ABEL Microsampler® Receives FDA Listing, Expanding Access to Nasal Liquid Biopsies for Research and Diagnostics

ABEL Microsampler® Gains FDA Class I Listing, Enhancing U.S. Research and Diagnostics with Advanced Nasal Liquid Biopsies

Diag-Nose.io Logo

Expanded configuration of the ABEL Microsampler®, ready for laboratory processing and omics analysis

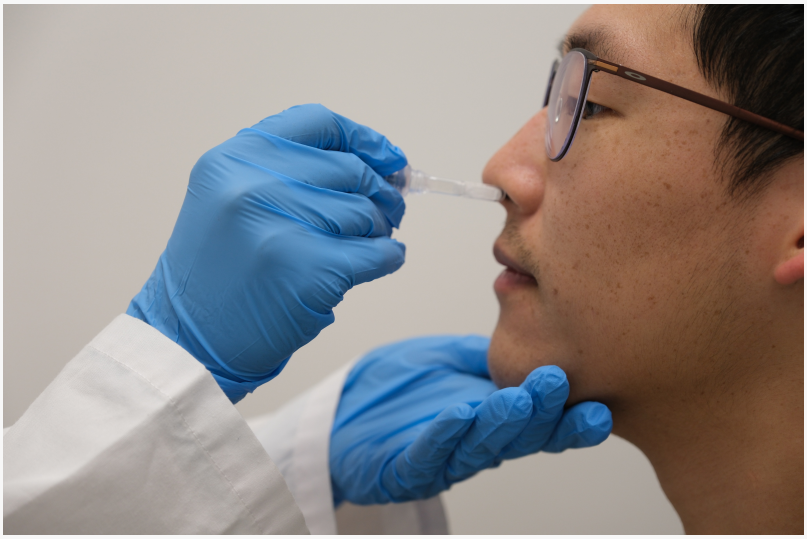
MENLO PARK, CA, UNITED STATES, March 26, 2025 /EINPresswire.com/ -- Diag-Nose.io, a leader in precision respiratory diagnostics, is excited to announce that its ABEL Microsampler® has been listed as a Class I Medical Device by the U.S. Food and Drug Administration (FDA). This regulatory milestone enables the ABEL Microsampler® to support cutting-edge research and diagnostics in the United States, transforming how nasal fluid samples are collected for biomarker discovery and omics-grade studies.

The ABEL Microsampler® is a patented, first-of-its-kind device engineered to collect precise volumes of nasal fluid with unparalleled ease and accuracy. Utilizing an innovative expanding probe made from an absorptive matrix, the device streamlines the collection of high-quality nasal liquid biopsies, making it ideal for omics-grade studies.

"The FDA Class I listing of the ABEL Microsampler® marks an important step in bringing this innovative tool to researchers and clinicians in the U.S.," said David Yen, Co-Founder of Diag-Nose.io. "This designation allows us to introduce the device to the U.S. market, expanding access to a reliable nasal sampling method that has the potential to support advancements in respiratory diagnostics, biobanking, and drug discovery."

In fields like proteomics, traditional nasal swabs often fall short due to inconsistent volumes, non-site-specific sampling, localized trauma, and susceptibility to contamination. ABEL bridges this gap by providing a patient-friendly, reliable, and precise alternative for nasal sampling.

The ABEL Microsampler® enables precise nasal fluid collection for diverse research applications, including respiratory diseases, oncology, neurodegenerative disorders, microbiome studies, and occupational health.



Standardized, non-invasive nasal fluid collection using the ABEL Microsampler® for high-quality biomarker results

Designed for researchers and clinicians, the ABEL Microsampler® simplifies biomarker-rich nasal fluid collection, supporting diagnostics, drug development, and clinical trials for respiratory biologics and precision medicine.

Dr. Jennifer Mulligan, Associate Professor of Otolaryngology at the University of Florida and investigator on prominent biomarker studies, highlighted the potential impact of the ABEL Microsampler® on her work: "The ABEL Microsampler will be a game-changer for our research. We are excited about its ability to collect precise and high-quality nasal fluid samples with minimal discomfort, enabling us to generate robust data and delve deeper into biomarker discovery for respiratory diseases. This tool bridges critical gaps in sampling methodologies and will help us set a new standard for nasal fluid research."

Diag-Nose.io is inviting early-access research partners and distributors to help expand the reach of the ABEL Microsampler®.

MEDIA CONTACT

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About Diag-Nose.io

Diag-Nose.io is a biotechnology company focused on translating the complexities of the unified airway into precision diagnostic and drug discovery solutions.

Their precision medicine technology combines advanced proteomics, computational biology, and AI (machine learning) to create a scalable respiratory biology model. This innovation aims to help clinicians prescribe the right treatments faster and enable researchers to accelerate the development of new therapies.

The company’s flagship platform, RhinoMAP™, leverages proteomic data to predict respiratory disease activity, monitor therapy response and predict treatment efficacy in advance, with an initial focus on anti-Th2 biologics.

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