (Nicotine/Tobacco)	0.03 mg/mL	0.03 mg/mL
Ethanol (Alcohol)	5% (v/v)	5% (v/v)

11. Clinical Performance

A clinical evaluation was completed to demonstrate the performance and intended use of the FINDER 1.5 Instrument and FINDER SARS-CoV-2 Test using SARS-CoV-2 positive and SARS-CoV-2 negative nasopharyngeal and nasal swab samples collected in VTM. Results obtained from testing completed using the FINDER SARS-CoV-2 Test were compared to an Emergency Use Authorization (EUA) authorized RT-PCR test method.

Samples utilized for the study consisted of leftover, de-identified samples and prospectively collected samples that were frozen prior to testing on the comparator and investigational methods. A total of 76 samples were tested in the study. These samples were collected in the following types of VTM: Bartels® FlexTrans™ Transport Medium.

Performance estimates for positive percent agreement (PPA) and negative percent agreement (NPA) are shown in Table 6 below.

Table 6 - Clinical Performance Summary

FINDER SARS-CoV-2 Test vs EUA-authorized Comparator Assay				
		EUA-Authorized RT-PCR Test		
		POSITIVE	**NEGATIVE**	**TOTALS**
FINDER SARS-CoV-2 Test	POSITIVE	29	0	29
	NEGATIVE	1	46	47
	TOTALS	30	46	76
PPA	96.7 (95% CI: 83.3 – 99.4%)			
NPA	100.0 (95% CI: 92.3 – 100.0%)			

12. Symbols and Abbreviations

The following symbols and abbreviations may appear on the product labels or labeling documents:

Symbol	Description
	Potential hazard
	Warning or Caution
	*In vitro* diagnostic medical device
	Reference item number
	Manufacturer name and/or physical location
	Date of manufacture
	Date of expiration, use-by date
	Lot number
	Storage or transit temperature limits
	Total number of tests that can be performed with the IVD
	Single-use only, do not re-use
	Consult instructions for use
	Keep away from sunlight
RX only	Prescription device only
QTY	Quantity of contents