proof™
Diagnostics

# Proof Lab User Manual

**COVID-19 TEST**

IVD

**For Use Under an Emergency Use Authorization (EUA) Only**

**For In Vitro Diagnostic Use**

© Copyright 2021 Proof Diagnostics, Inc.

# General Information

*Please review the contents of our User Manual. Contact Proof Diagnostics' Customer Support Team at support@proofdx.com, if you have any questions.*

## Copyright

This User Manual and all the contents contained are subject to copyright. All rights are reserved. No part of this user manual may be reproduced, copied, translated or transmitted in any form or by any means without the prior written approval of Proof Diagnostics.

## Manufacturer

**PROOF DIAGNOSTICS, INC.**
700 Main Street
Cambridge, MA 02139
USA

www.proofdx.com

PROOF-UM-1.1 | JULY 2021

# Table of Contents


**General Precautions and Safety Instructions ..... 1**
- General Precautions 1
- General Safety 2
- Biohazards 2

**Introduction ..... 3**
- About 3
- Intended Use 3
- Principles of the Procedure 4

**Operation ..... 5**
- Package Contents 5
  - Required Materials 5
- Quality Controls 6
  - Internal Control 6
  - External Positive and Negative Controls 6
- Test Kit Storage and Use 7
- The Proof Diagnostics Test System 7
- Basic Setup 8
  - Prepare Reader 8
  - Prepare Patient 8
- Running a Test 9
  - Powering Off the Reader 14
- Test Result Interpretation 15
  - Test Result Limitations 16
  - Conditions for Authorization 18
- Reporting Test Results 19

**Clinical Performance ..... 19**
- Patient Demographics 21
- Analytical Performance 21

Reader Maintenance ..... 25
Cleaning the Reader 25
Updating Reader Firmware 25
Error Alerts..... 26
Technical Specifications ..... 27
Table of Symbols ..... 28
Regulatory Notices ..... 29
Support ..... 30
Warranty ..... 30
Disposal ..... 30



# General Precautions and Safety Instructions

It is the sole responsibility of the user to ensure that they have read and understood this user manual before using the Proof Diagnostics Test System.

## General Precautions

**CAUTION:**

- For FDA Emergency Use Authorization (EUA) only.
- For in vitro diagnostic use only.
- For prescription use only.
- The Proof Diagnostics Test System has not been FDA cleared or approved; this test has been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.
- This test has been authorized only for the detection of SARS-CoV-2 nucleic acid, not for any other viruses or pathogens.
- The use of the Proof Diagnostics Test System has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of emergency use pursuant to Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1)), unless the declaration is terminated or authorization is revoked sooner.
- Single Use Only: Do not attempt to reuse any Test Kit consumables (cartridges, swabs or sample vials).
- The Proof Diagnostics Test System is only for use by healthcare professionals in a suitable laboratory, clinical environment or CLIA-waived environment.
- Do not use specimens stored in viral transport media; only use specimens stored in the Proof Diagnostics sample vial.

- Inadequate or inappropriate sample collection, storage and transport may yield false test results.
- Please follow the instructions provided in this manual to obtain accurate results. Ensure the Proof Lab Reader and Test Kit are maintained at room temperature: 15 to 30°C (59 to 86°F).
- Ensure the Proof Lab Reader and Test Kit are maintained at room temperature: 15 to 30°C (59 to 86°F).
- Do not use the Test Cartridge if the packaging appears damaged or the expiration date has passed.
- Do not use the swab or sample vial if the packaging appears damaged.
- For use with nasal swabs only.
- Only use the swab included with the Proof Diagnostics COVID-19 Test Kit.
- The Proof Lab Reader must be placed on a stable, level surface away from direct sunlight or other heat sources.

## General Safety

**WARNING:** To reduce the risk of electrical shock:

- Do not attempt to disassemble the Proof Lab. The Proof Lab contains no user serviceable parts. For technical assistance, see "Support" on page 31.
- Disconnect the device from the main power outlet before cleaning. Do not attempt to clean inside the cartridge insertion slot.
- Do not immerse the device in liquid.
- Only wipe the external surfaces of the device using the recommended cleaning agents. (For further information, see "Cleaning the Device" on page 25.)

## Biohazards

**WARNING:** To reduce the risk of exposure to any biological hazards:

- Always ensure that proper laboratory procedures are followed when handling and disposing of potentially hazardous material.
- Dispose of used and unused kit contents as biohazardous waste according to federal, state and local regulatory requirements.
- The use of Nitrile, Latex or other suitable safety gloves is strongly recommended while using the Proof Diagnostics Test System.



# Introduction

## About

Coronavirus disease (COVID-19) is an infectious respiratory disease caused by a novel human coronavirus and named by the World Health Organization (WHO) as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The COVID-19 virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs

or sneezes. While most people infected with the COVID-19 virus will experience only mild to moderate respiratory illness, the disease can also cause severe respiratory illness and death. The WHO declared the disease a pandemic in early 2020.

The COVID-19 assay is a rapid molecular in vitro diagnostic test utilizing isothermal nucleic acid amplification and CRISPR-mediated detection of the resulting amplicon.

The Proof Diagnostics Test System significantly reduces the amount of time taken for COVID-19 testing with results typically available in about 30 minutes.

## Intended Use

The Proof Diagnostics Test System is a molecular diagnostic test used for the qualitative detection of nucleic acid from SARS-CoV-2 viral RNA in nasal swabs taken from individuals who are suspected by a healthcare professional of having COVID-19 or individuals at risk due to contact with COVID-positive individuals. Testing of nasal swabs using the Proof Diagnostics COVID-19 Test 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 moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasal 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. Testing facilities within the United States and its territories are required to report all positive 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 should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary patient management, should be tested with different authorized or cleared molecular tests.

The Proof Diagnostics COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

## Principles of the Procedure

TBC



# Operation

### Proof Lab Test System

- 1 x Proof Lab Reader
- 1 x Quick Reference Instructions
- 1 x User Manual
- 1 x Power Cord

### Proof Diagnostics COVID-19 Test Kit

- 1 x Test Cartridge
- 1 x Sample Vial
- 1 x Nasal Swab
- 1 x Exact Volume Transfer Pipette
- 1 x Quick Reference Instructions

**NOTE:**

- Please check all packaging and contents for any visible signs of damage. If any damage is found, please contact Proof Diagnostics (see "Support" on page 29).
- The Quick Reference Instructions are for reference only. It is the responsibility of the laboratory or clinic to ensure that all users of the Proof Diagnostics System understand how to safely and correctly perform a test.

## Required Materials

**The following materials are required but not provided:**

- Positive and Negative Controls (described on the following page)

# Quality Controls

## Internal Control

The COVID-19 Test Kit also includes an Internal Control for the presence of human RNA. Human beta-actin primers are included in the Proof Cartridge amplification reaction to ensure the presence of human cellular RNA in the test sample and are used in determining the final test result.

## External Positive and Negative Controls

Proof Diagnostics recommends positive and negative controls be purchased separately from ZeptoMetrix (Buffalo, NY). Details are provided below.

- Positive Control: SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control. Catalog Number: NATSARS(COV2)-ERC1
- Negative Control: SARS-Related Coronavirus 2 (SARS-CoV-2) Negative Run Control. Catalog Number: NATSARS(COV2)-NEG1

The external positive and negative controls will monitor the entire test. External controls shall be evaluated:

- Once with each new reader set up.
- Once with each new lot of Test Kits received.
- Once with each new operator.
- When problems with testing are suspected or identified.
- As necessary to conform with local, state and/or federal regulations, accrediting requirements or your lab's standard quality control procedures.

If correct results are not obtained, discard the Test Cartridge and repeat the test with a new Test Kit. If the subsequent test fails, report the problem to Proof Diagnostics technical support (TBD).



# Test Kit Storage and Use

- Store Test Cartridges, swabs and sample vials at room temperature (15 to 30°C or 59 to 86°F) in their original packaging away from direct sunlight.
- All Test Kit consumables (cartridges, swabs and sample vials) are single use only.
- Do not remove the Test Cartridges, swabs or sample vials from their packaging until immediately prior to use.

# The Proof Diagnostics Test System

Proof Lab

Proof Diagnostics COVID-19 Test Kit

Nasal Swab | Sample Vial | Exact Volume Transfer Pipette | Test Cartridge

## Basic Setup

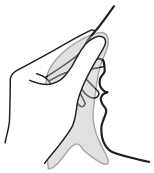
- The Proof Lab should be placed on a dry, level surface with clear access to a suitable power outlet.
- Make sure the workspace around the Proof Lab is kept clean and free of contaminates.

### Prepare Proof Lab

Place Proof Lab on a clean, dry surface. Firmly insert the power cord into the power socket on the Proof Lab. Connect the plug to your main power outlet. Once connected, the Proof Lab will automatically turn on.

The ring of LED lights on the Proof Lab will turn solid white when the device is ready to run a test. This is the Reader Ready State.

### Prepare Patient



Instruct patient to gently blow their nose into a tissue prior to test.

Discard tissue in a biohazard waste bin.



## Running a Test

Before running a test, make sure:

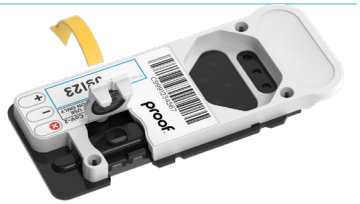
- You have read and understood all of the instructions contained in this User Manual including all safety warnings and cautions.
- You have powered on the Proof Lab, and it is ready to run a test (see “Prepare Device” on page 8).
- You have everything required for the completion of the test, including:
  - Proof Lab COVID-19 Test Kit
    - COVID-19 Test Cartridge
    - Nasal Swab
    - Sample vial
    - Exact volume transfer pipette
  - Personal protective equipment
  - Biohazard waste bin
  - A suitable pen to write the patient ID on the Test Cartridge and sample vial

**To run a test:**

1. Remove the Test Cartridge from the foil pouch. Place on a flat, clean, dry surface. Write the patient details in the Patient ID box on the label. Do not touch, press or write over the barcode.

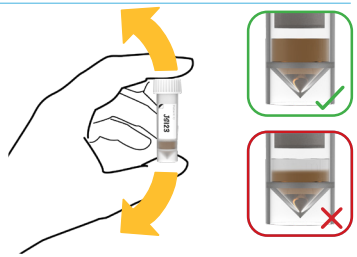
2. Remove the pull tab from the Cartridge and discard.

3. Fully open Cartridge door to expose Cartridge porthole.



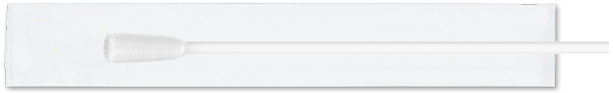

4. Write the Patient ID on the removable label found on the Sample Vial pouch. Remove and attach to the Vial.

5. Shake the Vial for 30 seconds until the liquid inside the Vial is uniformly colored.

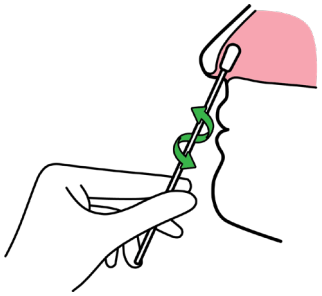


6. Unscrew cap from the Vial.

7. Remove the Nasal Swab from its packaging.



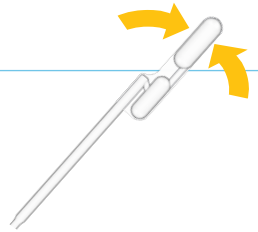
8. Insert the entire soft tip of the Swab inside the nostril until the tip is no longer visible. If the Swab meets with any resistance, do not insert any further. Firmly rotate the Swab in a circular path against the nasal wall 2-3 times. Repeat in the other nostril using the same Swab.



9. Place the Swab in the Vial and rotate in liquid 5-6 times, against the inner wall of the Vial, for about 10 seconds.

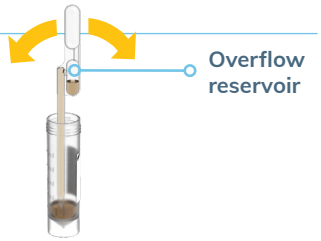
10. Remove the Swab from the Vial and discard the Swab in a biohazard waste bin.

11. Pick up the Exact Volume Transfer Pipette by the top bulb and squeeze the top bulb firmly between your forefinger and thumb.

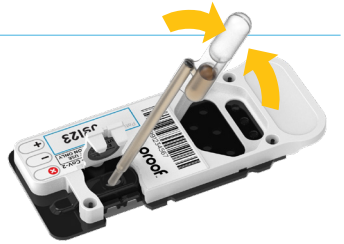


12. While still squeezing firmly on the top bulb, fully submerge the Pipette tip into the Vial liquid, so that Pipette tip is near the bottom of Vial.

13. Gently release the top bulb to allow the liquid to fill the Pipette stem. Note: It's normal and expected for excess fluid to fill the overflow reservoir.




14. Insert Pipette stem into the Cartridge porthole. Gently squeeze the top bulb to dispense the liquid into the Cartridge. Note: Liquid in the excess reservoir does not need to be dispensed.



15. Replace cap on Vial and retain until the test has returned a conclusive result.

16. Discard the Pipette in a biohazard waste bin.

17. Close Cartridge porthole door. You should hear an audible click when closing it.

18. Open lid of the Proof Lab and insert Cartridge. Push down on the Cartridge until it can't be pushed down any further.

19. Firmly close the lid of the Proof Lab. When the lid is closed, the Proof Lab will detect the presence of the Cartridge.

20. When the Cartridge is detected, the test will begin. **DO NOT OPEN THE LID WHILE THE TEST IS RUNNING.** This will invalidate the test. If the Cartridge is not detected, Proof Lab will return to the Ready state as indicated by the white LED ring shown in "Prepare Proof Lab" section on page 8. Start again by firmly re-inserting the Cartridge into the Proof Lab.

21. When the test is complete, the result will appear on the Proof Lab display. Record the test result shown on the Proof Lab. (For further information, see "Test Result Interpretation" on page 15.)

22. Open the lid of the Proof Lab and remove the Cartridge.

23. The test result will also be punched on the Cartridge. (For further information, see "Test Result Interpretation" on page 15 and "Reporting Test Results" on page 19.)

24. Record the result and discard the Cartridge in a biohazard waste bin.

## Powering Off the Reader

To power off the Proof Lab: Check to make sure that no Test Cartridges have been left in the Proof Lab. Unplug the power cord from the main power outlet.



# Test Result Interpretation

When the test is complete, the result will be shown on both the Proof Lab display and the Test Cartridge.

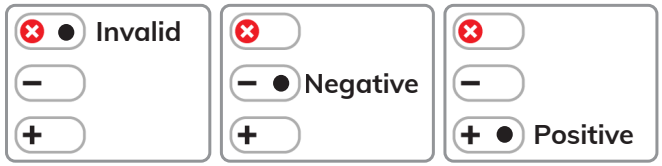
### Proof Lab Display

When the test is complete, the result will appear on the Proof Lab display. Record the test result shown on the Proof Lab.

Negative Positive Invalid

### Test Cartridge

The test result is also recorded on the Test Cartridge



### IF THE TEST RESULT IS NEGATIVE, SARS-COV-2 HAS NOT BEEN DETECTED

**Negative Result:** COVID-19 has not been detected in the tested sample. Although highly accurate, there is a small possibility that the test will give a false negative reading. It is the responsibility of the healthcare provider to determine the best care options based on the test result, possible exposure to the virus, the patient's symptoms and their medical history.

### IF THE TEST RESULT IS POSITIVE, SARS-COV-2 HAS BEEN DETECTED.

**Positive Result:** COVID-19 has been detected. Follow your local or state protocols for the reporting and treatment of patients with COVID-19. Although highly accurate, there is a small possibility that the test will give a false positive reading. It is the responsibility of the healthcare provider to determine the best care options based on the test result, possible exposure to the virus, the patient's symptoms and their medical history.

### IF THE TEST RESULT IS INVALID, THE RESULT IS INCONCLUSIVE

**Invalid Result:** The test result is inconclusive. Repeat the test using the specimen collected in the existing sample vial and a new Test Cartridge.
See "Error Alerts" on page 26 for further information.

## Test Result Limitations

- A negative test result may occur if the level of SARS-CoV-2 RNA in a sample is below the detection limit of the test or if the sample was collected or handled improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- Negative results should be treated as presumptive and, if consistent with clinical signs and symptoms or necessary for patient management, should be tested with a different authorized or cleared molecular test.
- If a test is determined to be invalid, discard the Test Cartridge and re-run the retained patient sample.

## Conditions for Authorization

The Proof Diagnostics COVID-19 Test Letter of Authorization[1], along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist in using the Proof Diagnostics COVID-19 Test, the relevant Conditions of Authorization are listed below:

- Authorized laboratories using your product will include with the test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product will use your product as outlined in the Proof Diagnostics COVID-19 Test System User Manual and Quick Reference Instructions. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, other authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Proof Diagnostics (TBD) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit and use your product in accordance with the authorized labeling.
- Proof Diagnostics, authorized distributors and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

1 The letter of authorization refers to "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation" as "authorized laboratories."

## Reporting Test Results

Test results should be reported to state and local public health authorities in accordance with applicable local, state or territorial laws within 24 hours of test completion. Consult your local, state or territorial health authorities for further information on reporting SARS-CoV-2 test results.

# Clinical Performance

The clinical performance characteristics of the Proof Diagnostics COVID-19 Test were evaluated in a multi-site prospective study in the U.S. in which patients were sequentially enrolled and tested. A total of three investigational sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who are representative of the intended users at CLIA-waived testing sites. In this study, testing was conducted by a minimum of four intended users. No training on the use of the test was provided to the operators. Operators used the Quick Reference Instructions to perform testing. To be enrolled in the study, patients had to be symptomatic and suspected/at-risk asymptomatic individuals at the participating study centers.

External control testing, using the Proof Diagnostics COVID-19 Test External Positive and Negative Controls, was performed prior to sample testing for each Proof Lab and by each user.

The performance of the Proof Diagnostics COVID-19 Test was established with [#] nasal swabs collected from individual symptomatic patients and asymptomatic at risk individuals who were suspected of COVID-19 under Institutional Review Board approval and Informed Consent.

Retrospective COVID-19 Positive and Negative Samples were included in the clinical study two weeks after prospective enrollment of subjects. These clinical specimens are included in the study data.

### Proof Diagnostics COVID-19 Test Performance Against Comparator Method:

| PROOF DIAGNOSTICS COVID-19 TEST | CDC 2019-NOVEL CORONAVIRUS (2019-NCOV) REAL-TIME RT-PCR DIAGNOSTIC PANEL | | |
|---|---|---|---|
| | POSITIVE | NEGATIVE | TOTAL |
| POSITIVE | TBD | TBD | TBD |
| NEGATIVE | TBD | TBD | TBD |
| TOTAL | TBD | TBD | TBD |
| Positive Agreement: TBD/TBD | TBD% (95% CI: TBD%-TBD%) | | |
| Negative Agreement: TBD/TBD | TBD% (95% CI: TBD%-TBD%) | | |



## Patient Demographics

Patient demographics (gender and age) are available for the [#] samples used in the analysis. The table below shows the positive results stratified by patient age.

| GENDER | PROOF DIAGNOSTICS COVID-19 TEST | | |
|---|---|---|---|
| | TOTAL | POSITIVE | PREVALENCE |
| MALE | TBD | TBD | TBD |
| FEMALE | TBD | TBD | TBD |

| AGE | PROOF DIAGNOSTICS COVID-19 TEST | | |
|---|---|---|---|
| | TOTAL | POSITIVE | PREVALENCE |
| ≤ 5 YEARS | TBD | TBD | TBD |
| 6 TO 21 YEARS | TBD | TBD | TBD |
| 22 TO 59 YEARS | TBD | TBD | TBD |
| ≥ 60 YEARS | TBD | TBD | TBD |

## Analytical Performance

### Limit of Detection (LoD)

The limit of detection for the Proof Diagnostics COVID-19 Test was determined by using viral genomic RNA diluted in pooled negative swab matrix and spiked onto sterile nasal swabs. Three-fold dilutions of the inactivated virus were prepared and then spiked onto negative nasal swabs in replicates of 3 swabs per dilution. Swabs were then processed to identify the preliminary LoD. The preliminary LoD was defined as the lowest concentration where 3 out of 3 replicates were detected as positive for SARS-CoV-2. The LoD was then confirmed with 20 replicates at the same concentration by spiking 20 swabs and processing them in the same manner.

This LoD study determined the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates tested positive. The LoD for the Proof Diagnostics COVID-19 Test was determined to be TBD.

| CONCENTRATION (PFU/ML) | NUMBER OF POSITIVE/TOTAL | % DETECTED |
|---|---|---|
| TBD | TBD/20 | TBD% |

## Analytical Reactivity (Inclusivity)

The inclusivity of the Proof Diagnostics COVID-19 Test was evaluated using in silico analysis of the assays primers and probes in relation to [#] SARS-CoV-2 sequences available in the GISIAD gene database for N gene. Results TBD

## Analytical Specificity (Cross-Reactivity or Exclusivity)

Analytical specificity of the Proof Diagnostics COVID-19 Test was evaluated by preparing triplicate negative nasal swabs spiked with each of the cross-reactivity organisms listed below. Swabs were placed into the sample vial and processed and analyzed as per the User Manual. No cross-reactivity was observed.

### Cross-Reactivity With Various Organisms

| PATHOGEN | CONCEN-TRATION (PFU/ML) | SARS-COV-2 DETECTED | PATHOGEN | CONCEN-TRATION (PFU/ML) | SARS-COV-2 DETECTED |
|---|---|---|---|---|---|
| Adenovirus (71) | | TBD | RSV (type A) | | TBD |
| Parainfluenza virus type 1 | | TBD | RSV (type B) | | TBD |
| Parainfluenza virus type 2 | | TBD | Human Metapneumo-virus | | TBD |
| Parainfluenza virus type 3 | | TBD | Enterovirus (EV68) | | TBD |
| Parainfluenza virus type 4 a | | TBD | Human Rhinovirus | | TBD |
| Influenza virus A/New Cale-donia/20/99 (H1N1) | | TBD | Human coronavirus NL63 | | TBD |
| Influenza virus A/Beijing/ 262/95 (H1N1) | | TBD | Human coronavirus HKU1 | | TBD |
| Influenza virus A/NewYork/ 55/2003 (H3N2) | | TBD | Human coronavirus 229E | | TBD |
| Influenza virus B/Florida/4/2006 | | TBD | Human coronavirus OC43 | | TBD |
| SARS-corona-virus | | TBD | MERS-coronavirus | | TBD |
| Chlamydia pneumoniae | | | | TBD | TBD |
| Haemophilus influenzae | | | | TBD | TBD |
| Legionella pneumophila | | | | TBD | TBD |
| Mycobacterium tuberculosis | | | | TBD | TBD |
| Streptococcus pneumoniae | | | | TBD | TBD |
| Streptococcus pyogenes | | | | TBD | TBD |
| Bordetella pertussis | | | | TBD | TBD |
| Mycoplasma pneumoniae | | | | TBD | TBD |
| Pneumocystis jirovecii | | | | TBD | TBD |
| Candida albicans | | | | TBD | TBD |
| Pseudomonas aeruginosa | | | | TBD | TBD |
| Pooled human nasal wash | | | | N/A | TBD |

### Interfering Substances

The Proof Diagnostics COVID-19 Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. Negative specimens were evaluated in triplicate to confirm that the substances were not cross-reactive with the test. Specimens containing SARS-CoV-2 at a concentration near the limit of detection were also evaluated in the presence of the substances in triplicate to confirm that SARS-CoV-2 could still be detected. Results of the study are below.

| INTERFERING SUBSTANCE | ACTIVE INGREDIENT | CONCENTRA-TION | SARS-COV-2 DETECTED (CROSS-REACTIVITY) | SARS-COV-2 DETECTED (INTERFERING SUBSTANCE) |
|---|---|---|---|---|
| Blood (whole) | Blood | 4% | TBD | TBD |
| Purified mucin protein | Mucin | 0.5% | TBD | TBD |
| Chloraseptic | Benzocaine, Menthol | 1.5 mg/mL | TBD | TBD |
| Naso GEL (NeilMed) | Naso GEL | 5% v/v | TBD | TBD |
| Nasal Drops | Phenylephrine | 15% v/v | TBD | TBD |
| Afrin nasal spray | Oxymetazoline | 15% v/v | TBD | TBD |
| Nasal spray | Cromolyn | 15% v/v | TBD | TBD |
| Zicam Cold Rem-edy | Galphimia glauca, Luffa operculate, Sabadilla | 5% v/v | TBD | TBD |
| Homeopathic (Alkalol) | Alkalol | 1:10 dilution | TBD | TBD |
| Sore throat phenol spray | Phenol | 15% v/v | TBD | TBD |
| Tobramycin | Tobramycin | 4 µg/mL | TBD | TBD |
| Mupirocin | Mupirocin | 10 mg/mL | TBD | TBD |
| Flonase | Fluticasone | 5% v/v | TBD | TBD |
| Tamiflu | Oseltamivir | 5 mg/mL | TBD | TBD |



# Proof Lab Reader Maintenance

## Cleaning the Reader

- Disconnect the Proof Lab from the main power outlet before cleaning. Do not attempt to clean inside the cartridge insertion slot.
- Do not immerse the Proof Lab in liquid.
- Only wipe the external surfaces of the Proof Lab using the recommended cleaning agents.
- Always ensure that proper laboratory procedures are followed when handling and disposing of potentially hazardous material.

The following cleaning steps can be performed when necessary.

1. Make sure that no Test Cartridge has been left in the Proof Lab.
2. Disconnect the Proof Lab power cord from the main power outlet.
3. Use a soft cloth with 70% isopropyl alcohol solution or 0.6% bleach solution to clean the outside surface of the Proof Lab.
4. Allow the Proof Lab to air dry.

## Updating Firmware

When Proof Lab firmware updates become available, they can be downloaded and installed using the Proof Diagnostics Update Application for tablets and mobile devices.

# Error Alerts

**ERROR STATE 1 – POWER ON ERROR**
**What to do**

1. Open Proof Lab lid.
2. If Cartridge is present, remove Cartridge. Note: If Cartridge is punched, record test result and discard. If not punched, record “no result” and discard.
3. Close lid. Wait 30 seconds for Proof Lab to return to Ready state. If the display returns to the Ready state, start a new test.
4. If error remains, contact Technical Support at (tbd).

**ERROR STATE 2 – INVALID**
**What to do**

1. Record Invalid result, then open lid.
2. Remove Cartridge from the Proof Lab and note if the result label is punched as Invalid. If so, record test result.
3. Close lid. Wait 30 seconds for Proof Lab to return to Ready state. If the display returns to the Ready state, start a new test.
4. If error remains, contact Technical Support at (tbd).



# Technical Specifications

| **PROOF LAB SPECIFICATIONS** | |
|---|---|
| Dimensions | 5.5 width x 5.5 length x 6.7 height (140 x 140 x 170 mm) |
| Weight | < 2.5 lbs (< 1.13 kg) |
| Power Supply Specifications | Low voltage power supply +12V, 24Watts |
| Operating Temperature | 64 to 86°F (18 to 30°C) |
| Operating Humidity | 15% to 80% relative humidity |
| Operating Altitude | Less than 2000m |
| **COVID-19 TEST KIT SPECIFICATIONS** | |
| Shelf Life | TBD |
| Storage Temperature | 64 to 86°F (18 to 30°C) |

# Table of Symbols

The following symbols are used on the Proof Lab and COVID-19 Test Kit packaging. [All symbols TBC]

| | |
|---|---|
| | Manufacturer |
| | Date of Manufacture |
| LOT | Batch Code |
| SN | Serial Number |
| REF | Reference |
| | Product Expiration Date |
| | Refer to User Manual |
| | Single Use Only. Do Not Re-Use |
| | Do Not Use if Package Is Damaged |
| IVD | For In Vitro Diagnostic Use |
| Rx only | Prescription Only |



# Regulatory Notices

## Declaration of Conformity

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

**WARNING:** Any changes or modifications not expressly approved by Proof Diagnostics could void the user's authority to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult with the dealer or an experienced technician for help.

# Support

(TBD)

# Warranty

The Proof Lab shall maintain accuracy over its lifetime (for at least 3 years) after post-manufacturing checks.

# Disposal

Please ensure the proper disposal of the Proof Lab according to all relevant local laws. Plastic and electronic components should be disposed of at a recycling facility. Please refer to your local regulations regarding the proper disposal of electronic devices.

proof™

ART-PI-EUA-B