ANAVASI DIAGNOSTICS®

FAQ's

About the Product

What is the AscencioDx® COVID-19 test system?

The AscencioDx COVID-19 test system has two elements: The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector. The kit is packaged and sold separately from the detector, but together they make up an *in vitro* diagnostic testing system for the presence of COVID-19. The test is intended to be used in a point-of-care environment for use by healthcare providers on individuals who are suspected of infection with the disease.

How does it work?

The AscencioDx COVID-19 test system works through a nucleic acid amplification method called RT-LAMP — or reverse transcriptase loop-mediated isothermal amplification. After the patient's sample is collected and prepared with the AscencioDx COVID-19 Test, a reaction tube is inserted into the AscencioDx Molecular Detector, where it is then heated and illuminated by the device. An internal sensor monitors the sample for fluorescence signals during analysis. When the test is completed, the test result is reported on the Detector's screen as either a Negative, Positive, or (very rarely) Inconclusive or Malfunction.

Is the AscencioDx RT-LAMP method different from a "traditional" amplification method such as PCR?

RT-LAMP (Reverse Transcription Loop-Mediated Isothermal Amplification) and RT-PCR (Reverse Transcription Polymerase Chain Reaction) are both NAATs (Nucleic Acid Amplification Tests). Both work by combining reverse transcription of RNA into DNA and the amplification of specific DNA targets for the detection of a specific RNA. This is achieved by monitoring the amplification reaction using fluorescence. RT-LAMP allows for a quicker analysis of genetic material than traditional PCR and has been successfully

used in the detection of the COVID-19 virus. Unlike RT-PCR, LAMP technology does not require thermal cycling, but relies upon isothermal technology that heats to a final temperature and remains consistent to amplify genetic material. Due to its accuracy and relatively simple equipment, this test can be performed in non-traditional institutions such as airports, mobile vans, or rural hospitals as well as urgent cares, assisted living centers, medical centers and clinics.

Has the test system been validated and approved for use by federal regulators?

The AscencioDx Covid-19 Test and The AscencioDx Molecular Detector have not been FDA cleared or approved, but have been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. 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.

How quickly are the test results obtained?

Positive results (i.e., indicating the presence of COVID-19 viral RNA in the sample), may be obtained in as little as 20 minutes. Confirming a negative result usually takes longer, but will almost always be less than an hour.

How many tests can be run with the AscencioDx COVID-19 test system?

The AscencioDx Molecular Detector is reusable for the lifetime of the device (projected to be thousands of tests) and capable of processing tests one-at-a-time and back-to-back. The AscencioDx COVID-19 Test, however, is only for single-use, capable of collecting and testing just one sample from one patient.

Can the AscencioDx test system be purchased over-the-counter for self-testing in home environments?

The AscencioDx is NOT available for home use. Under its EUA, it is approved for use in any CLIA-waived or higher accredited point of care settings/providers, such as medical practices, clinics or urgent care locations.

Where is the AscencioDx test system manufactured?

The AscencioDx system is manufactured and assembled in the United States.

Can the AscencioDx test system be used outside of the U.S. and its territories?

No. The AscencioDx test system is not yet registered, CE Marked, or approved outside of the US. There may be some exceptions where it may be available for use. Please contact sales@anavasidx.com for more information.

What sort of warranty is offered with the AscencioDx Molecular Detector?

Anavasi Diagnostics offers a full one-year warranty to the buyer that the detector is free from defects in material and workmanship under normal use. Please email quality@anavasidx.com for further information on the warranty. Technical support can be reached at support@anavasidx.com. Any questions or concerns can also be addressed by calling 1-888-ANAVASI (1-888-262-8274).

Using the Product

How is the AscencioDx COVID-19 test performed?

The AscencioDx COVID-19 test is performed by first collecting a low-depth nasal swab sample from a patient suspected of having COVID-19. The swab is then swirled in a tube of buffer solution, with a portion of the resulting

mixture being transferred with a pipette to a reaction tube which harbors a reagent. The reaction tube is then sealed and placed in the AscencioDx Molecular Detector for analysis. All the instruments needed to prepare the sample and run the test on the Detector are included in the AscencioDx COVID-19 Test Kit.

How quickly must patient samples be run on the Detector?

Anavasi Diagnostics advises a strict upper limit of 10 minutes to start the test after the reaction tube is removed from its foil pouch. Preparation of the nasal swab sample collection usually takes less than a minute. Tests which are not started on the detector within this time frame should be discarded. A new test must be used to collect a fresh sample for analysis.

Is any special training required to perform the test?

No. The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector present a straightforward testing method that can quickly be learned by any clinician in a POC setting. No special training is needed.

Is the nasal swab procedure the AscencioDx test requires uncomfortable?

No. It requires only a low-depth nasal swab—at a penetration of just ½"-¾" into each of the patient's nostrils. Unlike the invasive nasopharyngeal swab which reaches deep into the nasal cavity, this shallow swab will not cause pain or discomfort to the patient.

In what sort of environmental conditions should the AscencioDx Detector and COVID-19 Test Kit be used and stored?

Detailed environmental condition requirements may be found in the IFU for the Test Kit and User Manual for the Detector, but they should only be stored and used at room temperature (59°F to 86°F) and kept out of direct sunlight. The test should be performed in a room with adequate ventilation.

How portable is the Detector?

The detector should not be disturbed during the time a test is running. When not in use, the detector is very portable due to its small size.

How is the Detector cleaned? How often should it be?

The AscencioDx COVID-19 Test uses a sealed reaction tube, so the detector does not require cleaning between tests. When necessary, the detector can be cleaned by wiping the outer surface, including the area beneath the lid, with an antiseptic wipe containing ≥10% bleach solution or equivalent.

Reporting Results to Health Authorities

How are test results reported in clinical settings?

The AscencioDx Molecular Detector reports test results via a QR code displayed on the screen after the test result is shown. The QR code can be scanned with a phone camera or barcode reader that is connected to a computer. The test result is then transmitted to Anavasi's secure reporting website, where the relevant patient, clinic, and provider information can be entered. The data is then securely transmitted to the public health authorities. No patient information is ever entered, stored, or transmitted on or by the detector itself.

Are patient data and test results safeguarded by Anavasi Diagnostics?

Yes. The AscencioDx Detector Portal is secure and HIPAA compliant.

Are clinicians in POC settings required to submit patient or test data to Anavasi?

No. Anavasi Diagnostics facilitates reporting compliance by providing the QR code that can be scanned to access Anavasi's secure reporting website. Your

institution may choose to report test results to health authorities using other standard reporting procedures that are available in your area.

Purchasing

Where can The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector be purchased?

The AscencioDx system is available for sale from Anavasi Diagnostics or through one of our authorized distributors in accordance with its Emergency Use Authorization (EUA). For information, please email sales@anavasidx.com, or call 1-888-ANAVASI (262-8274).

Are quality control materials sold with The AscencioDx COVID-19 Test or The AscencioDx Molecular Detector?

No. They are sold separately. For positive control materials, Anavasi recommends the use of the commercially available ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 1.0 mL), Catalog No. NATSARS(COV2)-ERC1-IVD. The positive control tube contains enough fluid for 4 positive control tests. The positive control must be refrigerated (36–46°F / 2–8°C). Do not use after expiration. For the negative control, the nasal swab from The AscencioDx COVID-19 Test is used without modification.