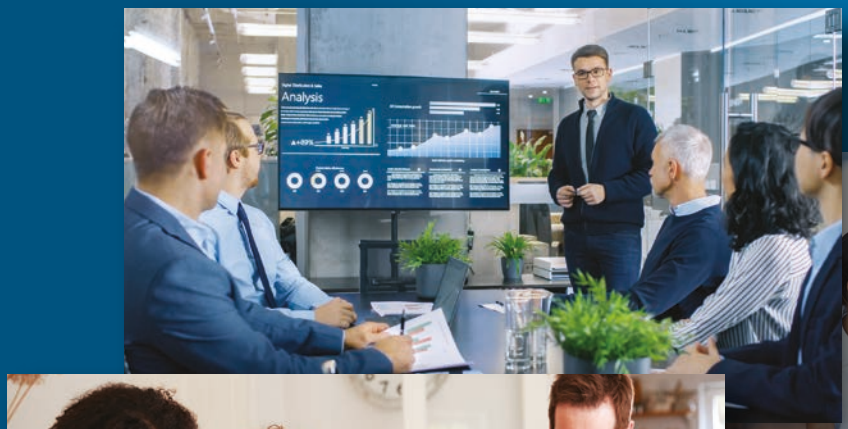
Published on:
Version 02

AirAnswers®

Key Customer Q&A:

The Company, Research, Device and Services





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Quality is core to Inspirotec

Inspirotec's products are certified by ISO 9001:2015, ISO 13485:2016, ISO 14001:2015, ISO 45001:2018, ISO/ IEC 17025

MISSION STATEMENT

Inspirotec's mission is to provide the highest quality of life for allergy sufferers and other indoor air quality stakeholders by giving them control of their environment. Our business focuses on devices and services to consumers, patients, and allergy professionals, and an array of air quality professionals that identify indoor airborne allergens, molds, and other biological materials with healthcare impact. Inspirotec considers environmental testing a key element in personalized healthcare management and this information will be critical in redefining the standard of care.

Our devices and services are designed to be consistently safe, effective, and of the highest quality. We maintain these high standards through metric- driven management and continuous improvement. The consistently reliable outcomes we deliver to our customers will establish confidence for all of our stakeholders.

Inspirotec employees, management, and investors are committed to delivering state-of-the-art quality through:

- Innovative product design based on unique in-house patented technology
- Well trained, accountable personnel
- Best practices in research and manufacturing
- A culture driven by continuous improvement
- A well-documented Quality System Conformance to all applicable regulatory standards
- Awareness of the importance of the environment in healthcare

Everyone at Inspirotec is committed to a customer focused, quality driven, and environmentally conscious culture.

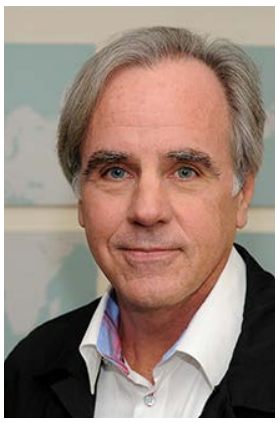
Certified
ISO 9001:2015, ISO 13485:2016
ISO 14001:2015, ISO 45001:2018

ABOUT US

As the inventor and manufacturer of AirAnswers air sampling device, Inspirotec Inc is the only commercial air sampling device that has the capability to collect ultra fine particles (0.1um) and can detect airborne allergens, molds, bacteria and viruses, including the capture of airborne COVID.

Our patented technology is researched in collaboration with leading American universities and published in peer-reviewed scientific literature.

Scientific Advisory Board



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THE COMPANY

Researched in collaboration with:

Johns Hopkins University | Argonne National Laboratory | Harvard University | The University of Chicago

PUBLICATIONS AND OTHER COLLABORATIVE RESEARCH

List of Inspirotec Publications:

1. Richardson, M., et al., Concurrent measurement of microbiome and allergens in the air of bedrooms of allergy disease patients in the Chicago area. Microbiome, 2019. **7**(1): p. 82

Abstract:

The particulate and biological components of indoor air have a substantial impact on human health, especially immune respiratory conditions such as asthma. To better explore the relationship between allergens, the microbial communit, and the indoor living environment, we sampled the bedrooms of 65 homes in the Chicago area using 23 the patient-friendly Inspirotec electrokinetic air sampling device, which collects airborne particles for characterization of both allergens and microbial DNA. The sampling device captured sufficient microbial material to enable 16S rRNA amplicon sequencing data to be generated for every sample in the study. Neither the presence of HEPA filters nor the height at which the air sampling device was placed had any influence on the microbial community profile. A core microbiota of 31 OTUs was present in more than three quarters of the samples, comprising around 45% of the relative sequence counts in each bedroom. The most abundant single organisms were Staphylococcus, with other core taxa both human and outdoor-associated. Bacterial alpha diversity was significantly increased in bedrooms that reported having open windows, those with flowering plants in the vicinity, and those in homes occupied by dogs. Porphyromonas, Moraxella, Sutterella, and Clostridium, along with family Neisseraceae, were significantly enriched in homes with dogs; interestingly, cats did not show a significant impact on microbial diversity or relative abundance. While dog allergen load was significantly correlated with bacterial alpha diversity, the taxa that significantly correlated with allergen burden did not exclusively overlap with those enriched in homes with dogs. Alternaria allergen load was positively correlated with bacterial alpha diversity, while Aspergillus allergen load was negatively correlated. The Alternaria allergen load was also significantly correlated with open windows. Microbial communities were significantly differentiated between rural, suburban, and urban homes and houses that were physically closer to each other maintained significantly more similar microbiota. We have demonstrated that it is possible to determine significant associations between allergen burden and the microbiota in air from the same sample and that these associations relate to the characteristics of the home and neighborhoods.

2. Gordon, J., et al., Validation of a novel sampling technology for airborne allergens in low-income urban homes. Annals of Allergy Asthma & Immunology, 2018. **120**(1): p. 96-+.

Abstract:

Background: For many years, vacuumed dust collection has been the preferred method for assessing allergen exposure because of its ease of collection. Ideally, allergen exposure assessment should be based on measurement of airborne concentrations as this is a truer reflection of airway exposure, but dust collection has been used as a surrogate. Available air sampling methods have been reported as cumbersome, expensive and time consuming. Therefore dust has remained as the standard method for measuring allergen exposure.
Inspirotec Inc. has developed a simple plug-in device for airborne allergen capture. It is compact, unobtrusive, and requires no technical expertise to operate. Though various methods of air sampling have been compared with dust collection, the Inspirotec sampler, has yet to be compared with other air dust and air sampling methods for allergen capture. The purpose of this study was to validate the performance of the Inspirotec air sampler against other available reference methods. In this study, the Inspirotec sampler has been placed side-by-side in homes with PM10 air filters and dust collection by vacuuming. This work is part of an ongoing trial where multiple analyses are performed in urban homes at baseline, 3 months, and 6 months.
Results & Conclusions: The Inspirotec sampler correlates with both PM10 and dust collectors for cat (Feld 1), mouse (Mus m 1) and dog (Can f 1) allergens. All 3 were most frequently found in homes. More positives and lower detection levels were found for all allergens, with the exception of birch pollen, by the Inspirotec sampler versus the PM10 due to large air volumes sampled per unit time by Inspirotec samplers. Less positives were found for cat, dog, dust mite, roach and mouse by the Inspirotec sampler versus dust collection due to more concentrated allergens in the dust. Birch pollen was found outside of the pollen season by both Inspirotec and PM10 for both outdoor pollen counts and indoor pollen allergen concentrations. The Inspirotec sampler showed Phlp 5 allergens within pollen season, while majority of positives were found outside of the season for the PM10 sampler.

3. Gordon, J., et al., Bedroom exposure to airborne allergens in the Chicago area using a patient-operated sampling device. Annals of Allergy Asthma & Immunology, 2018. **121**(2): p. 211-+.

4. Gordon, J., P. Gandhi, and P. Detjen, High Sensitivity Measurements of Airborne Allergens Using a Patient-Operated Sampling Device: A New Technology Reveals Indoor Aerobiome. Journal of Allergy and Clinical Immunology, 2017. **139**(2): p. AB120-AB120.

Abstract:

Background: In current practice, allergens in vacuum-collected dust are used as surrogates for inhalable allergens. We developed an air-sampling device that can be used by patients for direct measurement of airborne allergen concentrations in their own homes.
Objective: To demonstrate the use of this device to establish allergen concentration reference ranges in a target population and to evaluate associations between patient-reported information and measured allergen concentrations.
Methods: Patients from 5 allergist's practices in the Chicagoland region were provided with instructions, questionnaires, informed consent forms, and samplers to run for 5 days in their bedrooms. Samples were collected from cartridges and assayed by multiplex immunoassays for 12 common household allergens and enzyme-linked immunosorbent assay for ragweed.
Results: Unique allergen profiles were obtained for 102 patient homes. Samples with allergen concentrations above the limit of detection were as follows: total dust mite, 28%; cat, 61%; dog, 64%; mouse, 12%; rat, 0%; cock-roach, 4%; Alternaria, 6%; Aspergillus, 21%; birch pollen 1%; grass, 8%; and ragweed, 5%. Of those, 75 completed questionnaires, providing meta-data for further analysis. Pet allergens correlated significantly with number of pets owned. Humidity correlated with dust mite allergens, open windows with Alternaria and mouse allergens, and high-efficiency particulate air filter use with reduced levels of several allergens. Many other variables showed no significant correlations.
Conclusion: The combination of ease of use, high air-sampling rate, and sensitive immunoassays permitted the measurement of airborne allergen concentrations in homes and establishment of reference ranges. Patient-reported information permitted identification of factors that could relate to allergen concentrations and suggested remedial measures.

5. Gordon J, Detjen P, Kelso D, Gandhi P. A new patient-operated sampling device for measurement of aeroallergens. Ann Allergy Asthma Immunol. 2016;116:475–476.

Abstract:

Background: A simple plug-in device for air sampling, which is inconspicuous and requires no technical skill for operation in a variety of settings, has been developed. Performance compared with a reference method for mold species and bacterial microbiome analysis was examined. A study using this system for common allergen profiling in the homes of 22 patients has been previously presented. Selection criteria were homes of patients with allergic rhinitis and/or allergic asthma and ownership of cat, dog, or both.

Methods: Test results from samples in which patients ran the devices in the bedroom for 24 hours and 7 days. Patients executed Health Insurance Portability and Accountability Act and informed consent agreements. They were given a questionnaire with particulars about patient home environment and avoidance measures, including pet avoidance measures. Results: All patients successfully completed runs without supervision. The device incorporates a removable cartridge with releasable electrodes. The released stainless steel electrode strips are extracted directly with standard buffer. The extracts were analyzed with the MARIATM common household allergen multiplex assay6,7 by Indoor Biotechnologies (Charlottesville, VA).

All patients reporting cat ownership had some measurable level of cat allergen in the bedroom, except patient 20, who was apparently successful in excluding the cat from the bedroom and eliminated measurable airborne allergen. Homes with no dog had no detectable dog allergen, with one exception.

Conclusions: This data can be used to test for consistency with patient-reported presence or absence of pets and efficacy of reported mitigation measures. The ability of patients to generate allergen profiles of the breathable air in their own homes provides an otherwise unavailable adjunct to patient care.

6. Gordon, J., et al., Field Performance of a New Technology with the Potential to Identify Allergy and Asthma Triggers. Journal of Allergy and Clinical Immunology, 2015. 135(2): p. AB246-AB246.

Abstract:

Rationale: The Compact Ionic Capture Device (cICD) is a consumer friendly device that collects aerosol particles for testing. The aim is to evaluate its performance for a range of analytes and field conditions.

Methods: Sites were a clean bathroom, a basement with sump drain, and a hay storage room in an equestrian facility. The ICD was run for up to 24 hours at approximately 150 liters. Reference was 0.4 µm polycarbonate filters pumped at 15 lpm. Analytical procedures were MARIA™ 9-plex immunoassays for allergens (Indoor Biotechnologies), multiplex qPCR for 23 indoor molds (EMLabsP&K), and next generation (Illumina) sequencing with Procrustes analysis for V region of bacterial 16S rRNA.

Results: Despite the presence of a unique spectrum of analytes in each environment, there was concordance between cICD and filter for presence or absence of 7 allergens and 21 mold species across all environments. In several instances, significant levels of allergens or spore equivalents were found by the cICD and not by filters. The cICD and filters both showed concordant bacterial community compositions dominated by Actinobacteria, Cyanobacteria, Proteobacteria, and Bacteroidetes. The cICD's high flow rate permitted faster detection of analytes than the filter.

Conclusions: There was remarkable consistency between the performance of the cICD and filters over a wide range of environmental types and airborne analytes. Therefore, the cICD may be used to measure and discover new aeroallergens. In clinical practice, it may easily and reliably confirm suspected allergen exposure, direct avoidance recommendations and assist individualization of therapy for allergic patients.

7. Gordon, J., et al., A simple novel device for air sampling by electrokinetic capture. Microbiome, 2015. **3**.

Abstract:

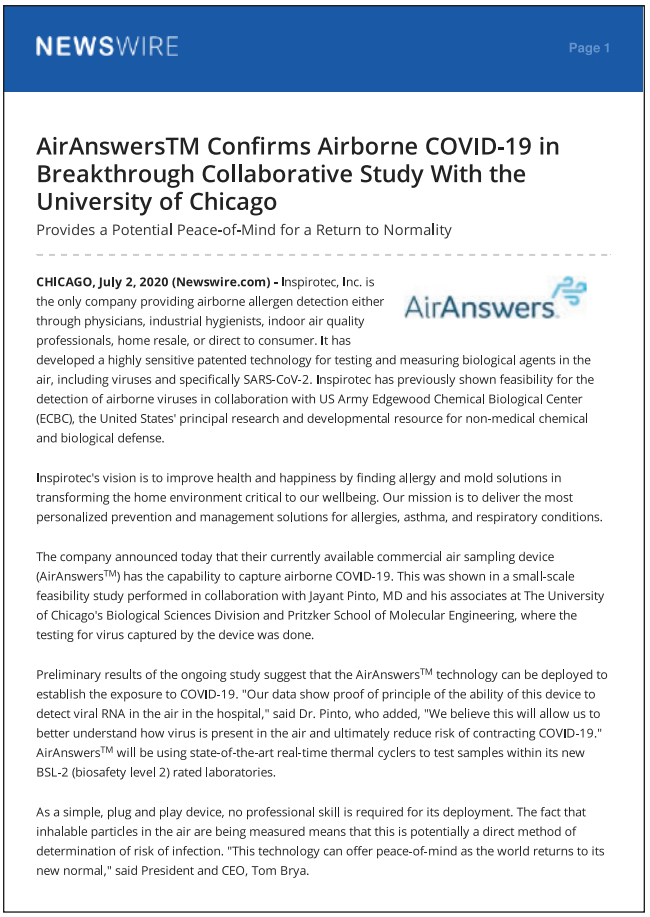
Background: A variety of different sampling devices are currently available to acquire air samples for the study of the microbiome of the air. All have a degree of technical complexity that limits deployment. Here, we evaluate the use of a novel device, which has no technical complexity and is easily deployable.

Results: An air-cleaning device powered by electrokinetic propulsion has been adapted to provide a universal method for collecting samples of the aerobiome. Plasma-induced charge in aerosol particles causes propulsion to and capture on a counter-electrode. The flow of ions creates net bulk airflow, with no moving parts. A device and electrode assembly have been re-designed from air-cleaning technology to provide an average air flow of 120 lpm. This compares favorably with current air sampling devices based on physical air pumping. Capture efficiency was determined by comparison with a 0.4 µm polycarbonate reference filter, using fluorescent latex particles in a controlled environment chamber. Performance was compared with the same reference filter method in field studies in three different environments. For 23 common fungal species by quantitative polymerase chain reaction (qPCR), there was 100 % sensitivity and apparent specificity of 87%, with the reference filter taken as "gold standard." Further, bacterial analysis of 16S RNA by amplicon sequencing showed equivalent community structure captured by the electrokinetic device and the reference filter. Unlike other current air sampling methods, capture of particles is determined by charge and so is not controlled by particle mass. We analyzed particle sizes captured from air, without regard to specific analyte by atomic force microscopy: particles at least as low as 100 nM could be captured from ambient air.

Conclusions: This work introduces a very simple plug-and-play device that can sample air at a high-volume flow rate with no moving parts and collect particles down to the sub-micron range. The performance of the device is substantially equivalent to capture by pumping through a filter for microbiome analysis by quantitative PCR and amplicon sequencing. different environments. For 23 common fungal species by quantitative polymerase chain reaction (qPCR), there was 100 % sensitivity and apparent specificity of 87 %, with the reference filter taken as "gold standard." Further, bacterial analysis of 16S RNA by amplicon sequencing showed equivalent community structure captured by the electrokinetic device and the reference filter. Unlike other current air sampling methods, capture of particles is determined by charge and so is not controlled by particle mass. We analyzed particle sizes captured from air, without regard to specific analyte by atomic force microscopy: particles at least as low as 150 nM could be captured from ambient air.

Conclusions: This work introduces a very simple plug-and-play device that can sample air at a high-volume flow rate with no moving parts and collect particles down to the sub-micron range. The performance of the device is substantially equivalent to capture by pumping through a filter for microbiome analysis by quantitative PCR and amplicon sequencing.

University of Chicago SARS-CoV-2 Collaboration



NEWSWIRE Page 1

AirAnswersTM Confirms Airborne COVID-19 in Breakthrough Collaborative Study With the University of Chicago

Provides a Potential Peace-of-Mind for a Return to Normality

CHICAGO, July 2, 2020 (Newswire.com) - Inspirotec, Inc. is the only company providing airborne allergen detection either through physicians, industrial hygienists, indoor air quality professionals, home resale, or direct to consumer. It has developed a highly sensitive patented technology for testing and measuring biological agents in the air, including viruses and specifically SARS-CoV-2. Inspirotec has previously shown feasibility for the detection of airborne viruses in collaboration with US Army Edgewood Chemical Biological Center (ECBC), the United States' principal research and developmental resource for non-medical chemical and biological defense.

Inspirotec's vision is to improve health and happiness by finding allergy and mold solutions in transforming the home environment critical to our wellbeing. Our mission is to deliver the most personalized prevention and management solutions for allergies, asthma, and respiratory conditions.

The company announced today that their currently available commercial air sampling device (AirAnswers™) has the capability to capture airborne COVID-19. This was shown in a small-scale feasibility study performed in collaboration with Jayant Pinto, MD and his associates at The University of Chicago's Biological Sciences Division and Pritzker School of Molecular Engineering, where the testing for virus captured by the device was done.

Preliminary results of the ongoing study suggest that the AirAnswers™ technology can be deployed to establish the exposure to COVID-19. "Our data show proof of principle of the ability of this device to detect viral RNA in the air in the hospital," said Dr. Pinto, who added, "We believe this will allow us to better understand how virus is present in the air and ultimately reduce risk of contracting COVID-19." AirAnswers™ will be using state-of-the-art real-time thermal cyclers to test samples within its new BSL-2 (biosafety level 2) rated laboratories.

As a simple, plug and play device, no professional skill is required for its deployment. The fact that inhalable particles in the air are being measured means that this is potentially a direct method of determination of risk of infection. "This technology can offer peace-of-mind as the world returns to its new normal," said President and CEO, Tom Brya.

COMPASS Study

Since 2018, Inspirotec has been collaborating with The University of Chicago in a long-term research program, The Chicago Multiethnic Prevention And Surveillance Study (COMPASS), that looks at the impact of factors such as lifestyle, healthcare access, the environment, and genetics on the health of Chicagoans. This longitudinal cohort study currently has over 6,000 participants throughout the city, with a long-term goal of 100,000 participants.

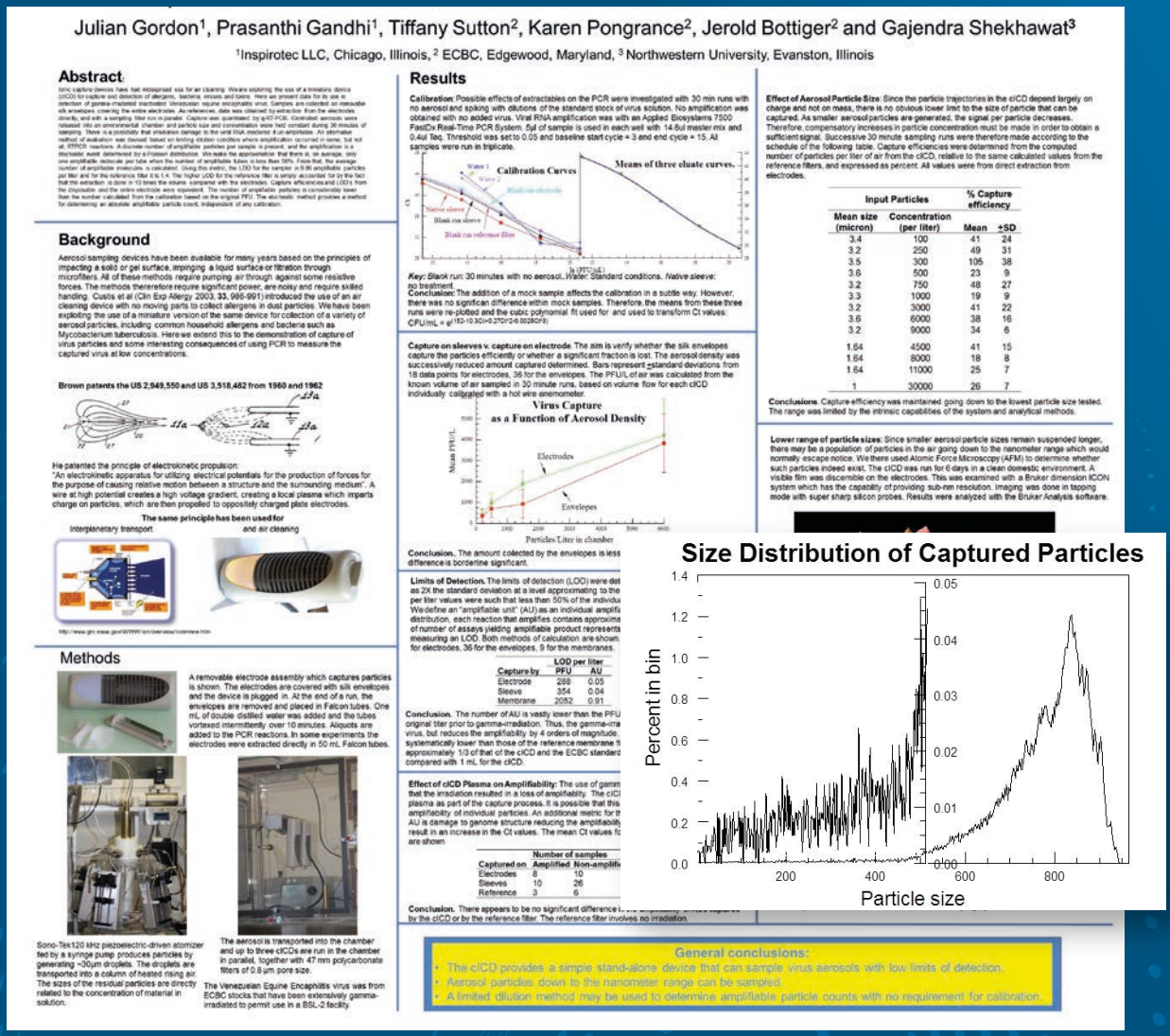
AT THE UNIVERSITY OF CHICAGO
COMPASS
CHICAGO MULTIETHNIC PREVENTION AND SURVEILLANCE STUDY

THE UNIVERSITY OF CHICAGO

Virus Evidence

Evaluation of an Ion Capture Method for Determination of Aerosolized Venezuelan Equine Encaphlitis Virus and a Novel Method for Absolute Particle Count Determination.

“Ionic capture devices have had widespread use for air cleaning_ We are exploring the use of a miniature device (clCD) for capture and detection of allergens, bacteria, viruses and toxins. Here we present data for its use in detection of gamma-irradiated inactivated Venezuelan equine encephalitis virus. Samples are collected on removable silk envelopes covering the entire electrodes. As references, data was obtained by extraction from the electrodes directly, and with a sampling fitter run in parallel. Capture was quantitated by q-RT-PCR. Controlled aerosols were released into an environmental chamber and particle size and concentration were held constant during 30 minutes of sampling. There is a possibility that irradiation damage to the viral RNA rendered it un-amplifiable. An alternative method of evaluation was devised based on limiting dilution condition where amplification occurred in some, but not all, RTPCR reactions. A discrete number of amplifiable particles per sample is present, and the amplification is a stochastic event determined by a Poisson distribution. We make the approximation that there is, on average, only one amplifiable molecule per tube when the number of amplifiable tubes is less than 50%. From that, the average number of amplifiable molecules is calculated. Using this metric, the LOO for the sampler is 0.06 amplifiable particles per liter and for the reference filter it is 1.4. The higher LOO for the reference filter is simply accounted for by the fact that the extraction is done in 10 times the volume compared with the electrodes. Capture efficiencies and LOD's from the disposable and the entire electrode were equivalent. The number of amplifiable particles is considerably lower than the number calculated from the calibration based on the original PFU. The stochastic method provides a method for determining an absolute amplifiable particle count, independent of any calibration.”



THE DEVICE

What are the dimensions of the AirAnswers® device?
6.91 inches x 4.93 inches
175.45 mm x 125.28 mm

What is the weight of the device?
The device weighs 240 grams (~0.5 Lbs)

How is the device powered?
A 15 w power adapter with DC jack is the primary source however for a limited time period the device can be powered via battery pack.

What does the device collect?
The device collects biological materials in the air including allergens, bacteria, fungi, and viruses. At a high flow rate of 150 liters of air per minute, AirAnswers® device has the ability to capture the smaller more harmful particles that can get deep into the lungs. AirAnswers® has the capacity to capture airborne fine particles as small as 0.1um

Can the device be overloaded?
Our device cannot be overloaded. There is no limited capacity as there is no filter to worry about clogging.

How does the device work?
The device uses Ionic propulsion to silently circulate air through the device, leaving ultra- fine particles bonded to the steel electrodes on the collection cartridge.

What is the device flow rate?
The device circulates air at a rate of 150 LPM, allowing for the capture of particles from 150 liters of air per minute. Over a 5-day period for allergen and mold testing, particles from close to 1-million liters of air travel through the device and are captured on the steel electrodes of the cartridge assembly.

How do you know the device can collect 150L of air per minute/ ~1.5M liters of air in 5 days? What evidence do you have on this specification?
We have validated the airflow of the device with a hot wire anemometer. This is a wire that keeps a constant temperature as cool air around it pulls heat off the wire. The device calculates the amount of heat lost and the corresponding airflow and displays the number on a computer. For the most accurate representation of total airflow of the device we have measured the flow of each of the over 200 holes on the device. Each individual hole was measured by our scientific inventor Dr. Julian Gordon, as well as separately by lab technicians and our manufacturers. One device from each batch produced is used for quality testing according to our standard operating procedure and part of that includes airflow measurement from the 3 separate parties.

How do you monitor and QA the Airflow?
These measurements are made before the insertion of the catalytic converter into the device. The catalytic converter converts any ozone exiting the device into oxygen. However, it causes the exiting air to become turbulent. The airflow measurements then become problematic. We have shown that capture of allergens is the same with or without catalyst present. We therefore rely on the more accurate air flow measurements that can be made before insetion of the catalyst.

Does the device have a filter?
No, Particulates are collected on a stainless steel cartridge.

Is the device loud?
The AirAnswers® device has no moving parts and therefore is silent.

What is included with the AirAnswers® device?
The AirAnswers® device comes with a power cord, a user manual, 4 cartridges in cartridge containers, and 4 prepaid shipping envelopes for returning the cartridges to our laboratory.

Does AirAnswers® come with a warranty?
Yes, AirAnswers® comes with a limited warranty. The warranty period begins on the date you receive the AirAnswers® device from us and lasts for a period of 30 days. Complete information on this limited warranty is included in the Directions for Use that come packaged with the AirAnswers® device.
https://www.airanswers.com/terms-conditions

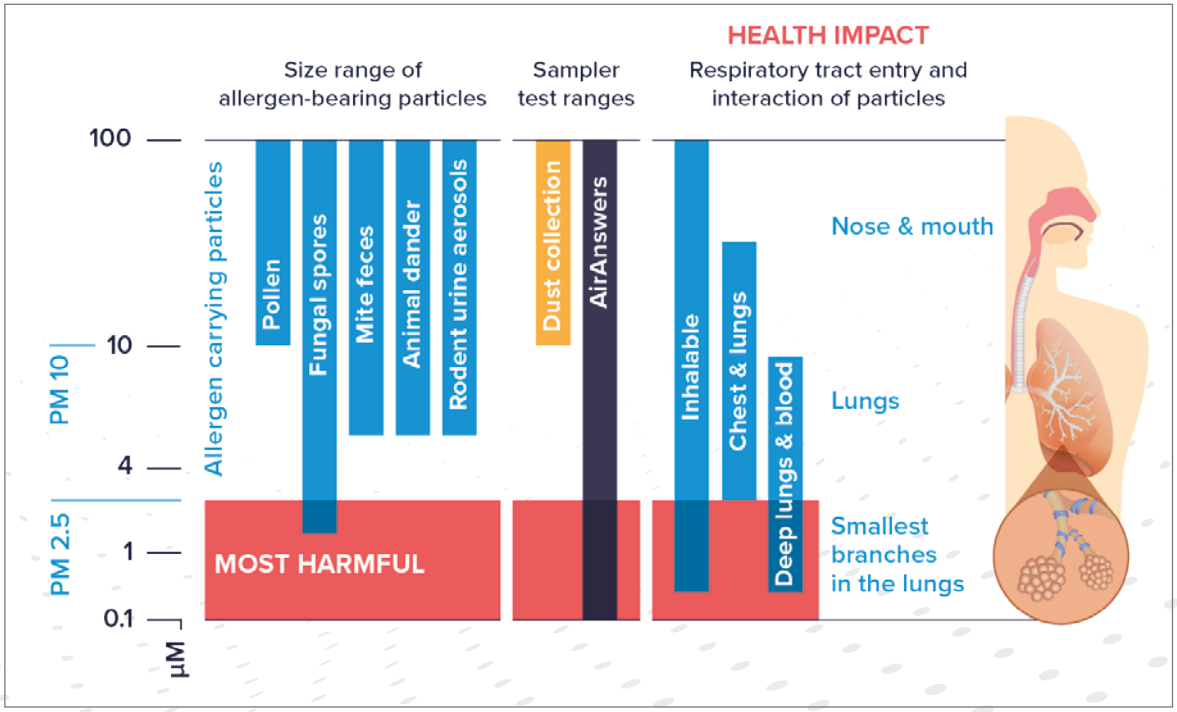
What is the largest particle size you capture?
We don't have an upper bound limit to detection. In an assessment of our device in a horse stable we captured many large particles as well as small flies (~2,000um) on our cartridge.

What size of particulate can the device measure?
The device can measure ultra-fine particles down to 0.1 microns in size.

Why are ultra-fine particles potentially harmful?
Ultra-fine particles are potentially harmful because they not only enter your lungs but can enter your bloodstream. This can exacerbate allergy & asthma symptoms, and could potentially be fatal.

What is the largest particle size you capture?
We don't have an upper bound limit to detection. In an assessment of our device in a horse stable we captured many large particles as well as small flies (~2,000um) on our cartridge.

How long do the particles stay stuck to the cartridge after it's unplugged?
The particles remain on the dry electrode until the surface is compromised, either by someone touching it or the lab extracting the particles off to perform the assessment. With our SARS-CoV-2 samples we have detected positive samples more than 10 days after the initiation of sampling.



OPERATION

How do I register my cartridge?
You can register your cartridge on the AirAnswers® website (www.airanswers.com) by going to the Cartridge Registration page.

How do I operate the device?
Remove the AirAnswers® device from the box, insert a cartridge, and plug-it into a standard outlet. Let it run for the appropriate time for your chosen assessment.

What is the device reset button for?
The device reset button is used between testing cycles. Once you have completed the testing cycle for its corresponding number of days, before beginning a new testing cycle you will press the reset button, as indicated in the instruction manual.

Where do I place the device when testing?
If you would like to test a whole indoor environment, we recommend putting the device in a centralized location, 36-48 inches off of the floor on a piece of furniture (table, bookcase, nightstand, or desk), near an air recycle point. Leave all interior doors to rooms open. If you would like to test a specific room, place the device in the room and make sure that the door is closed for the entire testing period.

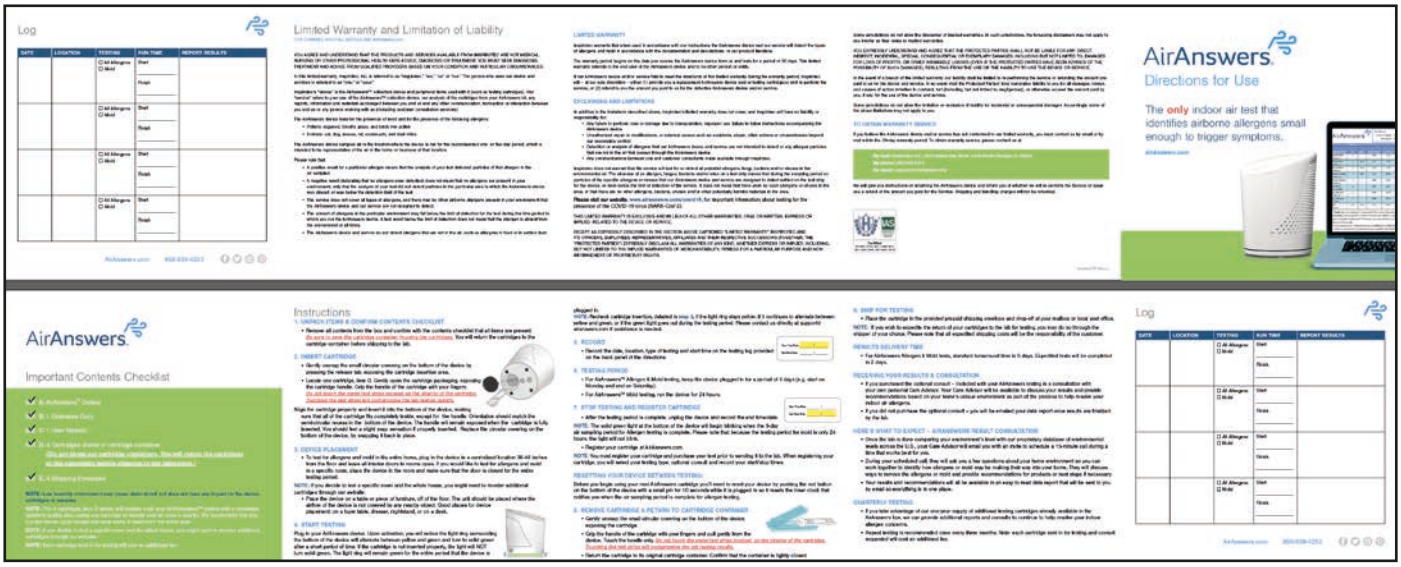
How do I know the device is working?
If the device is functioning properly, there is a light ring around the bottom of the device that will blink from green to yellow when you plug the device in and then maintain a steady green light after a few seconds and throughout the testing period. Once the 5-day cycle is complete, the device will stop collecting and the light ring will revert back to blinking . If after plugging in the device or pushing the reset button the light ring stays yellow or continues to alternate between yellow and green check the cartridge is inserted properly. If the green light goes out during the testing period contact us directly. If performing Mold only or Virus sampling you will have to be mindful of the time and unplug the device after the corresponding sampling days required.

Can the device be used in high dust areas, like factories?
Yes, being that our air sampling technology captures airborne particles on steel electrodes vs. filters, there is no chance of clogging of the AirAnswers® device or internal cartridge.

Does opening doors and windows impact SARS-CoV-2 testing?
We recommend people keep their exterior windows and doors closed during testing if they are typically closed during normal operation, as external airflow dilutes indoor levels of SARS-CoV-2.

Do I need to clean the device?
No - inside the device is a high voltage wire. When you remove the cartridge from the device, there is an internal "brush" which gently removes any particulate matter from the wire. We would recommend that the person wipe the exterior of the device down with a damp cloth soaked in a mild detergent.

How often should a home or space be tested?
We recommend quarterly testing of your space for allergens and molds. For virus detection or monitoring we recommend weekly testing.



How many devices do I need to test a home, school or business?
We recommend 1 device per HVAC system. This means most homes will require only one device. For schools or commercial spaces we recommend one device per open area being tested.

How long should I run the AirAnswers® device for both allergen and mold testing?
The device requires a 5 day run period to test for allergens. A mold determination can also be made from the 5 day sample.

How long should I run the AirAnswers® device for mold only testing?
The device requires a 24-hour run period to test for mold.

How long should I run the AirAnswers® device for virus testing?
As of today the device requires a 3 day run period to test for SARS-CoV-2 but we expect a shorter time period will be required in the future.

How do I remove the cartridge?
Unsnap the small blue circular covering on the bottom of the device by pressing the release tab, exposing the cartridge area. Grip the exposed handle with your fingertips (do not touch the metal test strips, this will compromise the lab test) you will feel a gentle pressure release as you slowly pull the cartridge straight out. Place it back into the plastic container it was packaged in to protect the sample.

How do I insert a new cartridge?
Unsnap the small circular covering on the bottom of the device by pressing the release tab, exposing the cartridge insertion area. Locate one cartridge and gently open the cartridge packaging, exposing the cartridge handle. Grip the handle of the cartridge with your fingers. Do not touch the metal test strips located on the interior of the cartridge.
Touching the test strips will compromise the lab testing results. Align the cartridge properly and insert it into the bottom of the device, making sure that all of the cartridge fits completely inside, except for the handle.
Orientation should match the semi-circular recess in the bottom of the device. The handle will remain exposed when the cartridge is fully inserted. You should feel a slight snap sensation if properly inserted. Replace the circular covering on the bottom of the device, by snapping it back in place.

How long are the cartridges valid?
Indefinitely, there is no liquid to worry about corrosion. There is no expiration date attached to the cartridge.

LAB TESTING

Where is the lab located?
Inspirotec laboratory operations are located at 3333 Green Bay Rd, North Chicago, IL 60064 North Chicago, on the Rosalind Franklin University campus.

What quality certifications does your lab possess?
Inspirotec has 5 critical ISO certifications: for manufacturing excellence (ISO 13485:2016), overall company quality processes and controls (ISO 9001:2015), personnel occupational health and safety management system (ISO 45001:2018), and best practices for protecting our environment (ISO 14001:2015). Inspirotec has successfully completed their laboratory audit and have received their AIHA ISO/IEC 17025 accreditation certificate for laboratory testing. ISO standards are internationally recognized by experts as an audited formula that describes the best way of doing something.

Is your lab CLIA Certified?
Inspirotec has multiple ISO certifications, we also have a BSL2 lab to safely handle SARS-Cov-2 samples. Since we are working with environmental and not human samples there is CLIA approval for our specific niche.

What allergens are you currently testing for?
Our lab is testing for 30+ allergens and molds:

- Pollens: Birch, Ragweed, Timothy grass
- Pets: Dog, Cat
- Pests: Cockroach, Mouse, Rat (coming soon)
- Dust-mites: 11 domestic and multiple storage mite species
- Mold: Our test is very sensitive and detects at least 23 species of mold.

What makes our lab testing unique?
Mold Testing: Inspirotec performs a kinetic test for the presence of (1→3)-β-d-glucan. A vast majority of mold species have (1→3)-β-d-glucan as part of their cell walls, spores, and as particulate matter emitted into the air. Mostly β-d-glucan is known as a cell wall component in

the form of aggregates. In contrast, AirAnswers® captures free β-d-glucan which is suspended in the air, These smaller particles are more likely to remain airborne longer and penetrate deep into the lungs. Those smaller size particles released into the air by germinating and growing fungi are selectively measured by Inspirotec's proprietary assay. With one result, you receive the total exposure to fungal mass in your home environment. Levels of (1→3)-β-d-glucan in the air are known to correlate with fungal mass and severity of symptoms. Results for spores from at least 23 species of mold can also be provided, for a separate charge given the complexity of the additional sample analysis.

Dust Mite Testing: Dust mites allergens, found on their waste and body parts, are the most frequent causes of allergies and asthma. Inspirotec's proprietary dust mite assay not only identifies allergenic particles emitted from the most prevalent species of house dust mites, D. farinae and D. pteronyssinus, it also identifies airborne allergens produced from multiple species of dust and storage mites lurking in your indoor environment.

What testing methods are used to analyze the sample for allergens and mold?
The Lab uses ELISA, ELISA-based multiplex assays, and kinetic assays for allergen and mold analysis.

What are the species of molds that AirAnswers® can detect?

- Acremonium strictum
- Alternaria alternata
- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus niger
- Aspergillus ochraceus
- Aspergillus sydowii
- Aspergillus versicolor
- Chaetomium globosum
- Cladosporium cladosporidides (Type 1)
- Eurotium (Asp.) amstelodami
- Memnoniella schianta
- Paecilomyces variotii
- Penicilium aurantiogriseum
- Penicilium brevicompactum
- Penicilium chrysogenum (Type 2)
- Penicilium pirpurogenum
- Penicilium variabile
- Scopulariopsis brevicaulis
- Stachybotrys chartarum
- Trichoderma viride
- Ulocladium botrytis

How long will it take to get my results back?
Allergens and mold results come back in 5 days unless you choose to expedite for an additional fee, in which case you get your results emailed in 2 days. Virus results have a 2-3 day turnaround time.

What happens when the lab receives my cartridge?
Once your AirAnswers® cartridge is received, lab testing is performed to determine the presence and quantity of allergens, mold, and/or SARS-CoV-2 in your tested location. After testing, your results are analyzed and incorporated into a customized profile of the air from your tested indoor environment. Your results will be finalized and your report will be emailed to you within your chosen turn-around-time.

What information is provided by the allergen and mold data report?
The data report provides customers with the concentration of allergen and actively growing mold, if present, expressed in pg/m3. Also provided, is the level (low, medium, high) of allergen/mold identified, the percentage of homes tested by AirAnswers® where allergens/mold were found, and common mitigation efforts to reduce the allergen and mold load in your indoor environment.

AirAnswers

Data Report
Customer Name: Unknown
Cartridge #: IACR1748200304D
Report Issue Date: 11/10/2020
Lab Testing Date: 10/21/2020
Testing Location:
Data Approved By: Not Approved

Allergen/Mold	Level [1]	Result pg/m3 [2]	% of Homes [3]	Recommendations [4]
Weed Pollen (Amb a 1)		ND	2.24	
Tree Pollen (Bet v 1)		ND	14.18	
Grass Pollen (Phl p 5)		ND	9.33	
Mouse Allergen (Mus m 1)	Medium	0.03	19.10	Clean all hard and soft surfaces throughout the home. Wash all bedding, couch covers, throw blankets, pillow, and curtains in hot water and be sure to dry on high heat.
Roach Allergen (Bla g 2)		ND	5.22	
Dust Mite (Dust Mite)		ND	33.83	
Cat Allergen (Fel d 1)	Low	0.12	51.49	Ask a non-allergic family member to clean the animal's bed or litter box. If you don't own a cat, you may be coming in-contact with a cat owner. Cat allergen can easily stick to clothing, hair, and skin and can be transferred between individuals.
Dog Allergen (Can f 1)	Low	0.08	61.19	Ask a non-allergic family member to clean the animal's bed. If you don't own a dog, you may be coming in-contact with a dog owner. Dog allergen can easily stick to clothing, hair, and skin and can be transferred between individuals.
MD (Mold)	Low	0.97	57.34	Control moisture in your environment. Using dehumidifiers in damp basements may be helpful.

[1] **Level**: Data is presented as "undetected" if the level is below the detection level of the AirAnswers™ device or below LOD for the assay. If the presence of allergen or mold is detectable, data is reported in terms of 3 levels (Low , Medium, High). Data from each allergen or mold assay is assigned to a range by comparing to all customer data that has been collected by AirAnswers™. The levels are based entirely on environmental measurements and not on health effects. All suggestions are provided by Inspirotec Indoor Air Quality Professionals.

- A Low concentration means an allergen or mold reading at the 33rd percentile or lower.
- A Medium concentration means an allergen or mold reading betw een 33-66th percentile.
- A High concentration means an allergen or mold reading at or above the 66th percentile.

Low Level:
Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist

Medium Level:
Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist Schedule an intervention consultation with an AirAnswers™ Care Advisor for allergen/mold remediation recommendations tailored to you and your indoor environment.

High Level:
Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist Schedule an intervention consultation with an AirAnswers™ Care Advisor for allergen/mold remediation recommendations tailored to you and your indoor environment
If you don't already have one, you may want to consider scheduling an in-home remediation consultation and visit with your local Indoor Air Quality expert (references are available)
If your symptoms persist, we strongly encourage you to schedule an appointment with a health care provider.

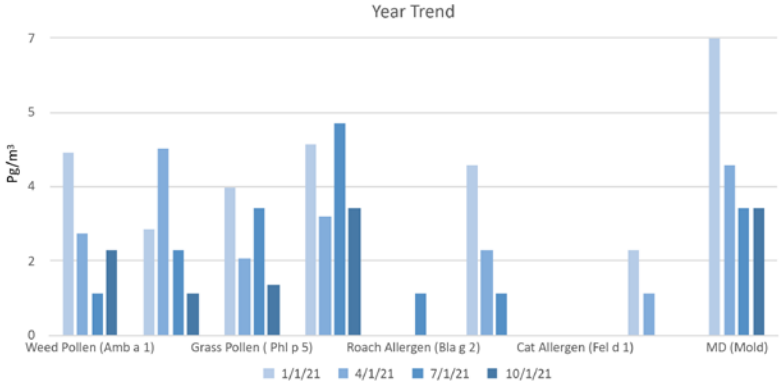
[2] **Result pg/m3:** Allergen and mold concentration is reported in the follow ing units: pg/m3(picograms/ cubic meter). LOD (limit of detection) is defined as 2 standard deviations above background. If reported allergen and mold value is above LOD, it is detectable. If the result is below LOD, it is reported as ND(not detected).

[3] **% of Homes:** Based on AirAnswers™ database of all customer samples, this is the overall percentage of tested locations where allergen and mold was detected using the AirAnswers™ device

[4] **Recommendations for allergen and mold control provided by the AAAAI and the EPA.** Results relate only to the items tested. All allergens are identified using ELISA (enzyme-linked immunosorbent assay) based methods. For mold testing, a kinetic assay specific for (1→3)-β-D-glucan is used. Inspirotec assays identify at least 23 species of mold and multiple species of dust mites and storage mites. All testing is provided by Inspirotec Inc. located at 3333 Green Bay Road, North Chicago, IL 60064.

Allergen & Mold Yearly Trend Analysis

	# of Tested	Yearly Results Pg/m²			
Allergen/Mold	30+	1/1/21	4/1/21	7/1/21	10/1/21
Weed Pollen (Amb a 1)	1	4	2.1	1.0	2.0
Tree Pollen (Bet v 1)	1	2.4	4.4	2.0	1.0
Grass Pollen (Phl p 5)	1	3.5	1.8	3.0	1.2
Mouse Allergen (Mus m 1)	1	4.5	2.8	5.0	3.0
Roach Allergen (Bla g 2)	1	ND	ND	1.0	ND
Dust Mite	9+	4.0	2.0	1.0	ND
Cat Allergen (Fel d 1)	1	ND	ND	ND	ND
Dog Allergen (Can f 1)	1	2.0	1.0	ND	ND
MD (Mold)	23+	7.0	4.0	3.0	3.0



What does a mold only lab report look like?

The lab report for a mold only assessment will look the same except it won't have any of the listed allergens.

AirAnswers

Data Report
Customer Name:
Cartridge #: IACR1748200304D
Report Issue Date: 11/10/2020
Lab Testing Date: 10/21/2020
Testing Location:
Data Approved By: Not Approved

Allergen/Mold	Level [1]	Result pg/m3 [2]	% of Homes [3]	Recommendations [4]
MD (Mold)	Low	0.97	57.34	Control moisture in your environment. Using dehumidifiers in damp basements may be helpful.

[1] **Level**: Data is presented as "undetected" if the level is below the detection level of the AirAnswers™ device or below LOD for the assay. If the presence of allergen or mold is detectable, data is reported in terms of 3 levels (Low , Medium, High). Data from each allergen or mold assay is assigned to a range by comparing to all customer data that has been collected by AirAnswers™. The levels are based entirely on environmental measurements and not on health effects. All suggestions are provided by Inspirotec Indoor Air Quality Professionals.

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Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist

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Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist Schedule an intervention consultation with an AirAnswers™ Care Advisor for allergen/mold remediation recommendations tailored to you and your indoor environment.

High Level:
Monitor and retest after 2-3 months if allergy and/or asthma symptoms persist Schedule an intervention consultation with an AirAnswers™ Care Advisor for allergen/mold remediation recommendations tailored to you and your indoor environment
If you don't already have one, you may want to consider scheduling an in-home remediation consultation and visit with your local Indoor Air Quality expert (references are available)
If your symptoms persist, we strongly encourage you to schedule an appointment with a health care provider.

[2] **Result pg/m3:** Allergen and mold concentration is reported in the follow ing units: pg/m3(picograms/ cubic meter). LOD (limit of detection) is defined as 2 standard deviations above background. If reported allergen and mold value is above LOD, it is detectable. If the result is below LOD, it is reported as ND(not detected).

[3] **% of Homes:** Based on AirAnswers™ database of all customer samples, this is the overall percentage of tested locations where allergen and mold was detected using the AirAnswers™ device

[4] **Recommendations for allergen and mold control provided by the AAAAI and the EPA.** Results relate only to the items tested. All allergens are identified using ELISA (enzyme-linked immunosorbent assay) based methods. For mold testing, a kinetic assay specific for (1→3)-β-D-glucan is used. Inspirotec assays identify at least 23 species of mold and multiple species of dust mites and storage mites. All testing is provided by Inspirotec Inc. located at 3333 Green Bay Road, North Chicago, IL 60064.

What if I want ongoing testing?
Additional testing packages are available for purchase through your AirAnswers® sales consultant.

Where should I dispose of my device if I no longer need it?
Our AirAnswers® device is designed to be used year after year so you can continue to monitor your home for allergens and mold as the air in your environment continues to change over time. However, if you decide that you want to dispose of your AirAnswers® device, we recommend you use the resource below to find a recycling center in your area that accepts electronics.
SustainableElectronics.org/recyclers

VIRUS DETECTION

What research do you have to support your virus detection claims?
AirAnswers® is involved in an ongoing study in collaboration with both the University of Chicago and Northwestern Memorial Hospital. We are involved in an independent study involving long term care facilities and patients who have tested positive for SARS-CoV-2.

Is your product FDA/ EPA/ CDC approved?
Our labs have multiple ISO certifications which ensure the highest standards in our laboratory practice. Since we are working with environmental and not human samples there is no FDA approval for our specific niche. EPA deals with certifying technology used in environmental sanitization and cleaning, we are a lab. We follow the CDC guidelines for safe handling of SARS-CoV-2 and we use their certified primers and probes.

Can the device detect viruses?
Yes, AirAnswers® can detect viruses including SARS-CoV-2 and the virus which causes equine encephalitis.

How long should I run for the AirAnswers® device for virus testing?
The device requires a 3 day run period to test for SARS-CoV-2.

What type of lab tests do you perform and how do you know they work?
To detect airborne SARS-CoV-2 we use the gold standard of detection, a reverse transcriptase quantitative polymerase chain reaction (RTqPCR). Essentially this assay converts SARS-CoV-2 RNA back into DNA which is amplified using primers specific to nucleic acid sequences in SARS-CoV-2. As any present DNA strands specific to identifying SARS-CoV-2 are amplified, the machine is looking for a fluorescent tag to indicate a detectable level of the virus. This lets us not only identify that SARS-CoV-2 is present, but also give an indication as to what quantity of RNA was present in the original sample - more cycle times of replication indicate lower sample levels of SARS-CoV-2. This is because it took more replications for the probe to surpass the threshold for detection indicating lower initial SARS-CoV-2 levels. Our methods have been validated through collaborating with U Chicago and PCR methods for SARS-CoV-2 detection are affirmed by the CDC. We use the primers and probes validated by the CDC as well. Our lab also has multiple ISO certifications which ensure high standards of laboratory practice and ethics.

Is there a minimum level of SARS-CoV-2 that needs to be present in the air for AirAnswers® to detect it?
The short answer is yes, but we are currently researching what this level is. At this time we have studies in progress with the University of Chicago to determine these levels and we will have more information soon.

How long will it take to get my results back?
Results will come back within 2-3 business days.

What kind of action plan will be provided for SARS-CoV-2 detection?
We will be reporting on virus presence. For an appropriate action plan, we recommend that customers consult with Indoor Air Quality Professionals.

What is the recommended use and testing frequency of AirAnswers® SARS-CoV-2 testing?
AirAnswers® testing can be paired with an air cleaning protocol and/or air cleaning technology for validation purposes. Running AirAnswers® can help keep you, your employees, and customers safe and provide peace-of-mind as we all return to the new normal. We recommend that testing be performed on a weekly basis.

Will one device suffice the entire home? (How about school, office, etc.?)
We recommend 1 device used per HVAC system.

Is it safe to touch the cartridge with bare hands?
Only touch the cartridge handle. Grip the handle of the cartridge and pull gently from the device. Do not touch the metal strips located on the interior of the cartridge.

What information is provided in a Virus only data report?
The virus lab report indicates if the virus is present in your tested indoor environment.

What does a Virus only lab report look like?

Airborne – SARS-CoV-2 Report

Data Approved By: R. Reboulet

Customer Name: Example **Report Issue Date:** 10/9/2020 **Site:** Various

Cartridge #	Test location	Lab testing date	Results[1]		
			nCov_N1 Ct	nCov_N2 Ct	Estimated Level
IACR1748200869A	Tech in ROOM BASE	10/9/2020	>40	>40	ND - Negative
IACR1748200215B	Tech in ROOM BASE	10/9/2020	>40	>40	ND - Negative
IACR1748200397A	Tech in ROOM BASE	10/9/2020	>40	>40	ND - Negative
IACR1748200215C	Tech TOP	10/9/2020	>40	>40	ND - Negative
IACR1748200395B	Tech TOP	10/9/2020	>40	>40	ND - Negative
IACR1748200400C	Tech TOP	10/9/2020	>40	>40	ND - Negative
IACR1748200395D	Tech TOP	10/9/2020	>40	>40	ND - Negative
IACR1748200869C	RM102BD	10/9/2020	37	38	Low
IACR1748200400A	UNIT RM207	10/9/2020	>40	>40	ND - Negative
IACR1748200869B	Patient Rm 103	10/9/2020	>40	>40	ND - Negative
IACR1748200400B	Patient Rm 207	10/9/2020	>40	>40	ND - Negative
IACR1748200400D	Rm 206	10/9/2020	>40	>40	ND - Negative
IACR1748200395C	AFTER Tech	10/9/2020	>40	>40	ND - Negative
IACR1748200215A	AFTER Tech	10/9/2020	>40	>40	ND - Negative
IACR1748299215D	AFTER Tech	10/9/2020	>40	>40	ND - Negative
IACR1748200003IB	RM 304	10/9/2020	>40	>40	ND - Negative
IACR1748200003IA	RM 311 RC	10/9/2020	23	24	High

Legal disclaimer: This report does not constitute legal advice or clinical representation of the presence or absence of the virus COVID-19. This report cannot be used to rule out the presence of virus in a facility. It provides only the results from the air tested. Positive test results indicate the presence of viral particles and may indicate that the air was contaminated by contact or proximity with an infected person. Inspirotec encourages individuals and organizations to take universal precautions based on the most current advice from public health officials. For additional information, please see https://www.cdc.gov/coronavirus/2019-nCoV/index.html.

Intended use:

[1] Samples are analyzed by RT-PCR using primers/probe sets and protocols designed and provided by the CDC (Center for Disease Control and Prevention). Testing has been adapted for the detection of airborne 2019-nCoV. Ct refers to the cycle threshold. It is the number of cycles of a thermocycler for which the amplifiable product begins to appear. The more viral RNA present, the lower the threshold number. If the Ct value is greater than 40, there is no virus detected. Results relate only to the items tested. Results are expressed as amplifiable 2019-nCoV.

The presence of 2019-nCoV does not guarantee the presence of infectious virus, but is highly suggestive of the presence in the unit tested of person or persons shedding virus into the air. According to CDC, state, and local guidelines as may be applicable at the time of testing, persons in the area should be evaluated medically, tested for infection and quarantined if necessary. Efforts should be made to clean or replace air and disinfect all surfaces. The absence of detectable amplicons is strongly indicative of the absence of infectious virus.

Level: Data is presented as "undetected" (ND) if the level is below the detection level of the AirAnswers™ device or below LOD for the assay. If the presence of SARS-CoV-2 is detectable, data is reported in terms of 3 levels (Low , Medium, High). All testing is provided by Inspirotec Inc. located at 3333 Green Bay Road, North Chicago, IL 60064

Patented Product Technology & Benefits:

Our high-volume air sampler is a whole-home approach for the capture of fine particle indoor airborne allergens. Inspirotec's device has been optimized for the capture of airborne biological material including allergens, mold, viruses, and bacteria using electrokinetic capture (US patent numbers 8,038,944, 9,216,421, 9,360,402, 9,481,904, and 9,618,431) allowing for the capture of particles from 100 liters of air per minute[1]. Over a 5-day period, particles from almost 1-million liters of air travel through the device.

Through an on-going collaborative study with the University of Chicago, the AirAnswers™ device has been found to collect SARS-CoV-2.

The Inspirotec sampling device has the ability to capture the smaller more harmful particles that can get deep into the lungs. Through collaborative studies with Northwestern University, we have shown that the Inspirotec device has the capacity to capture fine particles as small as 0.1um[1]. Allergen particle size determines the site of respiratory contact and is critical for the determination of health outcomes. Particles larger than 10um enter through the nose and may induce allergic rhinitis. Particles from 4-10um in size deposit in the lower airways and may induce asthma, and articles <4um can reach the alveoli, deep into the lungs, and cause much more severe responses. [2]

The Inspirotec air-sampling device has been validated in field studies through collaborations with The University of Chicago and with Johns Hopkins School of Medicine. Correlation with reference methods in 58 home visits in Baltimore [3] and reference values for assessment of 100 homes in the Chicago area have been shown [4].

1. Gordon, J., et al., A simple novel device for air sampling by electrokinetic capture. Microbiome, 2015. 3.
2. Raulf, M., et al., Monitoring of occupational and environmental aeroallergens - EAACI Position Paper Concerted action of the EAACI IG Occupational Allergy and Aerobiology & Air Pollution. Allergy, 2014. 69(10): p. 1280-1299.
3. Gordon, J., et al., Validation of a novel sampling technology for airborne allergens in low-income urban homes. Annals of Allergy Asthma & Immunology, 2018. 120(1): p. 96-+.
4. Gordon, J., et al., Bedroom exposure to airborne allergens in the Chicago area using a patient-operated sampling device. Annals of Allergy Asthma & Immunology, 2018. 121(2): p. 211-+

What part of the virus are you analyzing for? Can we know if it is live?
We are analyzing the RNA. As in the human diagnostic tests, viral RNA is not the same as infectious virus. However, the presence of viral RNA is a strong indicator that infectious virus is or has been present. It is prudent to err on the side of safety and assume that absence of viral RNA really means absence of virus.

How long before degradation of SARS-CoV-2 RNA begins once it's captured on the cartridge?
RNA is stable in a dry state, and our cartridges do not use liquid so they keep the particles dry. In our tests with SARS-CoV-2 and the University of Chicago we had samples in the cartridge sleeves for a week following the 3 day testing run time and still detected high levels of SARS-CoV-2 in positive samples. So even 10 days after the initiation of testing there were detectable levels of SARS-CoV-2.

Is the RNA from a virus "alive" or "dead"?
This is a complicated question - viruses, as a common controversy in the scientific community, aren't explicitly alive or dead. The question becomes is the RNA virulent, ie having the ability to infect people. Everyone measuring the virus has issues determining its ability to infect people as we all are analyzing viral RNA. According to the CDC, determining if RNA is infectious using a viral culture is incredibly risky and expensive.
(CDC COVID-19 FAQ)

What if the cleaning did not completely destroy the RNA but the live virus is killed. We want to reduce false positives.
RNA from its nature is very unstable. If RNA is found, more cleaning/ventilation should be done. False-positives happen in human testing due to procedural issues in handling human samples, not from the assay itself, but are rarer in air testing.

Is there an acceptable, safe level of virus presence?
Any SARS-CoV-2 found in the air is considered not acceptable. If the RNA is detected, it will never be acceptable to assume the environment is safe.

Why is it important to measure airborne levels of SARS-CoV-2?
The WHO and CDC have confirmed airborne transmission of SARS-CoV-2 *(CDC COVID-19 FAQ)* This means that SARS-CoV-2 can be spread through the air as well as by direct contact. Traditional swab tests for SARS-CoV-2 in spaces can only detect the virus on surfaces and neglect the aerosolized component of transmission. This gap is filled by testing for airborne SARS-CoV-2 with AirAnswers®, as it helps to provide a more complete picture of SARS-CoV-2 in the environment.

AURA THE UNIVERSITY OF CHICAGO

BSD IRB Committee B
The University of Chicago Biological Sciences Division/University of Chicago Medical Center
5841 S. Maryland Ave., MC7132, J-625, Chicago, IL 60637
FWA00005565

Notification of Initial Study Approval

Date of Letter: 5/26/2020
Protocol Number/Submission Link: IRB20-0665
Type of Submission: New Study
Status: Approved
Principal Investigator: Jayant Pinto
Protocol Title: Assessment of Aerosolized SARS-CoV-2 in the Hospital Setting
Risk Level: Minimal Risk
Consent Type: Informed Consent
Waiver of Consent Process and Consent Documentation
Written Consent Form: Signed consent will be sought from the subject or the subject's legally authorized representative
Authorization Type: Signed HIPAA authorization (combined with consent form)
Vulnerable Populations: None
Funding: Internally Funded
Protocol version: aerosolization proposal 05.11.20 clean.docx
Investigator Brochure(s):

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