InspectIR COVID-19 Breathalyzer (for use on PNY-1000)

For Use Under and Emergency Use Authorization (EUA)
For use with exhaled breath sample/specimen
For *in vitro* Diagnostic Use Only
℞ Only
Version 1.0: April 2022

INTENDED USE

The InspectIR COVID-19 Breathalyzer is a portable, rapid gas chromatography-mass spectrometry (GC-MS) test for the *in vitro* qualitative detection of five Volatile Organic Compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection in exhaled breath from individuals 18 years and older, with or without symptoms or other epidemiological reasons to suspect COVID-19.

Results are for the detection and identification of VOCs in breath. Positive results indicate the presence of VOCs markers associated with SARS-CoV-2 infection, but clinical correlation with patient history and other diagnostic information is necessary to determine SARS-CoV-2 infection status. Positive results should be treated as presumptive and confirmed with a molecular assay. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and should undergo follow up testing if necessary for patient management.

The InspectIR COVID-19 Breathalyzer is intended for use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law* to prescribe tests. The InspectIR COVID-19 Breathalyzer is only authorized to be used in an environment where the patient specimen is both collected and analyzed. The InspectIR COVID-19 Breathalyzer is only for use under the Food and Drug Administration's Emergency Use Authorization.

Test results will be reported by the ordering healthcare provider to relevant public health authorities in accordance with local, state, and federal requirements.

* Under section 201(a)(1) of the Act, the term "State" is defined to mean "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico."

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally, including in the United States.

The InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument is a qualitative assay for the detection of breath VOC metabolites associated with SARS-CoV-2 infection.

The non-invasive detection of COVID-19 provided by the InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument is based on VOC analysis. Exhaled breath is a rich source of biomarkers and is starting to be used in the context of medical and health-related issues [1]. VOCs are produced as the result of metabolic processes throughout the body and reach the breath via the bloodstream.

1) Product Overview/Test Principle:

The technology of the PNY-1000 instrument is a portable system for gas chromatography (GC) coupled with a quadrupole mass spectrometer (MS). The linear quadrupole is specifically designed to function as a GC detector. The analysis of unknown VOC mixtures is performed to identify specific VOC compounds at a high resolution to detect active SARS-CoV-2 infections.

The InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument is designed to detect Five VOCs from the ketone and aldehyde families associated with SARS-CoV-2 (COVID-19) viral infection from exhaled breath samples.

2) Description of Test Steps

A 0.25L breath sample is collected from the subject and the vacuum pumps evacuate the system until the predetermined vacuum is reached. At this point, the breath sample interacts with the pre-concentrator in the system to collect and concentrate the specific VOC targets that will be detected by the downstream Residual Gas Analyzer (RGA). The target analytes and specific elements are detected by the RGA. An algorithm is run to determine what VOCs are present and in what ratios in the Test Subject's breath to make a determination of SARS-CoV-2 'Detected' for a presumptive positive (+) or 'Not Detected' indicating a negative (-) result. All positive test results must be followed up test with a highly sensitive SARS-CoV-2 assay to confirm the positive result. Test results will be displayed on the instrument in less than 3 minutes.

COMPONENTS

Below is a list of components that make up the PNY-1000 spec, table 1 below.

Table 1. PNY-1000 component list

Component	Number/Amount	Description
PNY-1000 base unit (in case)	1	RGA-based vacuum system including turbo pump, diaphragm pump, gauges and micro-PC
Power block / power cord	1/1	Power inverter and plug connection to AC power

[1] N M Grob, M Aytekin, and R A Dweik. Biomarkers in exhaled breath condensate: a review of collection, processing and analysis. J Breath Res. Published online 2008 Sep 8. doi: 10.1088/1752-7155/2/3/037004.

Remote Entry Management	1	Bluetooth connected wireless keyboard and mouse
ORCA	1	InspectIR Systems pre-concentrator
Software: PNY-1000_OS	1	Automation software and COVID-19 detection (only)

Components Required but not Included with the Test:

Additional materials and/or equipment required:

- Disposable powder free gloves (latex or nitrile)
- Disposable isolation gowns
- Face shield or safety goggles
- Clean bench or workspace
- 100-240V power source

Consumables for PNY-1000 instrument:

- Sterile, one-use wrapped straw (.227" inner diameter)
- 30 nanometer filter
- Control material will include positive and negative control material

Note: All consumables for PNY-1000 can be purchased through InspectIR Systems.

PRECAUTIONS/LIMITATIONS

1. For Use Under Emergency Authorization Only
2. For *in vitro* diagnostic use.
3. For prescription use only
4. For use with adults 18 years and older
5. This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use at authorized settings; use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed.
6. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
7. This product has been authorized only for the detection of volatile organic compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection, not for any other viruses or pathogens.
8. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

9. Test results will need to be reported by the ordering healthcare practitioner to all relevant public health authorities in accordance with local, state, and federal requirements.
10. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
11. Proper sample collection is essential for correct results. Follow collection instruction described below precisely.
12. Do not reuse used collection device (straw).
13. The following components of this kit should be discarded as Biohazard waste according to Federal, State, and local regulatory requirements: collection tube (straw) and exit filter.
14. All trained personnel using this product must be appropriately trained and use appropriate laboratory and personal protective equipment when handling this device and use this product in accordance with the authorized labeling. All trained personnel using the assay must also be trained in and be familiar with the interpretation of results of this product.9.
15. Patients should be instructed not to EAT, DRINK, or USE ANY TOBACCO products 15 minutes before providing a breath sample.
16. The performance of the InspectIR COVID-19 Breathalyzer was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
17. False negative results may occur if a specimen is improperly collected or handled.
18. Positive test results do not rule out co-infections with other pathogens.
19. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
20. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
21. Interference testing with systemic Anti-viral/anti-bacterial drugs, nasal ointment, or corticosteroids has been conducted and may be a confounding factor for false results.
22. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2020 and February 2022. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time

Warnings

The PNY-1000 has undergone Electromagnetic Interference and Compatibility testing and is compliant to International Electrotechnical Commission (IEC) 60601-1-2 Edition 4.0:2014 for medical equipment in Class A building(s)/location(s):

1. This device should be used in a suitable environment for MEDICAL EQUIPMENT (ME) with the following precautions:
    a. "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

b. "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
c. "WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Instrument STORAGE AND STABILITY

The InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument has been designed to perform indoors in a climate controlled (temperature and humidity) setting between 20^{o}-30^{o} C (68^{o} - 86^{o} F) where Relative Humidity (RH) is between 40-60%.

A non-running or powered down instrument may be stored and transported in any orientation, level, on its side or upside down. The device may be transported in environments between -10^{o}C and 55^{o}C with Relative Humidity (RH) below 90%.

CONTROL MATERIAL and CALIBRATION CHECK

Calibration for mass spectrometry is important to match the relative intensity of the ions matching them to a known entity. The PNY-1000 is a linear quadrupole GC-Mass Spec analyzer, and its' operational performance can be observed and managed with an external control/calibrant check. If a calibration standard measures a minimum of three (3) points along the spectrum and is accurate at those points, the precision of the instrument is assumed to be accurate and correct across the entire spectrum.

While the instrument may be accurate, the instrument performance can be monitored through measurement of the volatile organic compounds (VOCs) of known analyte composition mixed in an inert gas to mimic an exhaled breath. The positive control uses a proprietary mix of specific VOCs associated with viral SARS-CoV-2 viral infection. The negative control contains highly purified nitrogen.

Instructions for use (IFU) for the control material is included to make sure users of the InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument provides consistently results.

The control material needs to be run daily, regardless of usage, or frequency of tests run. If the instrument does not give a "detect: Presumptive positive" result with the positive control, users will need to call or email InspectIR Systems Technical Support immediately and cease use of the device until it is properly calibrated.

The control material will be produced by InspectIR Systems in collaboration with the University of North Texas and will be sold with the PNY-1000 as part of the "materials needed but not provided", specifically Tedlar bag(s), control and 10µL syringe(s).

SPECIMEN COLLECTION AND HANDLING

Test specimens immediately upon collection 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) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Exhaled Breath Sample (0.25L)

This test kit is to be used for the detection of markers associated with SARS-CoV-2 infection from human breath that is exhaled directly into the PNY-1000 device.

SPECIMEN TRANSPORT AND STORAGE

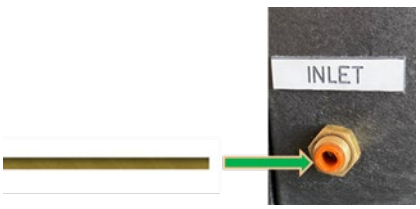
The design of the InspectIR COVID-19 Breathalyzer for use on the PNY-1000 takes exhaled breath *directly into the instrument* for immediate collection and analysis. There is no storage or transport of collected specimen available for this assay.

TESTING PROCEDURE

Breath Specimen Collection for use on the InspectIR PNY-1000:
Procedure for testing patients
Important: Prospective subjects should NOT have had anything to EAT, DRINK, or TOBACCO products 15 mins prior to blowing into the InspectIR COVID-19 Breathalyzer

1. To collect a breath sample, the operator carefully inserts the end of the collection tube (cardboard straw) into the instrument where it is labeled INLET figure 1.

Figure 1. inlet port on the PNY-1000

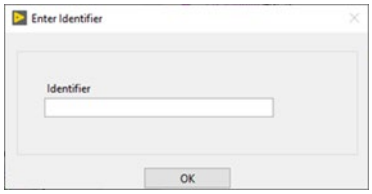


2. To start a test, the test operator will 'select' the large green START button, figure 2. below.

Figure 2. Start button

a. This will prompt the test operator to enter a unique identifier for the subject (patient number, QR code number, random alphanumeric, name, etc.) figure 3 below

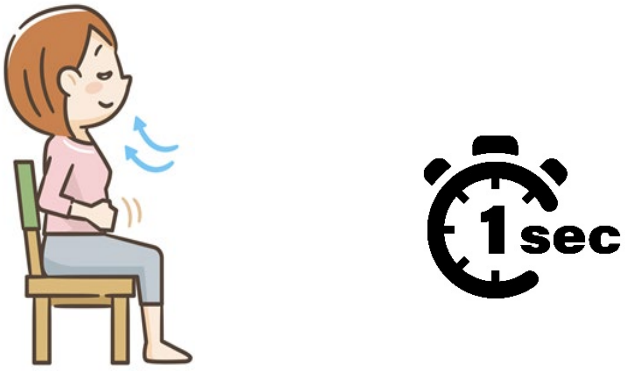
Figure 3. unique identifier



b. 'Select' "Ok"

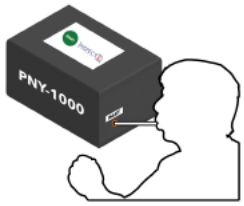
3. The operator then ask the subject to take a "deep breath and hold for one (1) second" figure 4.

Figure 4. subject deep breath and hold for 1 second



4. The subject will then be instructed to place their lips completely around the straw (forming a seal) and exhaling/blowing into the straw like they are 'attempting to blow up a balloon'. The subject's lips should remain in place until sample is completed Figure 5.

Figure 5. lips on straw



a. To collect the sample of 0.25L of exhaled breath most subjects will do this in 10 seconds or less. The software will have an indicator to provide verbal cues to progress, figure 6.
Figure 6. exhale for 10 seconds

b. The software measures progression towards completion
c. IF necessary, sample MAY BE collected in more than one exhaled breath.
    i. Subsequent breaths should be attained in the same (original) manner
        1. Deep inhale, hold for 1 second, blow
d. IF subject coughs, but provides necessary sample, test will proceed with 0.25L of breath
e. IF subject coughs, but DOES NOT provide necessary sample, like "c" above, sample MAY BE collected in more than one breath.
    i. Subsequent breaths should be attained in same (original) manner
        1. Deep inhale, hold for 1 second, blow
f. Upon successful completion, the operator may remove the collection tube (straw) and discard appropriately figure 7.
Figure 7. dispose of straw in biohazard bag

5. Breath is collected on patented InspectIR pre-concentrator (US 10,813,585).
6. Proprietary software package automates the rest of the test process
    a. Progress meters are part of the user interface (UI) and give a general timeframe until completion
    b. Identification and quantification of mass spectra and specific VOCs identified with COVID-19 will provide displayed result figure 8 and 9 below

Figure 8. negative result

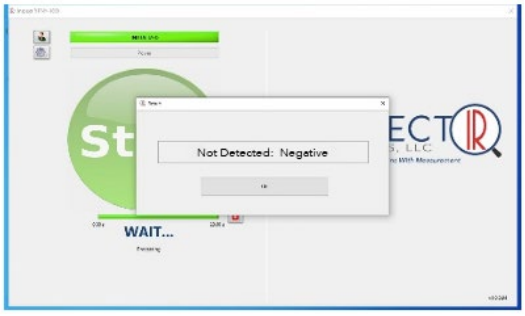
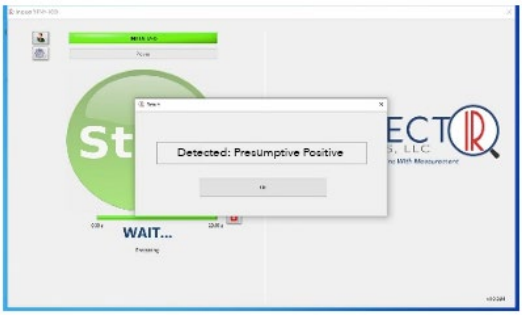


Figure 9. positive result



NOTE: The instrument is designed to run 'right side up' and the orientation is clear between TOP and BOTTOM. We will call this position zero degrees (0^o). While not ideal, measured on its' front rotational axis, the instrument will function on either its' left side (90^o) or right side (270^o). A good way to indicate this is to make sure the display screen is either facing up or is perpendicular to the surface the instrument is placed on. Running the instrument 'upside down' (display screen facing surface) is not recommended and may cause a catastrophic failure. Ideally the device should be placed at approximately 42 inches off level ground for optimal breath collection.

RESULT INTERPRETATION

The InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument is a qualitative assay for the detection of breath VOC metabolites associated with SARS-CoV-2 infection. This test detects five VOCs associated with SARS-CoV-2 infection. Software package and automation functions will provide results in less than 3 minutes displayed on the instrument. See table 2. below for the interpretation of results.

NOTE: The auto-interpreted results can be exported (.csv or .log file) for reporting in a specified format (such as excel or pdf).

Table 2. results for PNY-1000 COVID-19 Breathalyzer

Value	Result
Detected; Presumptive Positive	Presumptive Positive (+)
Not Detected; Negative	Negative (-)

- A positive result indicates the detection of VOCs associated with the presumptive detection of SARS-CoV-2 infection
- A 'False positive' result may occur, but all "positive" results must be confirmed with a highly sensitive FDA Authorized molecular assay. False positives results are not indicative of infectious virus or COVID-19
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- Negative results do not preclude infection with SARS-CoV-2 virus and should not be the sole basis of a patient management decision.
- False-negative results may arise from:
    - Improper sample collection
    - Mutation in the SARS-CoV-2 virus
    - Failure to follow instructions for use

CONDITIONS OF AUTHORIZATION FOR AUTHORIZED SETTINGS

The InspectIR COVID-19 Breathalyzer test for use on the PNY-1000 instrument Letter of Authorization, along with the authorized labeling, including a Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, and package inserts are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

However, to assist authorized test sites using the InspectIR COVID-19 Breathalyzer for use on the PNY-1000, the relevant Conditions of Authorization are listed below:

- Authorized Settings using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized Settings using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized Settings that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized Settings using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate.

- Authorized Settings must 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 you (via email: techsupport@inspect-ir.com, or via phone by contacting InspectIR Systems Technical Support at 1-469-206-4555) 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 in Authorized Settings under the supervision of healthcare providers must be appropriately qualified and 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.
- You and Authorized Settings using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

PERFORMANCE CHARACTERISTICS:

ANALYTICAL PERFORMANCE

1) ***Limit of Detection (LoD)***

The LoD was determined for each of the five VOC targets analytes using the InspectIR COVID-19 Breathalyzer test on the PNY-1000 instrument. Due to constraints in having breath samples (as controls (or reference panels)) for COVID-19, the analysis was conducted by having healthy individual (SARS-CoV-2 negative) breath into tedlar bag and have each of the five target analytes spiked in at a concentration of 10 part per billion (ppb). If any one of the target analytes is below the concentration of 10 ppb the device will not detect sample. The LoD of 10 ppb when all five of the analytes are present was confirmed with 20 of 20 replicates detected. The LoD study confirmed that when any of the five target analytes was tested at 1 ppb and the remaining four analytes were at 10 ppb the device did not detect the VOC profile associated with SARS-CoV-2. Each replicate was contrived with individual human breath collected in a tedlar bag and each of the five VOC targets spiked into the bag.

2) ***Repeatability:***

A Repeatability study was performed in-house to demonstrate agreement between multiple measurements from contrived samples across a 12 day period. Samples were measured in duplicate in the morning and in the afternoon. The panel consisted of a true negative and true positive at 3x LoD for the assay. Panel members were made from negative human breath collected in tedlar bags. The positive panel members were contrived from negative human breath was spiked with the five target VOCs. From the 72 data points collected the results were correctly called 100% of the time for the InspectIR COVID-19 Breathalyzer test.

3) ***Reproducibility:***

A Reproducibility study was performed at three different locations, to demonstrate if operator to operator, day to day or site to site agreement between multiple measurements

from contrived samples across a 5 day period. Samples were measured in duplicate in the morning and in the afternoon. The panel consisted of a true negative and true positive at 3x LoD for the assay. Panel members were made from negative human breath collected in tedlar bags. The positive panel members were contrived from negative human breath was spiked with the five target VOCs. From the 90 data points collected the results were correctly called 100% of the time for the InspectIR COVID-19 Breathalyzer test.

4) ***Interfering Substances:***

An Interference study was performed to demonstrate that other substances that may be encountered in exhaled breath (e.g., cigarette smoke, oral medication, mouth wash, toothpaste, etc.) do not produce a false positive result when tested alone and do not interfere with the InspectIR COVID-19 Breathalyzer test performance when spiked with the target VOCs (i.e. do not produce a false negative result). Interference testing was conducted by contriving samples with human breath. SARS-CoV-2 negative breath was spiked into tedlar bags, and each potentially interfering substances was added when the substance was quantifiable. For substances such as gum, mouth wash, alcohol, or anything the dissolves then the person who used the substance had their breath was collected immediately and again 15 minutes later. For interfering substances testing that used spiked analyte, the analyte concentration is listed below. The five target VOC analytes were spiked at a concentration of 3 x LoD. Each interfering substance was evaluated with (or without target VOC analyte) using 10 contrived samples for each condition.

The list of potential cross reactant or interfering substances is as follows:

- Throat spray (menthol/benzocaine, phenol)
- Throat lozenges (menthol/benzocaine, Dextromethorphan HBr)
- Dry mouth lozenges (Isomalt, xylitol, Glycerin)
- Robitussin syrup
- Nyquil syrup
- Emergen-C
- Breath mints
- Chewing gum
- Vaseline (petroleum jelly)
- Nicotine
- Alcohol
- Oral anesthetic and analgesic
- Whole blood (human)
- FLUMIST QUADRIVALENT
- Zinc (common ingredient in many nasal sprays)
- Nasal sprays (Afrin original nasal spray
- Nasal gel
- Homeopathic allergy relief medicine

None of these substances when tested alone in human breath cause a false positive result.

None of the interfering substances when tested in human breath and with the five target analytes spiked at a concentration of 3 x LoD cause a false negative result.

5) ***Carry-Over/Cross-Contamination:***

InspectIR System conducted a carryover analysis on its' COVID-19 Breathalyzer for use on the PNY-1000 (mass spectrometer). The study aim was to make sure that specimens are not contaminated by the previous sample, in this case, an individual with a high level of target analytes will produce a subsequent "positive" result for another individual with no analyte.

Samples were prepared by having healthy volunteer breath into a tedlar bag. The bag was then spiked with the five target analytes at a concentration of 1,000 x LoD. Over the period of two days, 20 runs of low, high, low were run on the InspectIR COVID-19 Breathalyzer. All results were as expected indicating that no carry-over was observed for the study.

6) ***Biosafety Evaluation***

The PNY-1000 instrument and the InspectIR COVID-19 Breathalyzer test are designed as a self-contained system to assess potential SARS-CoV-2 viral infection via breath sample in non-laboratory settings, including Point-of-Care (POC). However, it is prudent to adhere to standard biosafety practices. The system by design contains mitigation that include filter and heat to render the infectious viral particles in the machine to be rendered inactive.

7) ***Specimen Stability:***

The specimen is not subject to transport via any media or breath collection device. Exhaled breath is introduced directly into the instrument and analysis is done instantaneously.

Clinical Evaluation

8) ***Cross-Reactivity Study in Symptomatic Subjects***

A cross-reactivity study was conducted using breath samples from a diverse, symptomatic population to analyze and determine if VOC similarities exist between SARS-CoV-2 (COVID-19) and other identified upper respiratory pathogens. In the study, paired breath samples were analyzed using the InspectIR COVID-19 Breathalyzer test, (PNY-1000) instrument and with the BioFire Respiratory (RP) P2.1 Panel. The study enrolled only symptomatic subjects that had signs and symptoms of SARS-CoV-2 infections. Enrollment occurred at four locations listed below:

Orlando, FL at the Hyatt Regency Convention Center
Vail, CO at Vail Health (Vail/Frisco/Breckenridge)
Baton Rouge, LA at Integrated Health
Frisco, TX at InspectIR Systems

All subjects were tested with the InspectIR instrument, PNY-1000, to collect a breath sample. All breath samples were correlated to PCR results. PCR testing was done via nasopharyngeal swab. Collection of both samples was done in immediate proximity (less than 5 mins to each other).

Specifically at all site locations PCR testing was conducted using the BioFire Respiratory Panel 2.1 (RP2.1) on the BioFireRP2.1 Film Array system, which is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), in nasopharyngeal swabs (NPS) obtained from individuals suspected of COVID-19 by their healthcare provider.

Table 3. Cross-Reactivity Study Results

InspectIR COVID-19 Breathalyzer	COVID-19 BioFire RP2.1	
	(+)	(-)
(+)	45	3
(-)	1	340*

*52 subjects were positive for other upper respiratory viruses

In the symptomatic population a sensitivity of 97.8% (90% CI: 90.8% - 99.5%) and specificity of 99.1% (95% CI: 97.5%, 99.7%) was observed. With a single 'false negative result

PCR results determined that 46/389 (11.8%) of the symptomatic subjects were COVID-19 positive Table 3. above. 52 subjects were negative by subject and reference tests but were positive for the following other upper respiratory disease, using the Biofire RP2.1. To enrich for Influenza A/B a subset of samples were test results with an available standard of care test. The subjects who were positive with a standard of care test were then enrolled in the cross-reactivity study and were re-tested with the BioFire RP2.1 and found to be positive for Influenza A and negative with the subject breath test.

23 Influenza A/B
14 Rhinovirus/enterovirus
7 RSV
4 Parainfluenza
4 non-novel Coronavirus (OC43)

The results from the symptomatic cohort indicate that based on limited viral infections that were circulating during the spring, summer, and fall of 2021 there was no cross reactivity observed with SARS-CoV-2. The results indicate that the breath signature of an increase in volatile compounds, specifically several aldehydes and ketones may be used to effectively indicate SARS-CoV-2 active infection. The results indicate that the InspectIR COVID-19 Breathalyzer test is able differentiate and identify COVID-19 infected individuals from other respiratory viral illnesses based on the VOCs breath print associated with SARS-CoV-2.

9) ***Pivotal Clinical Study in Asymptomatic Subjects***

The purpose of the Prospective (All-Comers) Clinical Study was to evaluate the performance of the InspectIR COVID-19 Breathalyzer test for use with the PNY-1000 instrument in asymptomatic individuals. To confirm the InspectIR COVID-19 Breathalyzer test can diagnose SARS-Cov-2 in an asymptomatic individual a clinical study from the asymptomatic population was conducted. Subject who met the following criterion were excluded from the asymptomatic study:

- Recently traveled to an area with known local spread of COVID
- Had close contact with someone who had a laboratory confirmed COVID-19 diagnosis in the last 14 days
- Had a laboratory confirmed COVID-19 diagnosis in the last 14 days
- Had a fever (greater than 100.4^{o} F) or symptoms of lower respiratory illness (cough, shortness of breath, difficulty breathing or sore throat)

The study was conducted in four (4) separate and distinct geographic regions:
Colorado (Vail), a hospital facility, indoor temporary test center
Florida (Tampa), testing at a temporary drive-up testing tent.
Louisiana (Baton Rouge), in a dedicated clinical laboratory facility with walk in testing capabilities
Texas (Frisco), temporary test center in a permanent building.

The Breath samples were administered by trained operator. Across the four clinical sites a total of 11 different trained operators were used. The number of tests administered by each operator ranged from 41 tests to 350 tests. The same training material was used for training all the operators. Training material included

- the breathalyzer user manual
- COVID-19 symptom checklist
- InspectIR COVID-19 Breathalyzer training PowerPoint
- InspectIR COVID-19PNY-1000 training flyer and
- the Research_Recruitment_Script_Covid document.

Once trained the operator was observed while testing subjects for the next two hours.

All breath samples analyzed had a paired PCR result. PCR testing included collection with a nasopharyngeal (NP) swab. Collection of both samples was done in immediate time proximity (less than 5 mins to each other). Enrollment required participants to abstain from eating, drinking, or smoking for at least 15 minutes prior to collection of the breath sample. PCR analysis was conducted with one of the three FDA authorized or cleared test kits listed below:

- Fosun COVID-19 RT-PCR Detection Kit
- BioFire COVID-19 (BioFire Film Array 2.0)
- ThermoFisher TaqPath PCR test kit

The prevalence of SARS-CoV-2 based on PCR was 4.2% in the aggregate from the four locations where the clinical study was conducted. Below is the breakdown of prevalence by location:

- CO 4.93% (34/689) Hospital onsite indoor test facility
- TX 4.01% (33/822) Indoor/outdoor testing facility
- LA 4.08% (18/441) Indoor clinical lab test facility
- FL 3.72% (17/457) Outdoor mobile test facility

A total of Two Thousand-Four Hundred-Nine (2409) subjects participated from Nov 2020 to May 2021. Six Hundred-Eighty-Nine (689) were collected at Site A (Vail, CO), Eight Hundred-Twenty-Two (822) were collected at Site B (Frisco, TX), Four Hundred-Forty-One (441) at Site C (Baton Rouge, LA), and Four Hundred-Fifty-Seven (457) at Site D (Tampa, FL).

The InspectIR COVID-19 Breathalyzer test had a paired PCR result for each of the 2409 individuals that were enrolled. PCR results determined that 102/2409 (4.2%) of the subjects were SARS-CoV-2 positive, 2307/2409 (95.8%) of the subjects were SARS-CoV-2 negative, table 4. below.

The sensitivity for the InspectIR COVID-19 Breathalyzer test was 91.2% (90% CI: 85.4%, 94.8%) and specificity was 99.3% (95% CI: 98.8%, 99.5%). In a large cohort of "asymptomatic" individuals, there were (9) false negative results and 17 false positive results compared to PCR, so the calculated Negative Predictive Value was 99.6% (90% CI: 99.4%, 99.9%).

Table 4 Prospective Clinical Study Results

InspectIR COVID-19 Breathalyzer	PCR	
	(+)	(-)
(+)	93	17*
(-)	9	2290

Sensitivity: 91.2% (90% CI: 85.4%, 94.8%)
Specificity: 99.3% (95% CI: 98.8%, 99.5%)
Negative Predictive Value: 99.6% (90% CI: 99.4%, 99.9%)
*One subject tested SARS-CoV-2 positive with an alternate assay. Five subjects tested negative (agreed with the negative PCR result) upon re-test.

The results indicate that the InspectIR COVID-19 Breathalyzer test can differentiate and identify asymptomatic individuals who may be infected with SARS-CoV-2 via testing of their exhaled breath sample.

10) Omicron (B.1.1.529) Variant testing

Since Pivotal study was conducted prior to the emergence of the omicron variant an additional study was conducted to determine if there were any performance variations associated with the Omicron variant. An additional clinical study was conducted in Frisco Texas, targeting the symptomatic population during the month of February 2022. According to CDC surveillance data during the month of February 2022, Region 6 of the US was experiencing ≥99% of the circulating SARS-CoV-2 to be the Omicron variant. The study enrolled 12 subjects with signs and symptoms compatible with COVID-19. Subjects were swabbed in each nostril. One swab was submitted for comparator testing using the Roche cobas SARS-CoV-2 Test. The second swab was collected and sent off for sequencing to confirm the SARS-C0V-2 was the Omicron variant. The results in comparison to the cobas SARS-COV-2 PCR are shown in Table 5 below.

Table 5 Omicron Study Results

	Roche cobas SARS-CoV-2 Test comparator	
InspectIR COVID-19 Breathalyzer	PCR	
	(+)	PCR (-)
(+)	10	0
(-)	1	1

Sensitivity 90.9% (90% CI 67.7-98.0%)

The preliminary results provided indicate no concerns with detection of the omicron variant.

ORDERING AND CONTACT INFORMATION

InspectIR Systems
8000 Warren Parkway, Bldg 3, Suite 350
Frisco, TX 75033 USA
469.206.4555

PNY-1000: COVID-19 Breathalyzer
PNY-1000_OS: Operating System and Software for COVID-19 Breathalyzer
BT-227: Cardboard Collection Tube (Straw)

Technical Advice Support Line

Email: techsupport@inspect-ir.com
Phone: +1.469.206.4555

How to Perform a SARS-CoV-2 Breath Screening

READ THE MANUFACTURERS' INSTRUCTIONS CAREFULLY BEFORE YOU BEGIN

Preparation for SARS-CoV-2 Breath Collection and Testing

- InspectIR Systems PNY-1000 instrument
- Close access to 115VAC power supply with in-line surge protection.
- Personal protective equipment - gloves, medical mask, eye protection or face shield
- New (unopened) individually wrapped breath sample collection straw
- Medical waste container
- Disinfectant

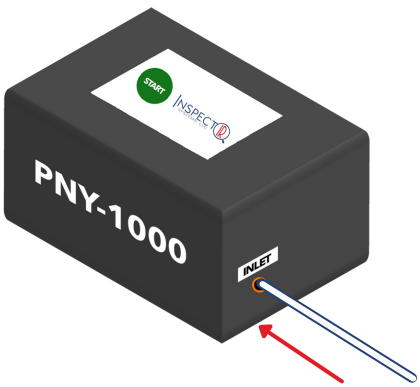
PNY-1000 Power Up Process

1. Plug-in PNY-1000 into 115VAC power supply with in-line surge protection per instruction manual.
2. Once onboard PC has started, power on PNY-1000 instrument keyboard. keyboard will connect to device via bluetooth.
3. Click on-screen Power button to initiate hardware and software applications. Instrument is ready for testing when large green "Start" button illuminates.

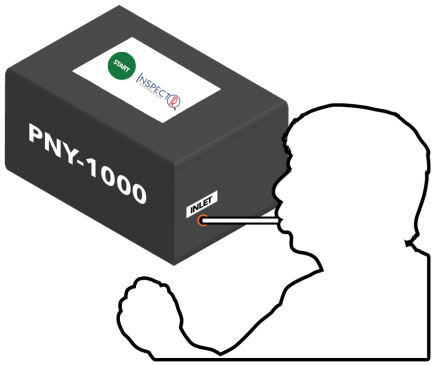
Important: Prior to blowing into the COVID-19 Breathalyzer, subjects 18 years of age or older should NOT have had anything to EAT, DRINK, or use TOBACCO products 15 minutes prior.

SARS-CoV-2 Breath Collection and Testing

1. Unwrap breath collection straw and insert into labeled "inlet" on PNY-1000.
2. Instruct subject to position themselves in front of device. Press large green "START" button to initiate test.
3. Enter unique subject identifier when prompted. Instruct subject to inhale deeply, hold it for 1 second.



4 Instruct subject to exhale steadily until told to stop. Monitor on-screen progress of PNY-1000 until breath collection is complete.

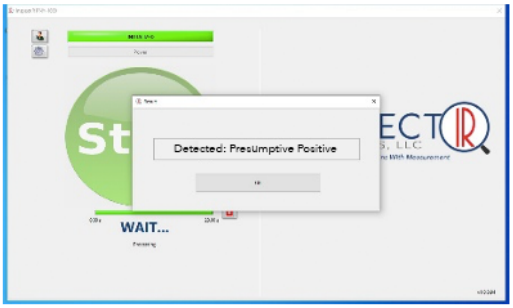


5 Dispose of straw into medical waste container. Monitor on-screen progress of PNY-1000 until results are provided.

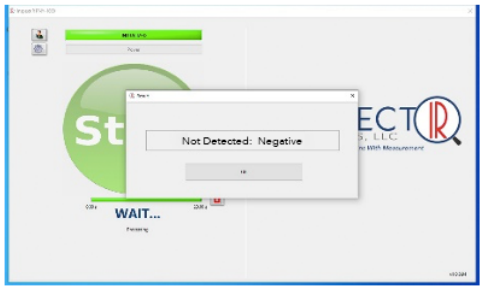
6 Read test results. See below for screen reporting.

Interpretation of Test Results

Positive:



Negative:



This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized settings; use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed;

This product has been authorized only for the detection of volatile organic compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection, not for any other viruses or pathogens; and,

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

8000 Warren Pkwy
Bldg 3, Suite 350
Frisco, TX 75034

www.inspect-ir.com

Office: (469) 206.4555
Tech Support: (844) 385-9593
techsupport@inspect-ir.com

INSPECT IR
SYSTEMS, LLC
Accountability Begins With Measurement

InspectIR COVID-19 Breathalyzer Test for Use on PNY-1000 User Manual

PNY-1000_revision_9.1

Contents

SYSTEM PREFACE

For Use Under and Emergency Use Authorization (EUA)
For use with exhaled breath sample/specimen
For in vitro Diagnostic Use Only

This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized settings; use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed;

This product has been authorized only for the detection of volatile organic compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection, not for any other viruses or pathogens; and,

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

SYSTEM OVERVIEW

The system consists of a TSI 5200 Gas Flow Meter, a National Instruments USB Digital Input/Output (DIO) card, a custom relay board, a Pfeiffer MVP Rough Pump, two Pfeiffer pressure gauges, a Pfeiffer MG250 PrismaPro Residual Gas Analyzer (RGA), and an InspectIR ORCA pre-concentrator.

A breath sample is collected from the user and the system is pumped down until it is under vacuum. At this point, the breath sample interacts with the pre-concentrator in the system in order to create a chemical reaction that is detected by the RGA. The chemistry and specific elements are detected by the RGA. An algorithm is run to determine what compounds are present and in what ratios in the Test Subject's breath to make a determination of pass/fail.

STEPS FOR SYSTEM FUNCTIONS

Powering Up/Turning the Device On

The InspectIR COVID-19 Breathalyzer is turned on in four steps:

1) Attach/Screw-in the power input into the InspectIR PNY-1000 device (see Figure 1).

2) Once the power input is attached to the device, plug the power cable into a power source.
3) With power to the device, the PC will startup and after one to two minutes, the device will display a computer screen (Microsoft Windows). Once test operator sees this screen, launch the InspectIR Breathalyzer program (see Figure 2).
4) When the program is open, the test operator will see a button/option that says Power (see Figure 3). Click on the power button. This will begin the pump down process for the device; bringing the device to its ideal internal pressure. Once this is done, wait until the green Start button becomes more vibrant and the bar above the power button is green and says Initialized. This process takes about 5 minutes (see figure 4).

Figure 1: External Power Connection

Figure 2: InspectIR COVID-19 Breathalyzer Software Icon (shortcut)

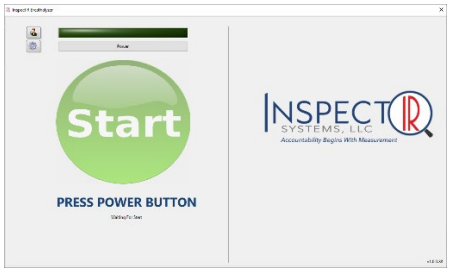


Figure 3: System Power On (startup)

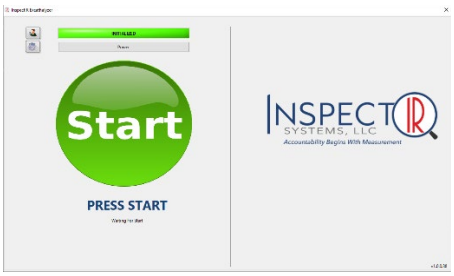


Figure 4: System Ready

Once all these steps are done, the device is ready to be used for data acquisition.

Data Acquisition

The InspectIR COVID-19 Breathalyzer is designed with minimal user interaction in mind. Upon the device's completion of reaching its ideal pressure, the green Start button becomes more vibrant (see figure 5).

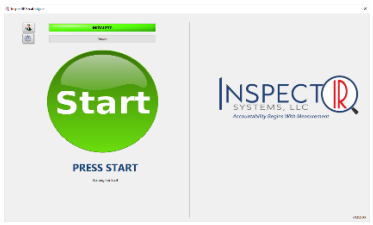


Figure 5: Start Button, Ready to Sample

To start the test, the test operator should press the start button. A dialog will be displayed asking the test operator to enter a unique ID for the Test Subject. This will be the identifier that allows the test sample to be associated to a unique test subject. Once the test operator has input the unique ID for the test subject, the test operator will press the OK button (see Figure 6).

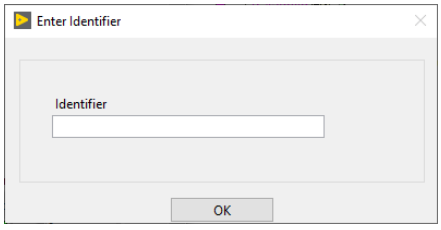


Figure 6: Unique Identifier Input

Once the test operator sees the "Begin Exhale" the test operator will insert a straw into the orange hole designated as "Inlet" (see Figure 7).

Figure 7: System Inlet

After the straw is inserted into the inlet, the test operator will prompt the test subject to begin blowing into the test straw. The test operator should advise the test subject to take in a deep breath, hold the breath for 1 second, and then blow as hard as they can into the straw. As breath is collected, the test screen will show the amount of air being collected on a progress bar (see Figure 8). The collection process takes roughly ten to twelve seconds, but the time required to fill the device can be greater than or less than that depending on the respiratory capabilities of the Test Subject.

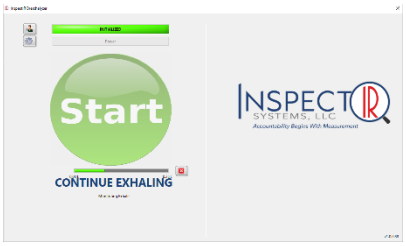


Figure 8: Breath Sample Collection – Progress Meter

Once the necessary amount of air is collected by the system, it will begin rough pumping until the desired pressure is reached. The status bar will show a pressure reading, giving feedback to the user on how close the system is to reaching an ideal pressure (See Figure 9).

Figure 9: Re-Establishing Vacuum

Once the system is at its ideal pressure, it will automatically communicate with the Residual Gas Analyzer (RGA) to prepare for sample (see Figure 10). Once this has been done, the system will automatically begin analyzing the data. Data will be collected over a period of 30 seconds. After 30 seconds, the breath sample will then interact with the pre-concentrator for a configurable timeframe (up to 500 milliseconds). During this interaction, data will continue to be acquired. After the interaction is complete, data will be collected for an additional 20 seconds until the system returns to a baseline value (see Figure 11).

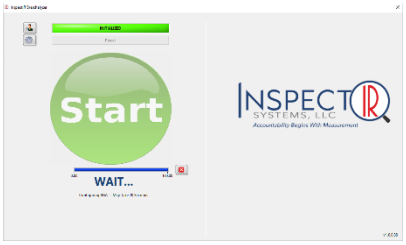


Figure 10: RGA Communication

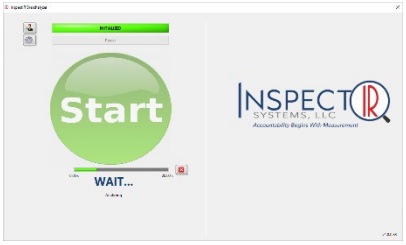


Figure 11: Analyzing Progress Bar

Upon completion of the analysis, the acquired data will automatically be analyzed and compared to the InspectIR database of compounds to determine whether a variety of substances, if any, are present in the breath sample. The result will be displayed to the test operator with a dialogue box that indicates the chemistry is not present or "Negative: Not Detected" for a negative sample (see Figure 12). For a positive sample, a similar dialogue box will appear with the phrase "Detected: Presumptive positive" (See Figure 13). All Positive results should be treated as presumptive and confirmed with a molecular assay

Figure 12: "Negative: Not Detected

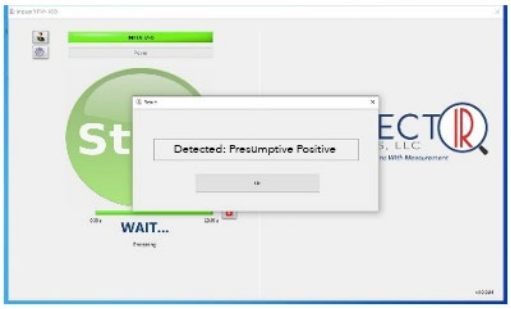


Figure 13: "Detected: Presumptive positive"

Powering Down the System

To power down the InspectIR COVID-19 Breathalyzer, the test operator will follow these steps:

1) Click on the power Button in the InspectIR COVID-19 Breathalyzer program. This will begin spinning down the rotor from 90,000 RPM. Once the rotor is spun down, the test operator should no longer see the bar above the power button as green, and the start button should become less vibrant.
2) After the device is powered down via the InspectIR COVID-19 Breathalyzer program, the test operator can exit the InspectIR COVID-19 Breathalyzer program and unplug the device from the power source.

Make sure the device is powered down in the program first before unplugging the device from the power source. [This process is the reverse of the start-up procedures and also fully automated]

Settings Screen

For authorized users, the settings screen may be used in order to set various configuration values for the system. This screen can be opened by pressing the settings button in the upper right corner of the main screen (see Figure 14).

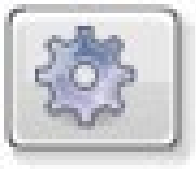


Figure 14: Settings Screen Button

Great care should be taken if these settings are to be changed, as incorrect settings can result in inability to communicate with the available instrumentation in the system.

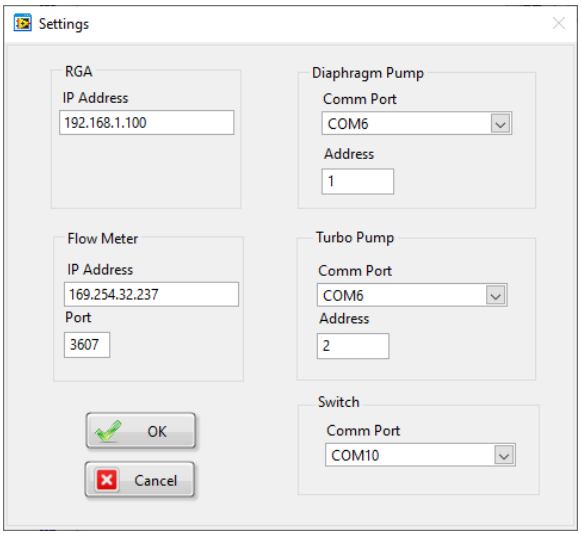


Figure 15: Configuration Screen

The flow meter and RGA communicate with the InspectIR COVID-19 Breathalyzer Application using TCP/IP connections. The application will attempt to communicate with the instrumentation at the addresses configured on this screen. Currently no direct communication is done directly with the vacuum pumps. They are controlled by relays and will be in a binary state of either on or off.

In the future it is possible we will more finely control the vacuum pumps through the application, so the configuration items are here as a placeholder. The switch configuration will set the address on which the application will communicate with the switch board in the system. Once all configuration items are set as desired, press the OK button in order to save the settings and close the window.

IEC 60601 Compliance

The PNY-1000 has undergone Electromagnetic Interference and Compatibility testing and is compliant to International Electrotechnical Commission (IEC) 60601-1-2 Edition 4.0:2014 for medical equipment in Class A building(s)/location(s): the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the test OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

The Equipment Under Test (EUT) is not PERMANENTLY INSTALLED

Declaration of Emissions :

This system is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.		
Emissions Test	**Compliance**	
RF emissions CISPR 11	Group 1	The EQUIPMENT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The EQUIPMENT is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

Table 16: Declaration of Emissions (EN/IEC 60601-1-2 Table 1)

CAUTION: The PNY-1000 system should not be used adjacent to or stacked with other equipment. The PNY-1000 Monitor should be observed to verify normal operation in the configuration in which it will be used. Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Declaration of Immunity:

This system is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment listed.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0	Voltage Dips 30% reduction, 25/30 periods At 0	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions	Voltage Interruptions	

	>95% reduction, 250/300 periods	>95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM radio Bands within 150kHz – 80MHz) 3 V/m 80 MHz to 2.7 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EQUIPMENT. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 17: Declaration of Immunity (EN/IEC 60601-1-2 Table 2)

EMC Performance:

Portable and mobile radio communications equipment (e.g., two-way radio, cellular/cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 18: Portable and mobile radio communications equipment distance requirements (EN/IEC 60601-1-2 Table 6)

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band [a] (MHz)**	**Service[a]**	**Modulation[b]**	**Maximum Power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[c] ±5 kHz deviation 1 kHz sine	2	0.3	28

710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1,3,4,25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Table 19: Immunity to RF Wireless Communications Equipment

InspectIR COVID-19 Breathalyzer Control Material for use on the PNY-1000 instrument

For Use Under and Emergency Use Authorization (EUA)

For use with exhaled breath sample/specimen

For in vitro Diagnostic Use Only

This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized settings; use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed;

This product has been authorized only for the detection of volatile organic compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection, not for any other viruses or pathogens; and,

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Background: Calibration for mass spectrometry is important to match the relative intensity of the ions matching them to a known entity. The PNY-1000 is a linear quadrupole GC-Mass Spec analyzer and its' operational performance can be observed and managed with an external control/calibrant check. If a calibration standard measures a minimum of three (3) points along the spectrum and is accurate at those points, the precision of the instrument is assumed to be accurate and correct across the entire spectrum.

While the instrument may be accurate, the instrument performance can be monitored through measurement of the volatile organic compounds (VOCs) of known analyte composition mixed in an inert gas to mimic an exhaled breath. The positive control uses a proprietary mix of specific VOCs associated with viral SARS-CoV-2 viral infection. The negative control contains highly purified nitrogen.

Trade Name: InspectIR COVID-19 Breathalyzer Control Material

Kit Components:

- One (1) InspectIR Positive (+) control material vial [ready-to-use liquid]
- Two (2) Tedlar Bags filled with Ultra High Purity (UHP) Nitrogen. One will serve as negative control, and one will be used to prepare the positive control

*The InspectIR COVID-19 Breathalyzer Control material is designed for and intended to be used solely with the InspectIR COVID-19 Breathalyzer for use on the PNY-1000.

Intended Use - Quality Control: InspectIR COVID-19 Breathalyzer Control material is intended for use as an external positive and negative control to monitor the accuracy, precision, and performance of the InspectIR COVID-19 Breathalyzer for use on the PNY-1000 instrument used for the qualitative detection of SARS-CoV-2 viral infection via exhaled breath.

As part of daily internal quality control (IQC) process(es), or prior to using the InspectIR COVID-19 Breathalyzer for use on the PNY-1000 instrument with subjects, both the COVID positive (+) and COVID negative (-) controls need to be run to ensure the validity of tests and overall assay performance.

Control Material Instructions for Use:

1. Prepare instrument (PNY-1000) for use according to User Manual
    a. Place on secure flat surface
    b. Connect power source
    c. Launch InspectIR Breathalyzer software
2. Prepare control(s)
    a. Gather Tedlar bag labeled 'positive' and InspectIR COVID Positive (+) material vial
    b. Allow InspectIR Positive (+) control vial to thaw and return to room temperature (20^{o}C)
    c. Invert vial three times to mix
    d. Use a micro-syringe with needle to draw 10µL of solution from the vial
    e. Insert syringe needle into the septum of the Tedlar bag
    f. Plunge entire contents (10µL) into the Tedlar bag
    g. Immediately invert and rotate the Tedlar bag to ensure that all liquid is dissipated
    h. Gather Tedlar bag labeled 'negative'
3. Run control(s)/data acquisition using InspectIR COVID-19 Breathalyzer software/test instructions according to User Manual or Quick Reference Guide
    a. Connect 'positive' control bag to instrument at 'inlet'
        i. Press START
        ii. Enter 'unique id' in Identifier pop-up window (we suggest test date or operator initials)
        iii. With both hands "squeeze the bag" and watch progress meter/bar to achieve 0.25L of air to trigger analysis
        iv. System automation will run the rest of the process
        v. Observe test result
            1. "Detected: Presumptive Positive" is a successful control, proceed to 'Step B' (below)
            2. "Not Detected: Negative" is NOT a successful control
                a. Prepare and re-run another positive control
                b. If second run is positive, proceed to Step B'
                c. If "Not Detected: Negative" is the result again, please contact InspectIR Technical Support
                d. DO NOT test breath samples from subjects
    b. Connect 'negative' control bag to instrument at 'inlet'
        i. Press START
        ii. Enter 'unique id' in Identifier pop-up window (we suggest test date or operator initials)
        iii. With both hands "squeeze the bag" and watch progress meter/bar to achieve 0.25L of air to trigger analysis
        iv. System automation will run the rest of the process
        v. Observe test result

1. "Not Detected" is a successful control
2. "Detected: Presumptive Positive" is not a successful control
    a. Re-run another negative control,
    b. If second run is negative, proceed to test breath samples from subjects.
    c. if "Detected: Presumptive Positive" is the result again, please contact InspectIR Technical Support
    d. DO NOT test breath samples from subjects

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended to be used as in vitro diagnostic control material.
- This product is only for use with InspectIR COVID-19 Breathalyzer and PNY-1000 systems. It does not contain any biologic or respiratory pathogens, specifically SARS-CoV-2.
- Appearance: Positive control material may be slightly cloudy.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- InspectIR COVID-19 Control material cannot be cloned, sold, or transferred without the explicit written consent of InspectIR Systems.

STORAGE and STABILITY:

InspectIR COVID-19 Control material should be stored frozen (-25°C to -15°C). Unopened InspectIR COVID-19 Control material is stable through the expiration date printed on the kit label when consistently stored frozen.

InspectIR COVID-19 Control material both Positive (+) and Negative (-) are for regular maintenance. Tedlar bags are intended for single use and should be discarded after use according to your local and federal regulations.

EXPECTED VALUES:

The expected results when the controls are analyzed are contained in Table 1.

Table 1: InspectIR COVID-19 Control material Results Summary

Control	Results
InspectIR COVID-19 Positive (+)	Detected; Presumptive Positive
InspectIR COVID-19 Negative (-)	Not Detected; Negative

Service/Maintenance Schedule: Control material needs to be used daily, as an external quality control and should be a part of initial daily instrument set up. If the instrument does not "alert" on the positive control, users will be instructed to call or email InspectIR Systems Technical Support and should not use the instrument in question for patient testing.

Instrumentation cleaning and maintenance intervals will be arranged and conducted on a regular cadence (contractual basis).

Manufacturing: This positive control material will be produced by InspectIR Systems in collaboration with the University of North Texas and will be sold with the PNY-1000 as part of 'Components Required but not included with the test", specifically Tedlar bag(s), control material and 10µL syringe(s).

Ordering Information: The product will be distributed by InspectIR Systems, 8000 Warren Parkway, Bldg. 3, Suite 350, Frisco, TX 75034 USA.

Customer Support and Technical Support: support@inspect-ir.com; 1.469.206.4555

For more contact information visit www.inspect-ir.com