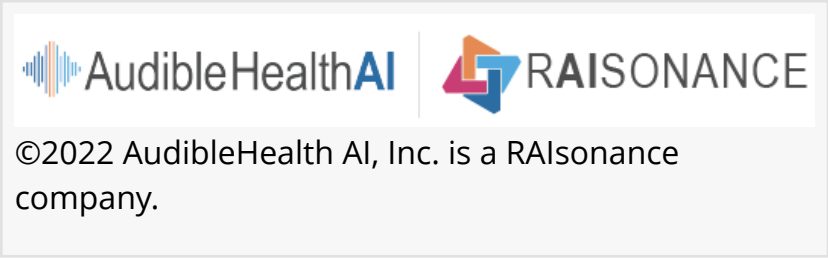
# RAIsonance Submits EUA Application to FDA for AudibleHealth Dx

*AudibleHealth Dx Software as a Medical Device (SaMD) is designed to diagnose COVID-19 illness by analyzing a user's cough sound via a smartphone app.*






GREENWOOD VILLAGE, CO, USA, September 27, 2022 / EINPresswire.com/ -- RAIsonance, Inc., today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of its AudibleHealth Dx Software as a Medical Device (SaMD). The device is designed to analyze a user's Forced Cough Vocalization-Signal Data Signature (FCV-SDS) in the diagnosis of COVID-19 illness. Results in the clinical validation study demonstrated a Positive Percent Agreement (PPA) of 84.39% and a Negative Percent Agreement (NPA) of 85.09% when compared to a reverse transcription-polymerase chain reaction (RT-PCR) test.

> I am thrilled to have submitted our EUA Application for AudibleHealth Dx. If authorized, we will immediately bring to market a COVID-19 test that will allow everyone to test as often as they wish."
>
> *RAIsonance Founder and CEO, Kitty Kolding*

"I am beyond thrilled to have submitted our EUA Application for AudibleHealth Dx." said RAIsonance Founder and CEO, Kitty Kolding. "If authorized, we will immediately bring to market a convenient, accessible, inexpensive, and innovative COVID-19 test that will truly allow everyone to test as often as they wish."

About the Clinical Trial

The submission comes after completion of the Clinical Trial conducted in Florida and enrolled 515 participants, which included 65 COVID-19 positive cases and 450 COVID-19 negative cases for a prevalence of 12.6%. The study was a prospective, multi-site, non-inferiority trial that compared the AudibleHealth Dx COVID-19 test to a highly sensitive de novo-authorized RT-PCR test to detect COVID-19 infections.

For the clinical validation study, the AudibleHealth Dx SaMD's ability to correctly diagnosis COVID-19 was compared to the BioFire RP2.1 Panel (the first FDA de novo-authorized test for COVID-19). The BioFire RP2.1 Panel runs on the BioFire® FilmArray® Torch and the BioFire®

FilmArray® 2.0 Systems in laboratories certified to perform CLIA high-complexity or moderate complexity tests.

When compared to this RT-PCR test, the AudibleHealth Dx has results demonstrating a Positive Percent Agreement (PPA) of 86.67% and a Negative Percent Agreement (NPA) of 85.20%.

Study participants included males and females aged 18 and older who presented for elective, outpatient COVID-19 RT-PCR testing and met the indications for use for the RT-PCR nasal swab test for COVID-19 using the comparator test and AudibleHealth Dx. All participants stated their willingness to comply with all trial procedures, and informed consent was obtained prior to testing.

The validation study included symptomatic and asymptomatic COVID-19 patients as well as healthy subjects who each utilized the AudibleHealth Dx SaMD device on a mobile phone and then immediately were swabbed with an RT-PCR test.

Usability Analysis Results

In addition to evaluating the NPA and PPA of the device, the company also conducted a separate, comprehensive Usability Analysis. Total usability enrollment was 443 participants. Participants included those between the ages of 18 and 88 as well as notable diversity in both ethnicity/race and educational level. Key Usability Analysis outcomes:

- 97% of participants completed the screens of the application completely independently.
- Over 90% felt confident they would know how to receive their results at home.
- 91% felt they would know how to handle a positive or a negative result correctly.
- 97.7% responded that they had a very easy or easy overall experience using the app.
- 98.4% responded that the app screens were very easy or easy to understand.
- 97.5% stated they would be very likely or likely to choose to take an AudibleHealth Dx test at home over other testing options.
- Average time to complete the test, from beginning the registration steps to the delivery of results, was 5.39 minutes.
- Overall successful test completion rate was 99.39%.

Mona Kelley, Chief of Clinical and Regulatory Affairs for RAIsonance is also pleased with the results. "Given the novelty of the test, understanding the usability of the test was essential. We are very excited about our Usability Analysis results and how well the device performed in that regard."

About RAIsonance

RAIsonance, Inc., a family of AI-powered technology solution companies headquartered in the Denver Tech Center, is focused on meeting today’s critical health and safety challenges. Founded in March of 2020, AudibleHealth AI, Inc. is the SaMD division of RAIsonance, specializing in AI/ML diagnostic solutions and platforms. Originally funded by an SBIR grant by the National Science Foundation, the team of medical, artificial intelligence, technology, and medical device specialists focuses on developing leading-edge AI/ML-based, scalable, cost-effective diagnostic products

across a range of acute and chronic health conditions. For more information visit us at RAIsonance.ai and AudibleHealth.ai.

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