Exploration Laboratory Analysis

M. Krihak,¹ K. Ronzano² and T. Shaw³

¹University of California Santa Cruz, NASA Ames Research Center, Moffett Field, CA
²Wyle Laboratories, NASA Ames Research Center, Moffett Field, CA
³NASA Ames Research Center, Moffett Field, CA

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Exploration Laboratory Analysis (ELA) – FY15 Project Overview

- Background
  - ExMC Risk and Gap
  - ELA Objective
- ELA Downselect
  - Criteria
  - Technology Selections
- Summary & FY16 Plans
Exploration Medical Capability (ExMC) Risk and Gap

Risk –

Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions

Med 13:

We do not have the capability to implement medical resources that enhance operational innovation for medical needs.

Research Approach for ELA:

Develop the capability to measure clinically significant laboratory analytes in a minimally invasive manner during exploration missions.
ELA Objective

Demonstrate the feasibility of emerging ELA operational and analytical capability as a biomedical diagnostics precursor to long duration manned exploration missions.
Exploration Laboratory Analysis

TECHNOLOGY DOWNSELECT
## ELA Operational Measurements

<table>
<thead>
<tr>
<th>Basic Metabolic Panel</th>
<th>Blood Gases Panel</th>
<th>Hematology</th>
<th>Cardiac Panel</th>
<th>Liver Panel</th>
<th>Urinalysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>PaO₂</td>
<td>WBC Count</td>
<td>Troponin I</td>
<td>Albumin</td>
<td>Specific Gravity</td>
</tr>
<tr>
<td>Calcium</td>
<td>PaCO₂</td>
<td>RBC Count</td>
<td></td>
<td>ALP</td>
<td>pH</td>
</tr>
<tr>
<td>Sodium</td>
<td>SaO₂</td>
<td>HCT</td>
<td></td>
<td>AST</td>
<td>Leukocytes</td>
</tr>
<tr>
<td>Potassium</td>
<td>HCO₃</td>
<td>Hgb</td>
<td></td>
<td>ALT</td>
<td>Nitrites</td>
</tr>
<tr>
<td>CO₂, Total Chloride</td>
<td>pH</td>
<td>Neutrophils</td>
<td></td>
<td></td>
<td>Proteins</td>
</tr>
<tr>
<td>BUN</td>
<td></td>
<td>Abs. Neutrophils</td>
<td></td>
<td></td>
<td>Glucose</td>
</tr>
<tr>
<td>Creatinine</td>
<td></td>
<td>Count</td>
<td></td>
<td></td>
<td>Ketones</td>
</tr>
<tr>
<td>Lactate</td>
<td></td>
<td>Lymphocytes</td>
<td></td>
<td></td>
<td>Urobilirubin</td>
</tr>
</tbody>
</table>

- Troponin I
- Albumin
- ALP
- AST
- ALT
- Specific Gravity
- pH
- Leukocytes
- Nitrites
- Proteins
- Glucose
- Ketones
- Urobilirubin
- Bilirubin
- Blood
Technology Status

Point-of-Care (POC) Devices

• For more than a decade, POC devices have emerged for:
  – Bedside care; doctor’s office.
  – Care in remote locations (e.g. 3rd World, developing nations).
  – Military operations in forward combat locations.

• POC technologies are generally compact instruments.
  – However, often limited in the breadth of measurements
  – Typically offer a subset of the ExMC operational analyte

• Clinically validated, commercial-off-the-shelf (COTS) instruments are emerging that can provide all measurements.
  – Mass, volume, power and space readiness do not align with exploration mission restrictions.
## ELA Technology Downselect Criteria

<table>
<thead>
<tr>
<th>Decision Factors</th>
<th>Criteria</th>
<th>Criteria Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Analysis</strong></td>
<td>Validated Measurements</td>
<td>Number of validated, operational measurements demonstrated by the analytical platform.</td>
</tr>
<tr>
<td></td>
<td>Assay Capability (Technology Limitations)</td>
<td>Technological capability to provide additional operational measurements beyond current menu.</td>
</tr>
<tr>
<td></td>
<td>Multiplexing</td>
<td>Multiplexed measurements capable on the analytical platform.</td>
</tr>
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<td></td>
<td>Reagent/Cartridge Shelf-Life</td>
<td>Demonstrated ambient storage</td>
</tr>
<tr>
<td><strong>Engineering</strong></td>
<td>Mass/Volume</td>
<td>Instrument mass</td>
</tr>
<tr>
<td></td>
<td>Fluidics</td>
<td>Instrument volume</td>
</tr>
<tr>
<td></td>
<td>Reagent/Cartridge Waste</td>
<td>Microfluidics transport and control</td>
</tr>
<tr>
<td></td>
<td>Space Readiness (Hardware maturity)</td>
<td>Volume of disposables per run</td>
</tr>
<tr>
<td><strong>Cost &amp; Schedule</strong></td>
<td>Instrument Cost</td>
<td>Cost to acquire an instrument</td>
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<td>Ability to Work with Manufacturer</td>
<td>Responsiveness to NASA</td>
</tr>
</tbody>
</table>
Downselect Technology #1
Cell Phone-Based Lateral Flow Assay for Blood Biomarker Detection

Intelligent Optical Systems (IOS) & Holomic LLC

IOS: LFA Development for Blood-Based Testing

Target Assay Panels:
- Cardiac Biomarkers:
  - Troponin I (TnI)
- Liver Function Panel:
  - Alanine Aminotransferase (ALT)
  - Aspartate Aminotransferase (AST)
  - Alkaline Phosphatase (ALP)
- Blood Chemistry Panel
  - Creatinine, Glucose, Na, K, BUN
- Dissolved Blood Gas Panel
  - Dissolved Oxygen, CO2, pH
Holomic, LLC: Development of a Prototype Fluorescent Reader and Data Processing Software for On-cell Phone

**Reader Dimensions**
- Designed with limited space consideration.
- Reader weight (including phone) is 10.8 oz.; reader volume is ~420 cm³.
- At the cost of a smaller imaging field-of-view, the height may be reduced to <5 cm by substituting an imaging lens with a shorter focal length.

**On Going Development:**
- Design and deliver a fully automated reader for various fluorescent assays.
- Automated mechanical switching of band-pass filters will enhance automation for measuring multiple panels.

Reader application screenshots of recently added features
Downselect Technology #2

rHEALTH Technology – DNA Medicine Institute

Spiral Vortexer

Optical Block

Nanostrip

Vitals Patch

C.H.A.S.

Microgravity

Small Sample
rHEALTH X Capabilities

Optical Block Performance

- 3-part counts
- Differential antibody staining

Optical block
405 nm, 532 nm lasers
3 single photon counters

WBC 3-Part Diff

Chan, E. et al. rHEALTH Sensor: Universal In-Flight Biomedical Analysis Technology. in 2013 NASA Human Research Program Investigators’ Workshop (Galveston, Texas, 2013)
Summary & FY16 Plans

• ELA Downselect technologies identified.
  – Intelligent Optical Systems/Holomic, LLC
    • Lateral flow strip assays read by smartphone analyzer.
  – DNA Medicine Institute
    • Handheld rHEALTH flow through analyzer.

• Delivered the ExMC Exploration Laboratory Analysis Downselect Recommendation Report (ARC Document No. 6973).

• FY16 objectives
  – Develop strategy that identifies roadmap to guide project completion.
  – Identify ELA integration points with an exploration medical system.