Detect-ION

2025 Annual Summary

DETECT-ION

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LETTER *from* OUR FOUNDER

Ashish Chaudhary, Ph.D.
Founder/CTO/CEO

As we reflect on 2025, I'm incredibly proud of the progress our team has made in advancing Detect-ION's mission to bring life-saving diagnostics to more people, in more places, and at the moments when they matter most. This year marked a turning point as CLARION moved from concept to demonstrated capability, with successful deployments across infectious disease, global health, oncology, and national security applications. These milestones are the result of years of foundational investment in chip-scale mass spectrometry and the dedication of a multidisciplinary team committed to translating deep science into real-world impacts.

In 2025, we validated our technology in diverse and demanding environments, from clinical studies here at home to field deployments in the Republic of Congo. We advanced detection algorithms for respiratory infections, malaria, and tuberculosis rigorously developed via clinical validations, and expanded our molecular libraries and strengthened our regulatory foundation through early engagement with the FDA. At the same time, we invested in the infrastructure and talent needed to support scale, including the addition of a dedicated breath research lab at our headquarters and the expansion of our technical and clinical teams. Together, these efforts are moving CLARION closer to practical, accessible deployment as a point-of-care diagnostic platform.

Looking ahead, 2026 will be a pivotal year as we advance clinical validation in lung cancer and pneumonia, launch the next generation of CLARION, and explore other meaningful clinical interventions. We remain deeply grateful to our partners, funders, and collaborators who share our belief that accessible, rapid diagnostics can improve outcomes and save lives. With their support, we are refining technology that not only advances molecular science, but also strengthens health, resilience, and readiness around the world.

OUR MISSION
To bring life-saving health diagnostics to the masses

OUR VISION
Accessible, fast, and reliable diagnostics improve personalized health and well-being for all.

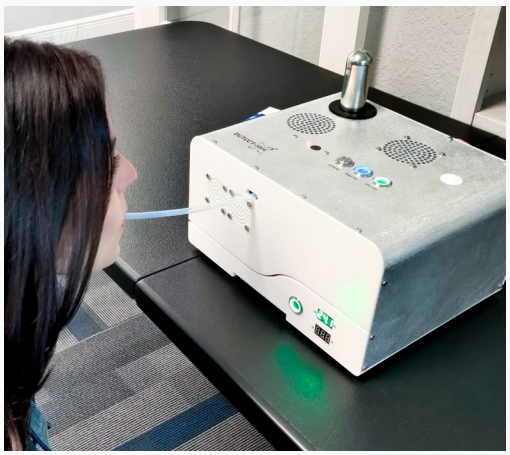
OUR PURPOSE
To transform mass spectrometry through next-generation sensor technology for day-to-day use.

ADVANCING CLARION:
Breath-Based Molecular Diagnostics *at the* Point of Care

Meet CLARION, our point-of-care breath diagnostics platform that delivers clinical-grade molecular analysis in minutes from a simple breath specimen. Powered by our patented chip-scale mass spectrometer (MS) and high-speed, low-thermal-mass gas chromatograph (GC), CLARION brings the gold standard of chemical analysis, GC-MS out of the laboratory and into field-ready use. By rapidly measuring trace volatile organic compounds (VOCs) in exhaled breath, CLARION can screen for multiple diseases and provide fast, actionable results at the point of care.

This first-of-its-kind device pairs laboratory-level sensitivity and accuracy with a compact, rugged system that integrates breath collection, analysis, and automated decontamination in one end-to-end workflow for precise disease detection.

In 2025, three CLARION-α prototypes were deployed in research studies spanning respiratory infections, malaria and tuberculosis, and lung cancer, demonstrating the platform's versatility and potential to transform pervasive disease detection capabilities. Meanwhile, we've been hard at work developing CLARION-β, a significantly more advanced and robust system with an interactive touch screen and a versatile sampling approach tailored for early technology adopters and commercialization.



CLARION-α prototype

CLARION-β prototype

Our Approach

Critical Need Identified
Deep domain expertise revealed the gap in low-SWaP chemical sensing for defense and survivability

Backed by $22M
Validated through high-risk, first-principles R&D funded by the U.S. government

Proven Versatility
Expanded high-value sensing applications, including health diagnostics

Productizing the Breakthrough
First-of-its-kind, integrated chip-scale technology is scalable, profitable, lifesaving, and venture-ready

Market-Ready
Poised to disrupt existing markets and unlock new ones

10	**30**	**2**	**5**
LITER	**SECOND**	**MINUTE**	**MINUTE**
Compact Form Factor	On-Demand Startup	Breath Sampling Time	Diagnosis

A Year *of* PROJECTS *and* VALIDATIONS

CLARION: Infectious Disease Detection in Warfighters

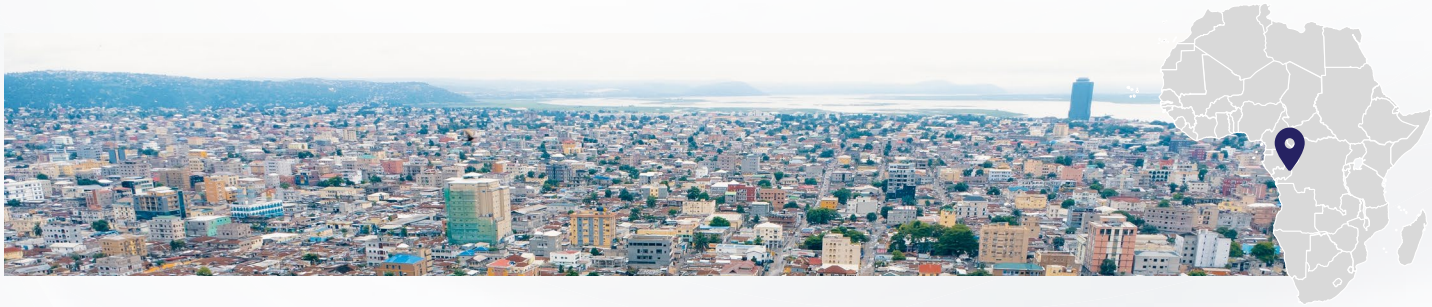
Status
Campaign-1 Completed
Campaign-2 Ongoing

Partners
University of South Florida (USF) & University of California, Davis

Funding
Defense Threat Reduction Agency (DTRA) & Defense Innovation Unit (DIU)

CLARION was developed to address a critical gap in infectious disease detection highlighted by the COVID-19 pandemic and to protect warfighter health and mission readiness. Building on chip-scale mass spectrometry advances from prior IARPA and DARPA programs, CLARION identifies infection-linked volatile organic compound (VOC) biomarkers and applies machine learning to enable real-time screening. Designed for austere environments where medical personnel and laboratory infrastructure are limited, CLARION aims to deliver a rapid, non-invasive, point-of-care breath test capable of screening multiple infections from a single specimen.

This year, Campaign-1 enrolled 100 healthy and symptomatic adults at USF's Global Health Infectious Disease Research Center. Participants provided breath specimen, nasal swabs and sputum, enabling immediate CLARION analysis and comparison with high-resolution mass spectrometry (HRMS). Clinical testing established ground truth for diagnostic model development, with early results indicating the ability to distinguish healthy from infected individuals, differentiate viral from bacterial infections, and begin identifying specific pathogens. Campaign-2 launched in October onsite at Detect-ION's Breath Research Lab and has enrolled more than 150 participants to date, advancing CLARION toward scalable, non-invasive respiratory infection detection.



MATTHIAS: Malaria & Tuberculosis Diagnostics in Low Income Regions

Status
Human Trials Completed
Data Analysis Underway

Partners
Labyrinth Global Health (LGH), Laboratoire Nationale de Santé Publique (LNSP) & Owlstone Medical

Funding
Gates Foundation

Our global collaboration with LGH, LNSP, and Owlstone Medical focuses on advancing infectious disease detection through rapid, non-invasive breath diagnostics at the point of care in low- and middle-income countries (LMICs). The program aims to make high-quality testing affordable, accessible, and deployable in settings where traditional laboratory infrastructure is difficult to sustain. This year, we completed two five-week human trials of CLARION in Brazzaville, Republic of Congo. Hundreds of participants were screened for malaria and tuberculosis, with paired breath specimen and sputum samples collected for HRMS and PCR testing respectively. These data support the identification and validation of candidate VOC biomarkers and strengthen CLARION's diagnostic models.

The deployments demonstrated both technical performance and operational readiness under real-world conditions, including intermittent power and complex logistics. Insights from patients and clinician use informed human-centered design improvements, while AI and machine learning are now being applied to refine pattern recognition and improve accuracy. Results are benchmarked against gold-standard diagnostics, supporting earlier detection, stronger surveillance, and more equitable access to care.

Early Lung Cancer Detection

Status
Underway

Partners
Moffitt Cancer Center

Funding
Detect-ION

We're partnering with Moffitt Cancer Center on a pilot to evaluate lung cancer detection using CLARION's rapid, non-invasive breath diagnostics. Current screening methods rely largely on low-dose CT scans and are typically reserved for high-risk individuals. By analyzing VOC biomarkers in exhaled breath, we aim to develop an ultra-low-cost, patient-friendly point-of-care test to make early screenings more accessible.

Initial efforts are focused on late-stage lung cancer patients to identify breath biomarkers. If successful, the pilot will expand to early-stage patients to evaluate if CLARION can diagnose lung cancer before symptoms appear. This work also establishes a foundation for extending breath-based diagnostics to other cancers, reinforcing our commitment to scalable, accessible diagnostic innovation.

Breath-Based Pseudomonas Detection

Status
Initial in-vitro VOC biomarker validation ongoing

Partners
Mayo Clinic Florida

Funding
Mayo MC-AIR Program

In December, we were selected by Mayo Clinic's Advanced Innovation Research Program to collaboratively evaluate the potential of a breath test to detect Pseudomonas aeruginosa (PA), a major cause of pneumonia in high-risk and immunocompromised patients. Current diagnostics are often slow and invasive, frequently relying on bronchoscopy, which can be unsafe for many individuals.

Beginning in 2026, the program will identify VOC biomarkers from cultured PA using high-resolution mass spectrometry and will inform CLARION diagnostics algorithms. The goal is to enable faster and more precise diagnosis, reduce unnecessary antibiotic use and invasive procedures, and support monitoring of disease severity and treatment response.

SPECTRAL: Aerosol & Vapor Chemical Threat Characterization Platform

Status
Completed

Funding
Office of the Director of National Intelligence (ODNI) and Intelligence Advanced Research Projects Activity (IARPA)

Expanding beyond breath, we've developed SPECTRAL through an IARPA research contract as an ultra-compact sensor platform for detecting and identifying aerosolized chemical threats in real-world environments. Our goal was to deliver laboratory-grade chemical analysis in the field using a low-SWaP system capable of autonomous operation. By integrating advanced aerosol collection with rapid gas chromatography, chip-scale mass spectrometry, and AI advancements, SPECTRAL enables rapid, high-confidence identification of a broad range of aerosolized and vaporized chemical threats.

In May, SPECTRAL was successfully tested by the PICARD Test and Evaluation Team at the Naval Research Laboratory under operationally relevant conditions, achieving Technology Readiness Level 5. Testing confirmed reliable trace-level detection in dynamic environments, including correct identification of true unknowns. Beyond defense applications, SPECTRAL establishes a foundation for broader use in public health, environmental monitoring, agriculture, and public safety.

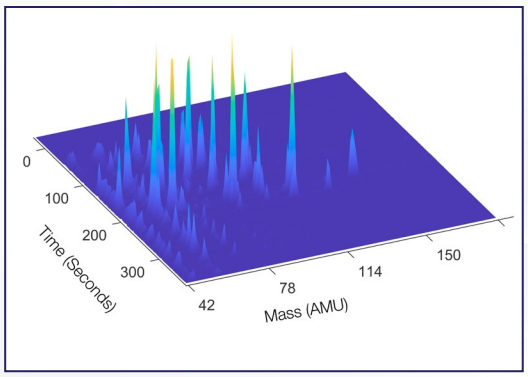
MAJOR 2025 MILESTONES

Biomarker Validation and Detection Algorithms

We expanded our mass spectral library for breath and chemical threat-relevant VOCs and confirmed repeated alignment with existing NIST/NIH/EPA libraries. High Resolution Mass Spectrometry (HRMS) was routinely used to corroborate CLARION findings and to augment CLARION detection algorithms.

We also advanced breath-based respiratory infection detection by building and refining breath VOC models that distinguish healthy individuals from infected patients and differentiate viral from bacterial infections. Using data from our inaugural breath research study, we developed detection algorithms for H. influenzae and rhinovirus. This progress supports earlier, more accurate diagnosis, enabling faster treatment, reducing the risk of severe disease and hospitalization, limiting transmission, and helping avoid unnecessary antibiotic use.

Beyond respiratory infections, we further advanced malaria detection algorithms using data from human trials conducted in the Republic of Congo. This work extends our breath-based approach into infectious diseases that carry a heavy burden in resource-limited settings and strengthens CLARION's potential to support earlier screening and treatment where rapid, accessible diagnostics can have the greatest impact.



Regulatory Preparation & FDA Feedback

We advanced CLARION's FDA regulatory readiness by initiating early discussions through a Pre-Submission to define intended use, confirm the most appropriate regulatory pathway, and understand the expected safety, analytical, and clinical validation requirements for a first-of-its-kind diagnostic. We also continued building the quality and documentation framework needed to support design controls, reproducible performance, and a scalable transition from R&D to a regulated product.

2025 Publications

Kibelka, G.; McRae, D.; Schweitzer, B.; Vasquez, G.; Strickrott, J.; Jabson, D.; Chaudhary, A. In-Situ and Instantaneous Detection of Aerosolized Chemical Threats Using Chip-Scale Mass Spectrometry. Proc. SPIE (CBRNE Sensing XXVI), 2025.

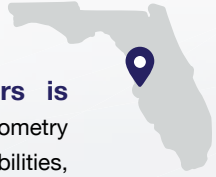
Kibelka, G.; McRae, D.; Alfonso, P.; Schweitzer, B.; Martinez, J.; Vasquez, G.; Strickrott, J.; Jabson, D.; Chaudhary, A. In-Situ and Instantaneous Detection of Aerosolized Chemical Threats Using Chip-Scale Mass Spectrometry. SPIE Defense + Commercial Sensing, 2025.

Manolakos, S.; McRae, D.; Schweitzer, B.; Miley, K.; Unnasch, T.; McCartney, M.; Davis, C.; Chaudhary, A. Chip-Scale Mass Spectrometry for Point-of-Care Breath Diagnostics. ASMS Conference on Mass Spectrometry and Allied Topics, 2025.

Schweitzer, B.; Manolakos, S.; Miley, K.; Joyce, M-R.; Trejo Paz, C.; Davis, C.; McCartney, M.; Borras, E.; Chaudhary, A. Chemometric Techniques for the Automated Batch Processing of GC-MS Data for Chemical Identification and Supervised Model Development. ASMS, 2025.

BUILDING CAPACITY TOWARDS COMMERCIALIZATION

Breath Research Lab Opens Onsite



Our 4,000 square-foot, state-of-the-art headquarters is located in Tampa, Florida. It features a deep-tech mass spectrometry instrumentation lab, a rapid prototyping shop, 3-D printing capabilities, and High-Resolution Mass Spectrometry (HRMS) for biomarker discovery.

This year, we've added an onsite Breath Research Lab with a private entrance and central access point for study participants. The lab streamlines research study operations, reduces delays between study phases, and enables real-time data integration and faster feedback loops between engineering and clinical teams. The dedicated space also improves the participant journey, creating smooth check-ins and consistent care.

Expanding Our Expertise

We're backed by a multi-disciplinary team with more than 100 years of combined expertise in analytical chemistry, vacuum technology, gas chromatography, mass spectrometry, embedded low-SWaP electronics, clinical research, AI/ML-driven data analytics and systems engineering. Our technical team hails from premier research organizations, including: SRI International, Draper, NASA, NIST, ChemImage, and the University of South Florida.

This year saw significant team expansion, building on our core team to accelerate R&D and productization as we move toward commercialization. This includes hires across engineering, data science, and business functions to support our growing portfolio of diagnostics and sensing technologies.

GROWING OUR CREDIBILITY *and* VISIBILITY

Attending key events and presenting our work is critical to validating our technology, sharing progress with the scientific and defense communities, building strategic partnerships, and ensuring our solutions are shaped by real-world needs.

This year, we exhibited CLARION at the eMerge Americas Expo, a premier global tech conference in Miami, and connected with tech industry leaders. We attended the SPIE Defense + Commercial Sensing exhibition to present on In-Situ and Instantaneous Detection of Aerosolized Chemical Threats Using Chip-Scale Mass Spectrometry. And, at the 73rd Conference on Mass Spectrometry and Allied Topics (ASMS), we presented on:

- Chip-Scale Mass Spectrometry for Point-of-Care Breath Diagnostics
- Chemometric Techniques for the Automated Batch Processing of GC-MS Data for Chemical Identification and Supervised Model Development
- A Novel Aerosol and Vapor Chemical Threat Characterization Platform

In addition, we attended numerous local and regional events throughout the year, including Moffitt Cancer Center's Business of Biotech, Military Health System Research Symposium (MHSRS), and Embarc Collective's Tampa Bay Healthtech Meetups.

View our posters and publications:
detect-ion.com/research

detect-ion.com

Launched in August, our new website was redesigned to clearly communicate who we are, what we do, and where we are headed. It offers a deeper look at the science and technical progress powering our platform and shaping the future of molecular analysis. The site also shows how our capabilities address today's challenges and anticipate tomorrow's needs across defense, health, environmental monitoring, and beyond.

Key News Coverage & Features

- AP News
- Tampa Bay Business Journal
- Healthcare Business Today
- BioFlorida
- Florida Georgia BioTech Networks
- Florida High Tech Corridor Impact Report Spotlight
- Hillsborough Co. Economic Development Innovation Initiative (EDi2) Update
- USF CONNECT Alumni Spotlight

2026 OUTLOOK

Looking ahead to 2026, we will build on the technical, clinical, and regulatory progress achieved this year to advance CLARION toward broader validation and real-world deployment. A key focus will be clinical validation in lung cancer and pneumonia alongside the launch of CLARION-β, which will incorporate performance, usability, and reliability improvements informed by ongoing studies. We also plan to initiate a breast cancer pilot, extending our breath-based approach into additional oncology applications.

In parallel, we will continue refining our regulatory strategy while launching early market pilots to evaluate CLARION's performance in intended-use settings and gather feedback from clinicians and partners. Together, these efforts position 2026 as a pivotal year for translating our technology from research and pilot studies into scalable diagnostic solutions for the battlefield, bedside, and beyond.

Learn More & Connect with Us

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Detect ION LLC