



THE CHALLENGE: INFECTIOUS THREATS

& The Need for Early Detection

magine breathing into a compact device that can screen for several respiratory infection types simultaneously in just minutes. With a swift diagnosis, you can quarantine, begin treatment, and help prevent community spread.

Infectious diseases, whether naturally occurring or weaponized, remain a significant threat to both warfighters and civilians, posing risks to public health, economic stability, and national security. The rapid spread of emerging pathogens, antibiotic resistance, and the potential for bioterrorism amplify these dangers, making early detection, quarantining, and medical countermeasures essential – yet traditional methods fall short in large-scale operational settings.

Gas Chromatography-Mass Spectrometry (GC-MS), a highly versatile analytical capability, has long been demonstrated to detect and quantitate volatile organic compounds (VOCs) in exhaled breath – thereby enabling use of VOCs as biomarkers for screening infections such as SARS-CoV-2, Malaria, TB, et cetera. Studies have shown that GC-MS can not only use the VOC patterns in breath to detect SARS-CoV-2, but can also distinguish between various variants, offering promise for unparalleled respiratory diagnostics precision and rapid response.

Despite its proven scientific capabilities, GC-MS has not been widely adopted for infectious disease detection outside of laboratory settings. Its size, power requirements, and operational complexity have hindered its integration into front-line healthcare

and military applications where rapid, portable diagnostics are critical. Today's technology is:

(-) Bulky & Fragile

Lab-grade GC-MS systems typically weigh over 200 pounds, significantly restricting their mobility and making them impractical for field deployment.

(-) High Power Consumption

These systems require a stable power source, the constant operation of vacuum pumps, and ventilation, further complicating their operation in the field.

(-) Complex & Slow

Long startup times, which can take 30 minutes to several hours, and helium dependencies with its storage demands further prevent usability in time-sensitive, front-line conditions.



DETECT-ION'S BREAKTHROUGH:

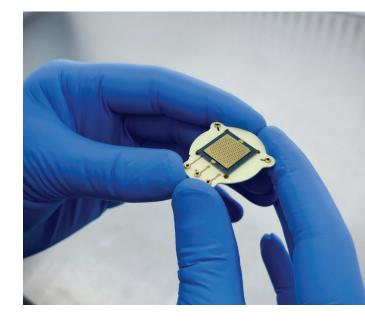
Chip-Scale Mass Spectrometry

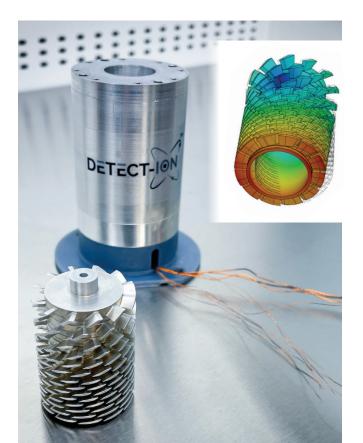
eep-tech startup, Detect-ION, has developed a novel GC-MS design to circumvent all the traditional GC-MS limitations and has created a rugged, portable 10-L shoebox-sized design as the first prototype. This groundbreaking device, named "CLARION", is now being adapted to deliver high-precision, point-of-care breath diagnostics in real-world conditions without the traditional logistical burdens or diagnostic delays. Several technological advances make this possible.

Chip-Scale Mass Spectrometry

Detect-ION's chip-scale mass spectrometry powers CLARION's breath diagnostics, delivering 1- atomic mass resolution (amu) mass spectral signatures in less than 3 W power. The technology leverages approximately 200 microfabricated ion traps operated simultaneously with precise oscillating electric fields to trap and discriminate ions and analyze the organic content of exhaled breath. This approach, when coupled with Detect-ION's low-thermal-mass GC, delivers a full cross section of VOCs from exhaled breath for data analysis and detection algorithms enabling seamless integration of four critical analytical stages into a single device:

- Breath Collection Non-invasive sampling captures exhaled breath.
- Preconcentration (Thermal Desorption) VOCs are concentrated for detectability.
- Gas Chromatography VOCs are separated for precise identification.
- Mass Spectrometry VOCs are measured, identified, and quantified.



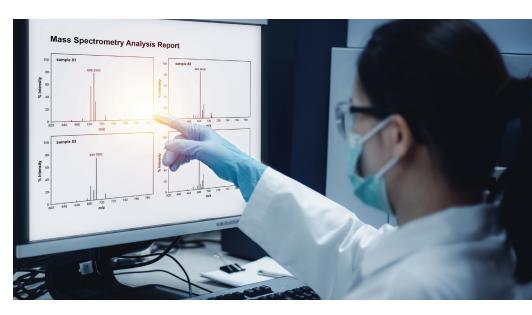


Moving to an On-Demand Paradigm

Traditional mass spectrometers require constant low-pressure environments for the ionization and ion detection stages, which are maintained by large, continuously running vacuum pumps. Because of their need for constant power, they are tethered to fixed locations, such as labs, airports, or factories, and moving them is a meticulous process requiring significant down time.

CLARION eliminates these constraints with an on-demand approach. Precision engineering allows for smaller, rapidacting pumps that create ideal ionization conditions only when needed. Unlike conventional systems with lengthy warm-up times, CLARION's electron impact ionization source operates at room temperature, enabling immediate analysis without any stabilization time. When powered down, the system is filled with an inert environment to preserve sensitive components, ensuring it remains ready for rapid deployment and be back up and running in minutes, not hours or days.





Embedded Breath Collection Eliminates Sample Preparation, Storage, and Transport

Traditional breath analysis relies on Tedlar bags or sorbent tubes for breath collection followed by laboratory analysis. Instead of such storage media, which require certain storage conditions, may have sample loss over time, and are typically overwhelmed with intrinsic contaminants, CLARION uses an embedded breath collector to collect exhaled breath. This approach enables a fully integrated single hardware for breath collection, immediate analysis, and disease detection all in a matter of a few minutes. This reduces the time and completely removes the traditional complexity of sample collection, transport, and preparation in the field.

AI/ML Drives Batch Processing of Big Breath Data to Speed-up Diagnosis

Traditional breath diagnostics depend on expert-driven, manual analysis – a slow and labor-intensive process. CLARION automates this workflow using Al-driven software and machine learning (ML). The system is built on a comprehensive reference library of known chemical markers, developed through high-resolution mass spectrometry (HRMS) analysis of breath samples.

CLARION's embedded processor cleans the raw data, filters out background noise, and adjusts for any inconsistencies. Using a combination of advanced search algorithms and pattern recognition, CLARION matches chemical signatures against the reference library to identify the breath's chemical signature and compare it to known infection profiles. Machine learning models then determine whether the sample belongs to a healthy individual or someone with a respiratory infection in real time, enabling faster, more accurate diagnoses at scale.



CLARION's breakthrough lies in its seamless integration of advanced chip-scale mass spectrometry, on-demand vacuum technology, and AI-driven analysis into the first-of-its-kind, all-in-one, field-deployable system.

BRIDGING THE GAP:

From Lab to Field-Ready Solutions

LARION is the first solution to address the Department of Defense (DoD)'s need for a real-time, field-ready diagnostics matching the precision of traditional laboratory diagnosis. By combining cutting-edge mass spectrometry with intrinsically robust parts, subsystem, and Aldriven automation, CLARION delivers unprecedented diagnostics for the warfighter's safety and well-being. Key CLARION features:

(+) Compact, SWaP-Optimized

CLARION is a 10-L volume prototype weighing 6 kg delivering unprecedented portability for bedside or point-of-care applications for warfighters who may need it the most during active missions.

(+) Unmatched Sensitivity to Screen Multiple Infections

CLARION achieves part-per-trillion (PPT) detection levels in just minutes, making it ideal for detecting subtle VOCs patterns relevant to viral, bacterial, and fungal infections. It is capable of differentiating critical pathogens like SARS-CoV-2 and Streptococcus pneumonia, offering a capability not previously achievable by a single diagnostics device in minutes.

(+) Fieldability

Built with intrinsically robust components and planned for MIL-STD-810H standards, CLARION operates reliably in extreme temperatures, humidity, and rugged conditions.

(+) Long Shelf Life and Rapid Startup

CLARION has a long shelf-life and powers up in 30 seconds for on-demand sampling, conserving energy when not operational for extended field use.

(+) Secure Data Connectivity

Equipped with AES-256 encryption and seamless integration into the Android Team Awareness Kit (ATAK), enabling live analysis, secure data transfer, and algorithm updates supporting real-time decision making.

This breakthrough ensures critical operations have access to rapid, accurate results in any environment – without reliance on centralized labs, complex logistics, or extended wait times. Whether deployed in remote locations, high-risk zones, or military operations, CLARION provides an unprecedented level of diagnostic capability, transforming how and where infections can be detected.

Beyond accuracy, Detect-ION is optimizing CLARION's size, weight, and power (SWaP) efficiency while reducing costs. The goal is to develop a miniature breath collector for under \$1,000, a sensor system for under \$15,000 and a diagnostics cost of less than \$1 per breath test, ensuring affordability and scalability for widespread DoD adoption.

Additionally, CLARION can be rapidly adapted for a broad range of CBRNE threat detection, including but not limited to, toxic industrial compounds/materials (TICs/TIMs), chemical weapons agents (CWAs), pharmaceuticals-based agent (PBAs), explosives, and per- and polyfluoroalkyl substances (PFASs).





WHERE WE GO FROM HERE:

Field Trials & Clinical Validation

etect-ION is actively refining CLARION's capabilities to meet the growing demand for rapid, field-ready diagnostics. Building upon prior successes in government-led field validations—such as the USAF-led flight testing in C-130 aircraft to measure and profile methyl salicylate concentrations inside the aircraft, and DHS-led Chem-Bio testing in a New York City subway station to monitor the subway air environment—Detect-ION is now validating CLARION for breath diagnostics in a clinical trial underway in Tampa, Florida.

In this DTRA-funded clinical trial, CLARION is being evaluated for its ability to detect pathogen-specific VOC biomarkers, including those linked to contagious respiratory infections such as SARS-CoV-2, Influenza, Streptococcus pneumoniae and Acinetobacter baumannii. Detect-ION is partnering with the University of South Florida's Global Health Infectious Disease Research Center and the University of California, Davis to access well-established clinical setups. Currently in the first phase of the campaign, Detect-ION is using both HRMS and CLARION to process breath and compare diagnostics performance.

Through these advancements, CLARION is poised to set the standard for portable diagnostics, supporting the DoD's EXHALE mission to provide handheld, scalable solutions for rapid and reliable disease detection for warfighter wellness and assurance. By transitioning labgrade mass spectrometry into a compact, portable system, CLARION delivers real-time breath analysis, enabling a new class of clinically meaningful diagnostics for DoD preparedness. Its rugged, MIL-STD-compliant design ensures dependable performance in extreme conditions, making it ideal for front-line use.

As real-world testing drives further optimizations, CLARION is poised to transform diagnostics saving lives, improving operational readiness, and delivering fast, reliable results wherever they are needed.



Other Applications:

- (+) Air-quality testing
- (+) Soil and water quality assurance
- (+) Explosives analysis
- (+) Chemical warfare agent detection
- (+) Chemical exposure monitoring
- (+) Boarder security and customs inspection

Sources

- Magnano, M.C., et al. Exhaled volatile organic compounds and respiratory disease. Trends in Analytical Chemistry, 176 (2024).
- Sharma, A., et al. Smelling the Disease: Diagnostic Potential of Breath Analysis. Mol Diagn Ther, 27 (2023): 321–347.
- Maidodou, L., et al. Unraveling VOC devices for disease detection. Front. Chem. 11 (2023): 1282450.
- Issitt, T., et al. Volatile compounds in human breath. J. Breath Res. 16 (2022): 024001.
- McCartney, M.M., et al. Predominant SARS-CoV-2 variants and breath analysis. Comm Med, 2 (2022): 158–166.
- Keogh, R.J., & Riches, J.C. (2022). The Use of Breath Analysis in the Management of Lung Cancer: Is It Ready for Primetime? Current Oncology, 29(10), 7355–7378.

Detect-ION is a trailblazing deep-tech startup founded in 2021 and headquartered in Tampa, Florida. At the forefront of developing next-generation sensor technologies for CBRNE applications, Detect-ION's groundbreaking innovations have broad impacts in national security, public health, environmental monitoring, and life sciences.