DETECT-ION

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CLARION

Point-of-Care Breath Diagnostics

Multiplexed Respiratory Infection Screening for Warfighter Readiness and Global Health

In collaboration with
The University of South Florida (Center for Global Health and Interdisciplinary Research) and the University of California, Davis

Supported by
The Defense Threat Reduction Agency (DTRA) and the Defense Innovation Unit (DIU) under the EXHALE Program

A manuscript is under preparation for submission to the Journal of Breath Research

Executive Summary

Detect-ION deployed the CLARION breath diagnostics platform for the first clinical validation of point-of-care, breath-based screening of respiratory infectious diseases, conducted under the Department of Defense EXHALE program funded by the Defense Threat Reduction Agency (DTRA) and the Defense Innovation Unit (DIU). Respiratory pathogens, whether naturally emerging, endemic, or deliberately introduced, pose an outsized threat to warfighter readiness and force health, spreading rapidly through the close-quartered settings in which military personnel live and operate. The program set out to answer a direct question: can a single, field-deployable device screen exhaled breath for multiple respiratory infections in minutes, without swabs, sample transport, or a centralized laboratory?

Across two clinical campaigns in Tampa, Florida, CLARION collected and analyzed exhaled breath from symptomatic and asymptomatic adults, with every subject benchmarked against multiplex RT-PCR (BioFire FilmArray) as the diagnostic reference standard and against laboratory high-resolution mass spectrometry (HRMS) as an orthogonal analytical layer. From approximately 140 volatile organic compounds (VOCs) resolved in breath, supervised machine-learning models identified compact, largely non-overlapping biomarker signatures for influenza, coronaviruses, and rhinovirus, achieving per-pathogen receiver-operating-characteristic areas under the curve (ROC-AUC) of 0.78, 0.80, and 0.77, respectively.

Two findings carry strategic weight. **First**, breath-based respiratory diagnostics are clinically feasible at the point of care, using a rugged device engineered for the field rather than the bench. **Second**, the VOC signatures distinguishing the three viruses were largely distinct (only three compounds were shared across them), demonstrating that CLARION resolves pathogen-specific molecular fingerprints rather than a generic host-inflammation signal. Together these results establish the evidentiary foundation for a multiplexed CLARION respiratory screen: one breath specimen, several pathogens, a result in minutes, built first for the warfighter and scalable to the far larger public-health need for rapid, non-invasive infection surveillance.

Problem Statement

Infectious diseases remain among the most disruptive threats to military forces and civilian populations alike, and respiratory infections carry a particular operational danger: they move rapidly through the close-quartered environments (barracks, ships, aircraft, and forward operating bases) where warfighters live and work. A single undetected respiratory infection can sweep through a unit in days, degrading readiness at the moment it matters most. The very pathogens that jeopardize mission assurance (influenza, coronaviruses, emerging respiratory viruses, and bacterial pneumonias) impose an enormous parallel burden on global public health, and the prospect of naturally emerging or deliberately engineered agents only sharpens the need for early, decentralized detection. The COVID-19 pandemic laid bare how thin the diagnostic margin truly is.

Figure 1. Respiratory pathogens threaten both force readiness and global public health, demanding detection at the point of need.

Existing diagnostic modalities present substantial practical limitations in these settings. Polymerase chain reaction (PCR) assays are the clinical gold standard for sensitivity and specificity, but they are centralized, resource-intensive, and time-consuming, requiring invasive specimen collection, sample transport, and laboratory processing that preclude real-time, population-scale screening.[1] Rapid antigen tests offer faster turnaround but sacrifice sensitivity, particularly during early or asymptomatic infection, and are generally limited to a single pathogen per test.[2] In the absence of timely, specific results, clinicians fall back on empiric broad-spectrum antibiotics, accelerating antimicrobial resistance while doing nothing for viral disease.

The analytical infrastructure itself compounds the problem. Laboratory gas chromatography–mass spectrometry (GC-MS), the reference method for VOC analysis, typically weighs over 200 pounds, depends on stable power and helium supply, and can take 30 minutes to several hours to start up, rendering it impractical anywhere beyond a fixed laboratory. The result is a persistent gap between where respiratory infections must be caught (at the point of need, in minutes) and where they can actually be diagnosed today.

The Mission

Non-invasive breath analysis represents a potentially transformative shift in how respiratory infections are detected and managed.[3,4,5] A validated breath-based platform would eliminate the specimen-collection barriers, cold-chain dependencies, and laboratory overhead that currently delay diagnosis and exclude the settings where speed matters most. By enabling accurate detection from exhaled breath alone (no swabs, no sputum, no laboratory), such a technology could screen multiple respiratory pathogens simultaneously in minutes, allowing clinicians and commanders to isolate, treat, and contain before an infection spreads through a unit or a community.

That promise rests on a substantial peer-reviewed foundation, and on one analytical method above all: gas chromatography–mass spectrometry (GC-MS) is the established gold standard of human volatilomics. In infectious disease, thermal-desorption GC-MS of exhaled breath separated SARS-CoV-2 Delta from Omicron infections, with classifier accuracy improving from 0.73 to 0.82–0.84 when each variant wave was modeled independently[6] — direct evidence that breath resolves distinctions finer than the mere presence of infection. Beyond respiratory pathogens, a 1,404-subject study spanning 17 disease conditions reported 86% classification accuracy from exhaled breath[7], and GC-MS and related mass-spectrometric studies established breath-based detection of lung cancer in patient cohorts benchmarked against clinically confirmed disease[8,9,10]; and a systematic review has mapped the volatile metabolites of the bacteria most implicated in pneumonia and sepsis[11]. Two decades of mass-spectrometry evidence point to a consistent conclusion: the signal in breath is real, reproducible, and chemically identifiable; the limiting factor has been instrument form factor, not biology.

The operational payoff is direct: faster identification preserves force readiness, curbs transmission in high-density environments, and enables targeted therapy in place of empiric antibiotics, a meaningful lever against antimicrobial resistance. The public-health payoff is larger still. The same capability that protects a deployed force can anchor decentralized surveillance and pandemic early-warning at the population scale, extending accurate diagnosis to austere operational theaters, remote clinics, and mobile screening programs operating far beyond the reach of centralized laboratories.

Figure 2. A single missed infection can cost more than one warfighter's readiness; it can cost the mission.

Detect-ION's Solution: The CLARION Platform

For all its scientific promise, breath analysis has never reached routine clinical practice, held back not by a shortage of candidate biomarkers but by the absence of a standardized measurement engine that works outside the laboratory. Traditional GC-MS, the gold standard for VOC analysis, remains large, power-hungry, and tethered to a fixed bench, leaving the field rich in biomarker candidates yet chronically short on deployable solutions. CLARION is engineered to be that missing engine.

CLARION integrates breath collection, thermal-desorption preconcentration, chromatographic separation, and mass-spectrometric detection into a single point-of-care instrument. Its chip-scale mass spectrometer[12,13] operates roughly 200 microfabricated ion traps in parallel to deliver 1-amu mass resolution using < 3 watts, paired with a low-thermal-mass gas chromatograph. An on-demand vacuum architecture and room-temperature electron-impact ionization source let the system power up in about 30 seconds (analysis in minutes, not hours), and an embedded breath collector obviates the dependencies on Tedlar bags, sorbent tubes, and cold storage that traditional workflows typically need. On-board AI/ML, trained against a high-resolution reference library, cleans the raw signal, matches chemical fingerprints, and classifies infected versus healthy states in real time.

A range of alternative sensing approaches trade molecular specificity for logistical simplicity, and each fall short of the interpretability that clinical decisions demand. Pattern-based systems, such as metal-oxide and conducting-polymer sensor arrays ('electronic noses'), chemiresistive nanomaterial sensors, gravimetric quartz-crystal-microbalance (QCM) and surface-acoustic-wave (SAW) devices, and catalytic or calorimetric thermal sensors, respond to bulk or aggregate breath properties rather than resolving individual compounds, which makes their signals difficult to calibrate, interpret, and transfer across instruments and sites. Chromatographic systems built on universal, non-identifying detectors, such as gas chromatography with flame-ionization (GC-FID), thermal-conductivity (GC-TCD), or photoionization (GC-PID) detection, separate volatiles but cannot assign them a molecular structure, while ion-mobility methods (standalone IMS, FAIMS, and GC-IMS) sharpen separation yet still lack the mass-resolved, library-matchable identification that ties a biomarker to a specific molecule. By pairing chromatographic separation with true mass spectrometry, CLARION delivers that compound-level identification: the quantitative, interpretable, and reproducible molecular fingerprint on which trustworthy diagnostics are built. Where decades of breath-biomarker research produced compelling science without a viable delivery mechanism, CLARION provides the platform that finally makes clinical translation possible.

Figure 3. Left: In the background, a laboratory-bound Shimadzu TD-GC-MS traditionally used for breath analysis. Right: A subject breathing into the Point of Care Breath Diagnostic Platform (CLARION-β) for real-time health assessment.

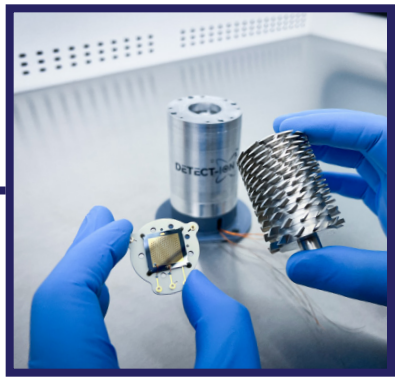

Figure 4. CLARION's chip-scale mass spectrometry and custom vacuum solution enables a new class of breath diagnostics.

CLARION collapses a 200-pound, lab-bound GC-MS into a 15-pound field device: laboratory-grade molecular specificity, wherever the warfighter is.

EXHALE Clinical Study

Validating a breath diagnostic requires more than controlled laboratory conditions; it demands paired, ground-truth-referenced data collected from real patients. Under the EXHALE program, Detect-ION conducted a two-campaign clinical investigation in Tampa, Florida, in collaboration with the University of South Florida (USF) and the University of California, Davis (UCD). Adults presenting across the spectrum of respiratory symptom status (from symptomatic to asymptomatic) were enrolled from the greater Tampa Bay community, providing paired biological specimens (nasopharyngeal swab and sputum/saliva) and exhaled-breath samples at a single study visit. Every participant's infection status was established by multiplex RT-PCR using the BioFire FilmArray platform, with the Pneumonia (PN) panel in Campaign 1 and the Respiratory 2.1 (RP2.1) panel in Campaign 2, providing a rigorous, laboratory-confirmed reference standard against which CLARION's breath-based VOC detection was benchmarked. In parallel, breath was captured on sorbent tubes and archived for independent analysis by high-resolution mass spectrometry (HRMS), furnishing an orthogonal analytical layer that corroborates CLARION's findings and strengthens the evidentiary foundation of the dataset. Studies were conducted under institutional review board oversight at USF (#STUDY006316) and WCG (#20251937), with written informed consent from all participants.

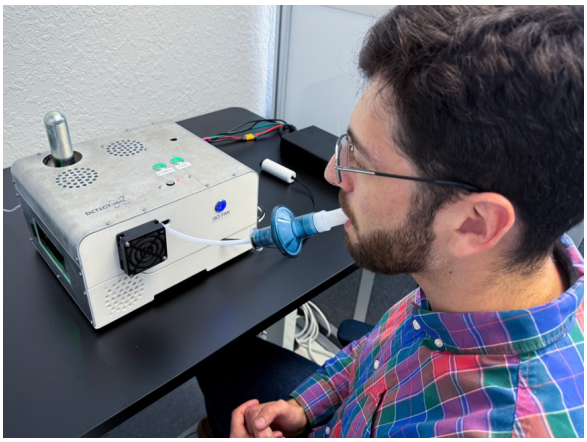

Figure 5. Point-of-care breath analysis using CLARION-α at the Detect-ION's Breath Research Laboratory: collection and analysis in a streamlined real-time workflow.

Table 1. EXHALE clinical study design across two campaigns. PN: Pneumonia panel; RP2.1: Respiratory Panel 2.1; TD-GC-TOFMS: thermal-desorption gas chromatography time-of-flight mass spectrometry; HRMS: high-resolution mass spectrometry; IRB: Institutional Review Board.

	Campaign 1	Campaign 2
Study period	Mar 2024 - Jun 2025	Oct 2025 - Feb 2026
Enrollment	Cohorts 1 & 2 (n = 101)	Cohort 3 (n = 222)
Population	Symptomatic and asymptomatic adults (ages 18–55), greater Tampa Bay community	
Reference standard	BioFire FilmArray Pneumonia (PN) Panel, multiplex RT-PCR	BioFire FilmArray Respiratory 2.1 (RP2.1) Panel, multiplex RT-PCR
VOC validation	Paired sorbent-tube TD-GC-TOFMS high-resolution MS (Agilent 7250 Q-TOF)	
Point-of-care instrument	CLARION chip-scale thermal-desorption GC-MS (TD-GC-MS)	
Ethics oversight	USF IRB #STUDY006316	WCG IRB Protocol #20251937

Data Analysis

CLARION's on-site analytical capability enabled breath VOC detection in near real-time at the point of collection, while archived sorbent-tube specimens were processed at Detect-ION's laboratory by high-resolution mass spectrometry to provide an independent corroborating dataset. For HRMS, sorbent tubes underwent automated thermal desorption (Markes TD-100) with a moisture-reduction purge, cold-trap refocusing, and transfer onto an Agilent HP-5MS UI capillary column driven by an Agilent 8890 gas chromatograph; VOCs were then detected on an Agilent 7250 Q-TOF high-resolution mass spectrometer under 70-eV electron ionization across an m/z range of 45–350. Putative compound identifications were assigned by matching acquired spectra against the NIST 2023 library and by comparing measured Kovats retention indices to literature values, with system blanks, Grob and EPA-624 standards, and C7–C20 alkane ladders run alongside every batch to monitor performance and retention-time drift.

The full breath dataset was carried through a multi-stage processing pipeline: background subtraction to isolate endogenous VOC signals from ambient and instrumental noise[14], signal denoising, and systematic feature extraction to surface candidate biomarkers across the cohort. The resulting feature sets were used to train supervised machine-learning classifiers, developed and internally validated against the multiplex-PCR ground truth, to distinguish infected from healthy states and to resolve pathogen-specific signatures, setting the stage for the performance findings that follow.

Key Results

VOC Biomarker Discovery & Validation

Across the enrolled cohorts, CLARION resolved approximately 140 volatile organic compounds in exhaled breath. From this pool, the predictive models converged on compact, pathogen-specific biomarker panels: 11 VOCs predictive of viral influenza, 5 predictive of coronaviruses, and 19 predictive of rhinovirus, with only 3 compounds shared across the three signatures. This molecular separability is the central scientific result. Despite the overlapping clinical presentation of these respiratory viruses, each was predictable from a largely discrete, non-redundant VOC fingerprint, evidence that CLARION is not merely detecting a generalized host response to infection but resolving disease-specific metabolic perturbations, the prerequisite for any breath diagnostic intended to differentiate among co-circulating pathogens.

Diagnostic Model Performance

The breath-based classifiers demonstrated meaningful diagnostic performance across all three viral targets when tested against PCR-confirmed status. In an initial feasibility analysis from Campaign 1, models distinguished rhinovirus-positive individuals from healthy controls with a sensitivity of 0.78 and specificity of 0.86 despite a limited number of positive cases. As the dataset expanded across cohorts, the multiplexed models achieved per-pathogen ROC-AUCs of 0.78 for influenza, 0.80 for coronavirus, and 0.77 for rhinovirus, with the sensitivity and specificity profiles summarized in the figure below.

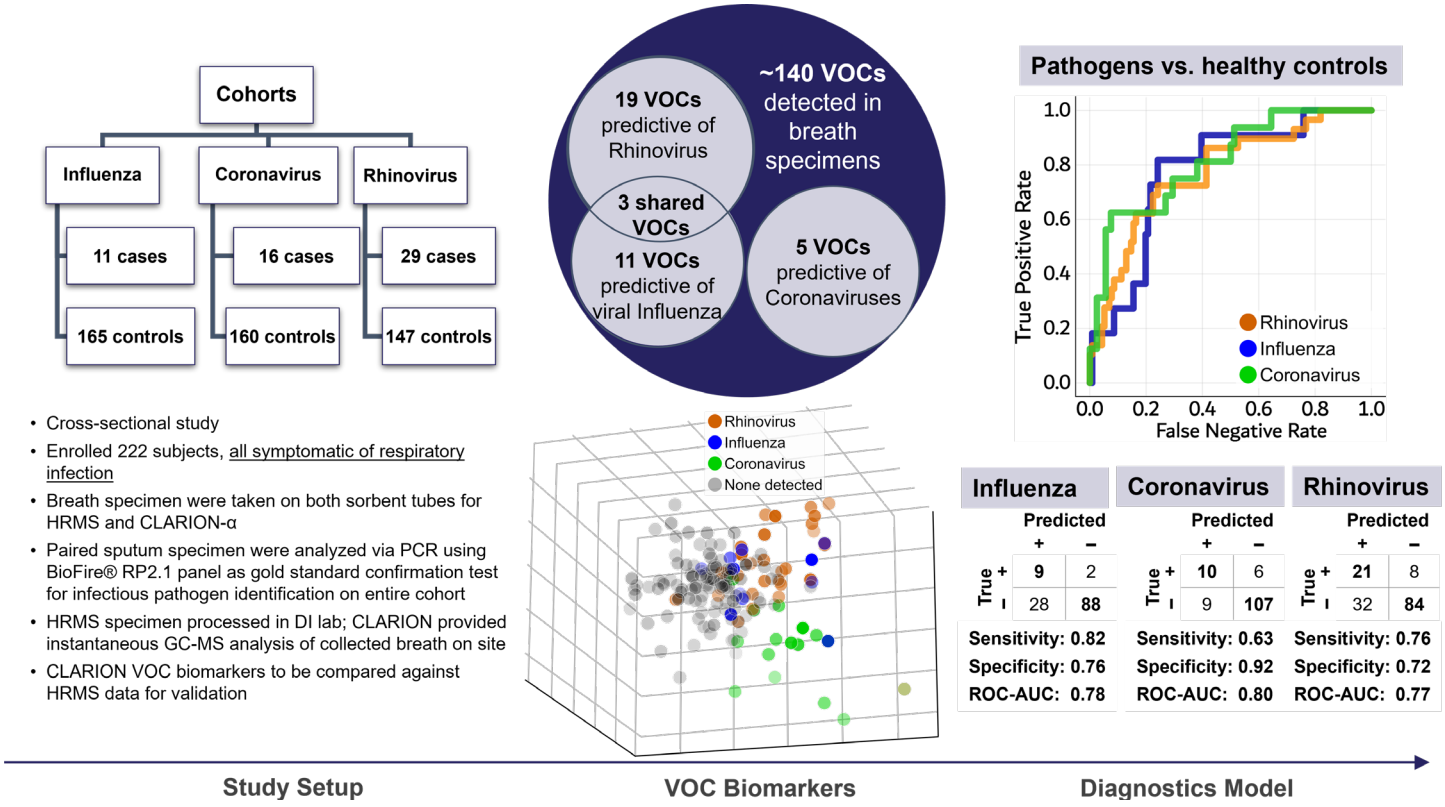

Figure 6. EXHALE study overview: campaign-2 cohort enrollment across influenza, coronavirus, and rhinovirus; VOC biomarker discovery (~140 VOCs detected, with 11 influenza-, 5 coronavirus-, and 19 rhinovirus-predictive compounds and 3 shared); and diagnostic-model performance against PCR-confirmed status (ROC-AUC 0.78 / 0.80 / 0.77).

Beyond classification performance, the biological plausibility of the signal is well grounded. The emanation of VOCs during viral infection is thought to arise from host immune response and the oxidation of host-cell membranes during the viral replication cycle[15], and the compound classes surfaced here are consistent with breath biomarkers reported in the peer-reviewed literature for respiratory infection, including prior GC-MS studies that resolved SARS-CoV-2 and its variants from breath[16,17]. Critically, the predictive VOC signatures identified by CLARION were independently corroborated by HRMS analysis of the archived breath specimens, providing orthogonal confirmation that the platform detects real disease signal rather than instrument artifact.

Next Steps: Adding More Rigor & Scope to Clinical Validation

The EXHALE study represents Detect-ION's first clinical validation of breath-based VOC diagnostics for respiratory infectious disease. The performance reported here was achieved on early-generation hardware, on modest cohorts, and against only three viral targets, and still resolved compact, largely non-overlapping molecular signatures. That is the strongest argument for widening the aperture: the biological information carried in breath appears to exceed the clinical question so far asked of it. The near-term priority is therefore to establish systematically what CLARION can biologically distinguish, and then to determine which of those distinctions would change clinical decision-making. Rigor matters as much as scope. The next studies will therefore enroll

larger cohorts across multiple collection sites, both to stress-test and to refine the diagnostic models. The refined models will then be locked and validated on a held-out test set kept fully separate from the training data.

The most consequential question left unanswered in this study was whether CLARION's VOC signatures could distinguish bacterial from viral etiology. It was in fact a pre-specified objective of the EXHALE study, but the enrolled cohorts yielded too few PCR-confirmed bacterial cases to train and test a bacterial panel. Powering a cohort specifically for that comparison is therefore the first priority of the next campaign. Most respiratory presentations are clinically indistinguishable at the bedside, and in the absence of a rapid answer clinicians default to empiric broad-spectrum antibiotics. A breath screen that separates bacterial from viral infection[18] in minutes (before culture, before PCR turnaround) would resolve that ambiguity at the first patient encounter. That distinction is the lever that lets clinicians withhold antibiotics when they will not help, directly addressing antimicrobial resistance while accelerating appropriate care.

Beyond etiology, the same analytical architecture invites a broader set of clinical objectives, each testable against infrastructure already in place. Candidate avenues include organism-level bacterial identification, beginning with Pseudomonas aeruginosa screening in cystic fibrosis, bronchiectasis, and ventilator-associated pneumonia, where early detection of colonization changes therapy and where the organism's volatile metabolites are already well characterized[19]; other high-consequence pathogens amenable to volatile detection, including Mycobacterium tuberculosis, Aspergillus species, and Staphylococcus aureus; triage of urological disease, where volatile signatures could reduce reliance on surveillance cystoscopy and on culture in complicated urinary tract infection; early warning for sepsis and other acute deterioration, where minutes of lead time translate into survival; and antimicrobial-response monitoring, using serial breath measurements to confirm days earlier that a therapy is working. Candidates will be prioritized against one criterion: clinical meaningfulness. A distinction is worth pursuing where a faster, non-invasive answer changes what a clinician does — narrowing or withholding antibiotics, escalating care sooner, avoiding an invasive procedure, or catching a deterioration in time to intervene. The aim is not breadth for its own sake, but applications in which CLARION measurably improves outcomes and, in the highest-acuity settings, saves lives.

The development roadmap follows the science. Building on the analytical architecture validated in Tampa, Detect-ION is advancing CLARION toward a next-generation, field-hardened form factor (CLARION-β) optimized for portability and deployment resilience, a device that goes to the patient rather than requiring the patient to reach a laboratory. Because breath collection requires no specimen handling, that same architecture opens a self-test modality: an unattended kiosk where a user provides a breath sample and receives a result on the spot, with no clinician or phlebotomy step in the loop. Sited at base entry points, clinic waiting rooms, transit hubs, and workplaces, such kiosks would extend screening from the clinical encounter to the places where transmission actually begins. Paired with aggressive SWaP-C targets, including a per-test cost roadmap that falls steeply with volume, this positions CLARION to serve the DoD's force-health mission and, on the same technology base, to anchor decentralized biosurveillance and pandemic early-warning across civilian public-health systems.

One breath specimen, screened for multiple respiratory pathogens, in minutes, at the point of need — first for the warfighter, and ultimately for anyone, anywhere, whom timely diagnosis can protect.

ACKNOWLEDGEMENTS

Detect-ION thanks our multi-disciplinary team of collaborators, whose complementary expertise shaped this study. At UC Davis, Cristina Davis, PhD (Co-Principal Investigator) and Bioinstrumentation and BioMEMS senior researchers Mitchell McCartney and Eva Boras, PhD brought deep experience in human breath research, guiding our study design and keeping the program on a rigorous path. At the University of South Florida Center for Global Health and Inter-Disciplinary Research, Kristi Miley, PhD (Co-Principal Investigator) and students Mary-Ruth (Molly) Joyce and Camila Trejo Paz brought the clinical enrollment and laboratory testing expertise the work depended on. Across both campaigns, Molly and Camila executed on the ground, carrying our first IRB submission through approval, sourcing and consenting subjects, administering the questionnaire, collecting specimens, and analyzing every sample by PCR to establish the ground truth behind our diagnostic models. We are grateful they housed our very first prototype and supported us with timely data and IRB oversight.

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