AI-Enabled VOC Sensor Arrays for Infection Risk Stratification and Clinical Decision Support

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Introduction

Limitations in Infection Detection for Decision support

- Microbial culture technique is essential for organism identification and susceptibility testing:
  - *Challenge: Delayed or unavailable in austere and Role 1 and 2 care.*
- Molecular panels are faster but target-limited set of microbes but can also detect dead microbes/pathogens
  - *Challenge: Requires specialized skillsets, power requirements and the physical footprint may not be feasible in austere environments.*

Potential Solution for the Limitations of Unmet Clinical Need

- Rapid detection solution using rugged diagnostic sensors that can be rapidly tailored to theater-relevant pathogens.
- Provide earlier clinical decision support than current available diagnostics.
- An adjunct aid for medicine support in the large-scale combat environment of high-risk individuals.
- Validated AI-driven solutions for medics/clinicians to monitor, aid with decision support and potential triage support in far forward (role 1 and 2) environments.

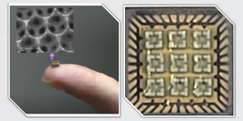
Our Technology and Solution

Technology

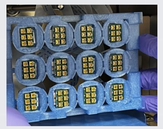
- Patented Volatile Organic Compound sensing nanoarray technology, miniaturized, customizable to different environments and microbes.
- Nanosensory array is integrated into the iNose™ system
  - High-sensitivity and high throughput system with minimal footprint

Anticipated end-state design of the technology for decision support in role 1-2 environment

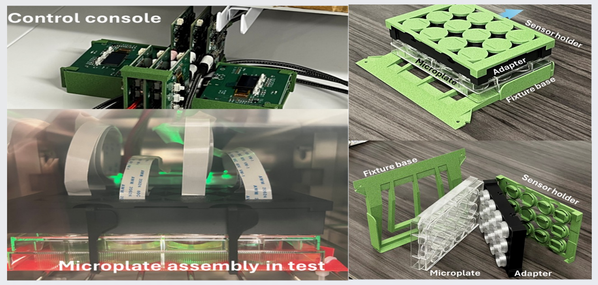
Advanced Prototype - iNose™



A multiplexed sensor array with up to nine channels, each incorporating a distinct functional sensing material



Nanosensors integrated into the sensor holder cover to detect VOCs on COTS 12-well plate

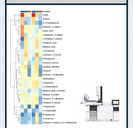


Core Assembly of the Platform

On the left, iNose™ is recording the VOCs from the infected samples that are obtained from clinics. On the right components of iNose™ platform

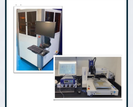
Experimental Workflow

GC-MS VOC Targeting



Identify key microbial VOCs from GC-MS

Nano-ink Printing

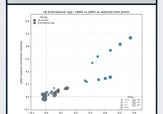


Print proprietary nano inks on the sensor substrates

High-throughput Screening

Test & grade hundreds of sensors per day

AI-guided Customized Array



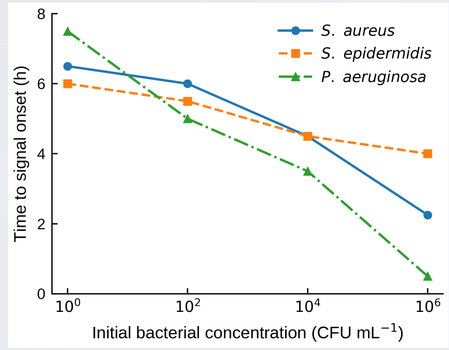
Monitor microbial VOCs. e.g. Normalized *responses*=$|\Delta R/R_0|$

Sealed 12-well Matrix Testing

Test Clinical Matrices. Time-to-Detection defined

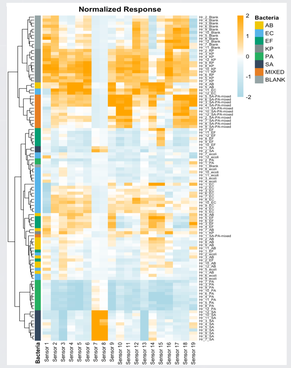
Study Component	Materials / Conditions
Foundational pathogen panel	ESKAPEE species: *E. faecium, S. aureus, K. pneumoniae, A. baumannii, P. aeruginosa, E. coli,* and *E. cloacae*; one *S. aureus*/*P. aeruginosa* mixed culture; sterile controls
Clinical-matrix model	Pooled, de-identified, uninfected human synovial fluid derived from 205 remnant specimens; enriched 1:1 and spiked with *S. aureus*, *S. epidermidis*, or *P. aeruginosa* at 1–10^6 CFU/mL
Sensor hardware	Foundational 19-type sensing array; optimized six-sensor array; integrated incubation/headspace system; Compact 12-well fixture
Expanded internal program	~100 clinically relevant targets, including representative near-neighbor, mixed-culture, and selected fungal conditions

Results



Semi-Quantitative Burden Estimation via Onset defined Time-To-Detection (TTD)

- For all three organisms, TTD decreased as initial bacterial concentration increased.
- *S. aureus* was detected at 2.3 hr at 10^6 CFU/mL and 6.5 hr at 1 CFU/mL. Similar inverse relationships were observed for *S. epidermidis* and *P. aeruginosa*.
- This platform was extended to ~100 clinically relevant targets, including near-neighbor organisms, mixed bacterial cultures, and selected fungal pathogens.



Distinct VOC Fingerprints Supported Multiclass Pathogen Classification

- Seven ESKAPEE pathogens
- Data has 96% mean classification accuracy, and the mixed-culture class achieved 99.8% mean class-wise accuracy.

Conclusion I Impact to Warfighter

Conclusion

- The platform differentiated 17 clinically relevant pathogens, near-neighbor organisms, mixed cultures, and selected fungal pathogens.
- Data has 96% mean classification accuracy, and the mixed-culture class achieved 99.8% mean class-wise accuracy using low-power VOC signatures with <5% variance for key analytes.

Developmental Status of the Technology

- TRL 5/6 platform with portable prototype devices and preliminary evaluation on clinical synovial fluid samples
- Ongoing development is focused on actionable readouts within 12 hrs, broader pathogen coverage, and matrix expansion to urine and blood.

Impact to Warfighter:

- The customizable sensor-manufacturing and analytics workflow supports theater-specific deployment, expansion toward >100 pathogen targets
- Earlier decision support for wound infection surveillance, casualty prioritization, and empiric treatment selection in austere settings.

Applicability to Medical Roles of Care:

- iNose can support Role 1-4 infection screening and triage by providing rapid infection risk assessment and classification support
- Samples include Gram-positive vs Gram-negative signatures and in body fluids when culture is unavailable, delayed, or resource-intensive.

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