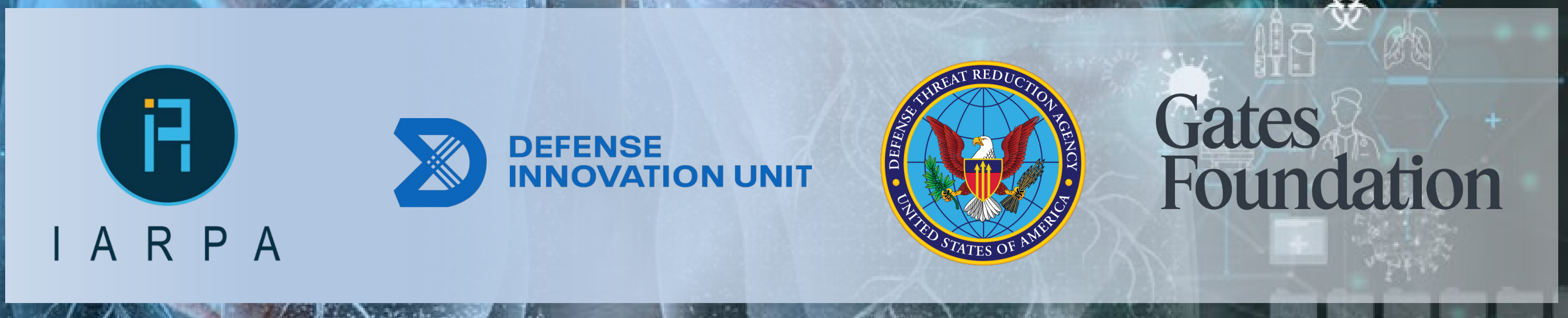


# Fieldable GC-MS for Biothreat Detection, Warfighter Health and CBRNE Sensing

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## Problem Statement

Infectious pathogens, whether weaponized through bioterrorism or naturally encountered degrade combat effectiveness. For US forces, success hinges on detecting pathogen exposure early, accurately, and far forward. Today's diagnostics force a hard tradeoff: laboratory assays deliver accuracy but depend on sample collection, cold chain, and reach-back, introducing unacceptable delays, while rapid field tests reduce that latency at the cost of sensitivity and accuracy.

Breath offers a way past this tradeoff, sampled in minutes, non-invasively, and without reagents or cold chain. Yet breath-based VOC analysis has long depended on gas chromatography-mass spectrometry (GC-MS), the gold standard, which remains confined to centralized laboratories. Detect-ION's CLARION Point of Care Breath Diagnostics Platform breaks this constraint, by pairing patented chip-scale mass spectrometry with low-thermal-mass gas chromatography in a ruggedized form factor that brings laboratory-grade confidence to the point of care.



Figure 1. CLARION collects and analyzes exhaled human breath in a field-forward austere environment thereby enabling laboratory-grade GC-MS analytical capability in a decentralized outdoor setting.

## Biomarker Discovery & Diagnostics Model

To develop CLARION's diagnostic model (or "breath test"), paired breath specimens were collected from human subjects for both high-resolution mass spectrometry (HRMS) and CLARION analysis. HRMS was used to identify candidate VOC biomarkers tied to a specific pathogen or disease, while PCR analysis provided ground-truth confirmation of each subject's condition. These HRMS-derived biomarker signatures and PCR labels then trained and developed CLARION's diagnostic models, enabling rapid, fieldable point-of-care breath analysis for the targeted disease.

## CLARION: Breath Diagnostics

Detect-ION has applied CLARION breath diagnostics across four clinical pilots spanning a diverse range of disease targets and deployment settings: (1) infectious disease, (2) lung cancer, (3) pneumonia, and (4) malaria and TB in low- and middle-income countries. Diagnostic performance results from the completed studies, namely the DIU/DTRA funded Infectious disease diagnostics and Gates Foundation funded malaria/TB diagnostics are presented below, while the lung cancer and pneumonia studies will be completed by end of Summer 2026.



Figure 2. Detect-ION deployed an early-stage variant of the platform, CLARION-α, directly in the field. Brazzaville, the capital of the Republic of Congo, was selected as the study site for deliberate scientific and epidemiological reasons: the city carries a high dual burden of malaria and TB, operates within a healthcare infrastructure representative of the broader sub-Saharan African context, and hosts institutional partners capable of supporting rigorous clinical research.

In these cross-sectional studies, CLARION collected 4 L of exhaled breath which typically requires 4 min of subject interaction. The common inclusion criteria included no food or drink within 1 hr. of breath collection. CLARION analyzed the breath in real time, while the paired breath specimen for HRMS analysis collected on sorbent tubes were sent back to Detect-ION for processing.

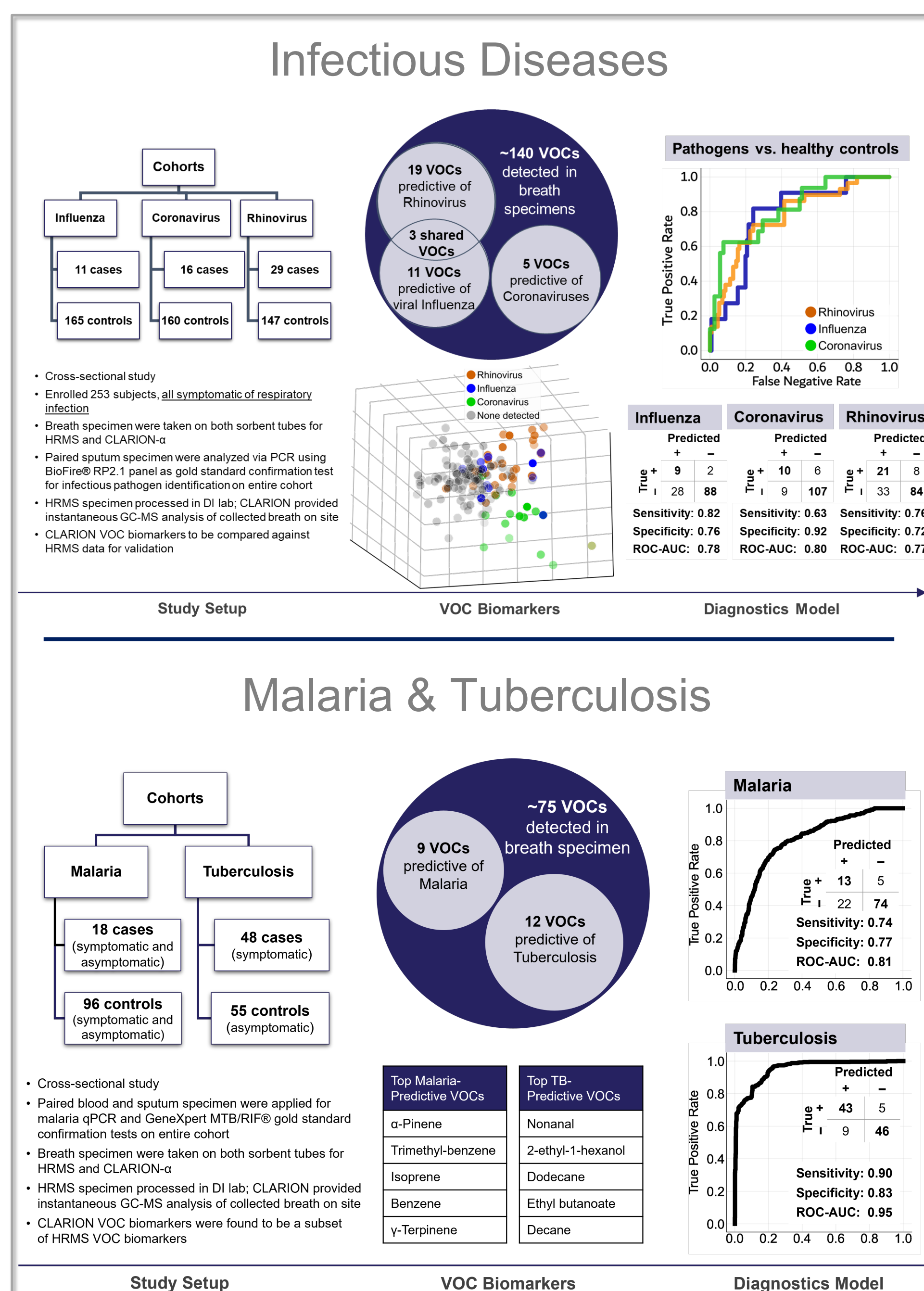


Figure 3. Diagnostics models developed using exhaled breath after a rigorous multi-stage data processing pipeline applied to the full breath dataset: background subtraction to isolate endogenous VOC signal from ambient and instrumental noise, signal denoising to improve spectral clarity, and systematic feature extraction to identify candidate biomarker VOCs across the cohort. The resulting feature sets were then subjected to multivariate statistical analysis to develop and internally validate diagnostic classification models for the disease state.

## CLARION: CBRNE Sensing

CLARION's GC-MS stage has also been adapted for sensing under the IARPA PICARD program, extending the platform beyond breath diagnostics into CBRNE threat detection. The same architecture that resolves trace VOC biomarkers in breath brings laboratory-grade molecular analysis into the field, collecting volatile and semi-volatile organic compounds (VOCs and SVOCs) and aerosols from ambient environments. Combining high sensitivity and specificity, CLARION leverages a NIST/EPA/NIH-style mass spectral library and onboard detection algorithms for rapid chemical identification.

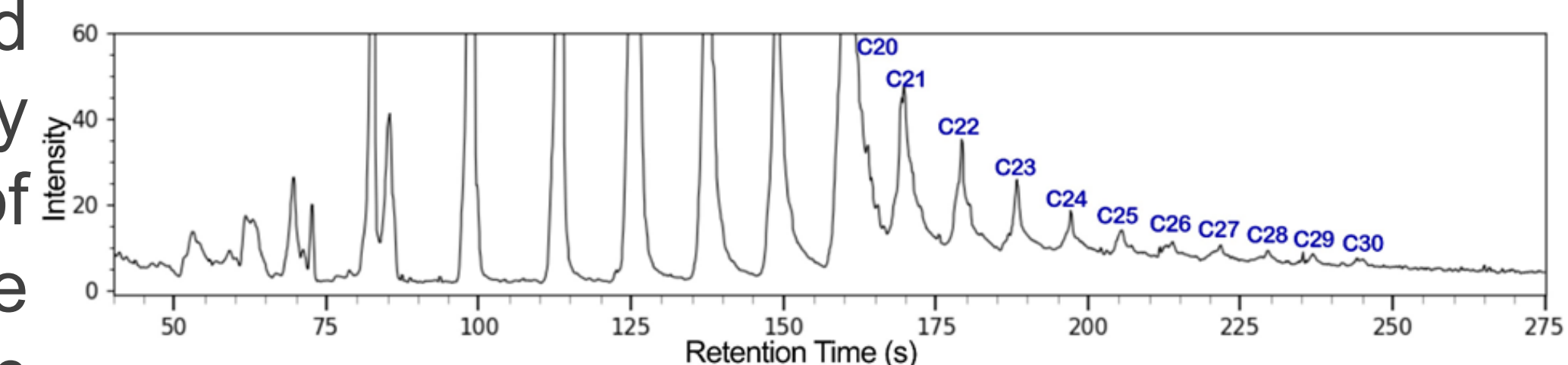


Figure 4. Display of the TIC generated by the CLARION system showing the chromatography performance for the alkane standard (Sigma-Aldrich 49451-U) [1 μL injected diluted C7-C30 at 300 μg/mL (C20 600 μg/mL)]. This data demonstrates that CLARION detects low vapor pressure chemicals which is a critical requirement for analyzing explosives, opioids, pharmaceutical based agents, etc.

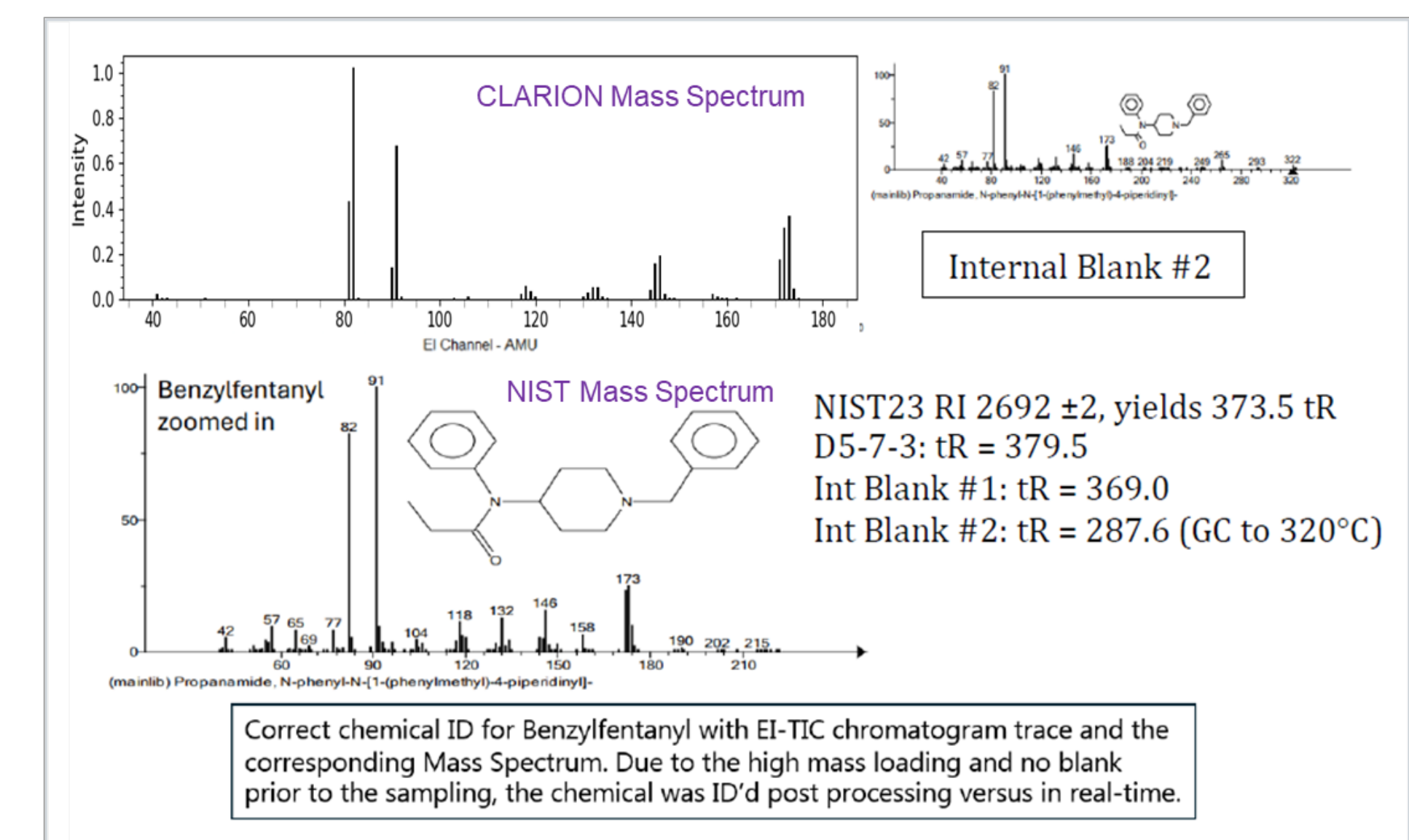


Figure 5. An excerpt from IARPA PICARD Government Test-3 Report showing the detection of Benzylfentanyl (CAS No. 1474-02-8) using CLARION. In this test, Detect-ION used the impactor stage instead of the sorbent for aerosol collection and desorption. [LTM GC - 10 m x 0.250 mm x 0.25 μm].

## Ongoing CLARION Advancements

- Expanded sampling methods:** Extending beyond breath/air sampling to include direct liquid injection and dynamic headspace analysis, broadening accessible specimen types and matrices.
- Real-time chemical deconvolution & identification:** Upgrading the interactive user interface to deliver on-the-fly identification, putting actionable results directly in the operator's hands.
- Auto calibration routines:** Autonomously offsetting long-term system drift to preserve analytical accuracy across extended field deployments.

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