Exploration Laboratory Analysis

M. Krihak,[1] K. Ronzano[2] and T. Shaw[3]

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

Basic Metabolic Panel	Blood Gases Panel	Hematology	Cardiac Panel	Liver Panel	Urinalysis
Glucose Calcium Sodium Potassium CO_2, Total Chloride BUN Creatinine Lactate	PaO_2 $PaCO_2$ SaO_2 HCO_3 pH	WBC Count RBC Count HCT Hgb Neutrophils Abs. Neutrophils Count Lymphocytes Monocytes Eosinophils PLT	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.

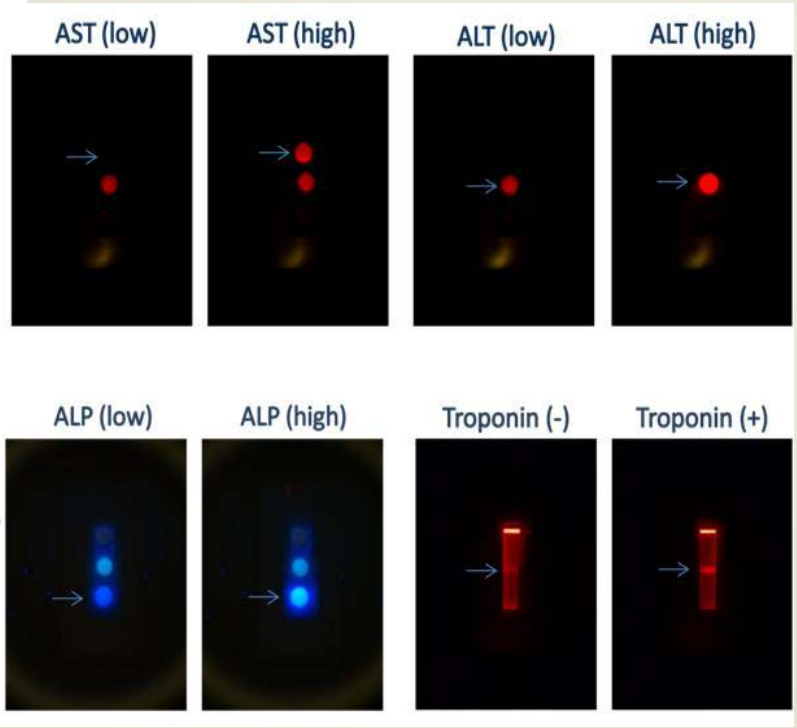
ELA Technology Downselect Criteria

Decision Factors	Criteria	Criteria Definition
Clinical Analysis	Validated Measurements	Number of validated, operational measurements demonstrated by the analytical platform.
	Assay Capability (Technology Limitations)	Technological capability to provide additional operational measurements beyond current menu.
	Multiplexing	Multiplexed measurements capable on the analytical platform.
	Reagent/Cartridge Shelf-Life	Demonstrated ambient storage
Engineering	Mass/Volume	Instrument mass Instrument volume
	Fluidics	Microfluidics transport and control
	Reagent/Cartridge Waste	Volume of disposables per run
	Space Readiness (Hardware maturity)	Device complexity; space readiness
Cost & Schedule	Instrument Cost	Cost to acquire an instrument
	Ability to Work with Manufacturer	Responsiveness to NASA

Downselect Technology #1

Cell Phone-Based Lateral Flow Assay for Blood Biomarker Detection

Intelligent Optical Systems (IOS) & Holomic LLC

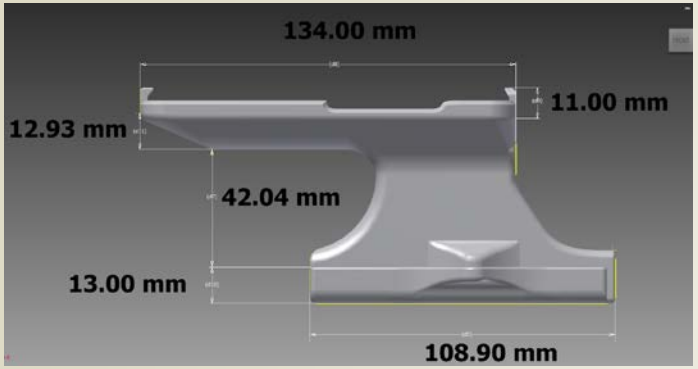


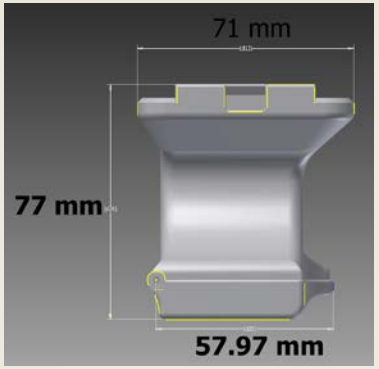
IOS: LFA Development for Blood-Based Testing

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

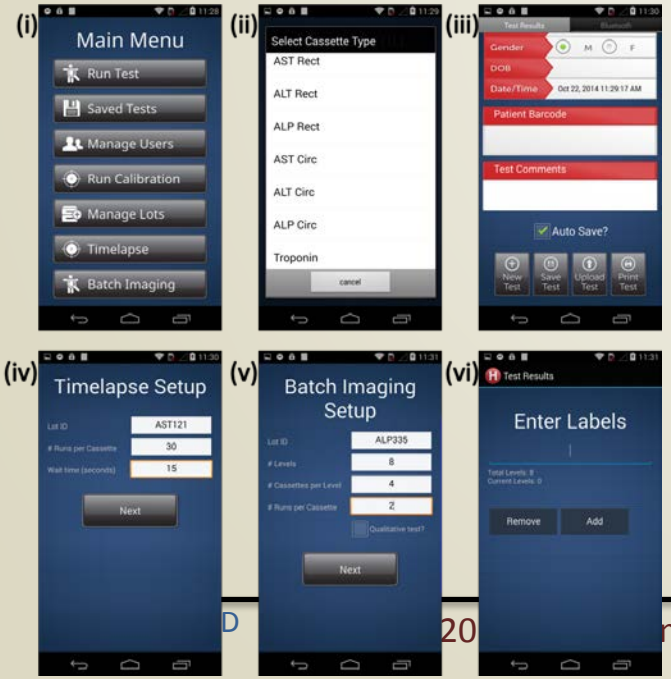
Holomic, LLC: Development of a Prototype Fluorescent Reader and Data Processing Software for On-cell Phone





Reader Dimensions

- Designed with limited space consideration.
- Reader weight (including phone) is 10.8 oz.; reader volume is ~420 cm^3
- 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.



Reader application screenshots of recently added features

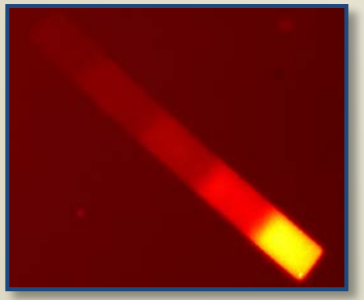
On Going Development:

- 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.

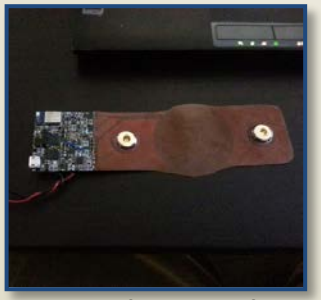
Downselect Technology #2
rHEALTH Technology – DNA Medicine Institute

Spiral Vortexer

Optical Block



Nanostrip



Vitals Patch

C.H.A.S.

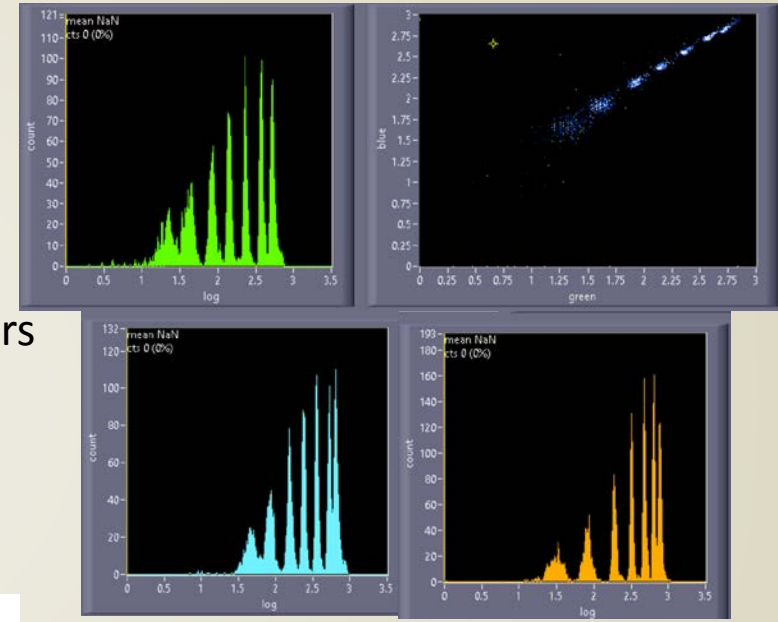
Microgravity

Small Sample

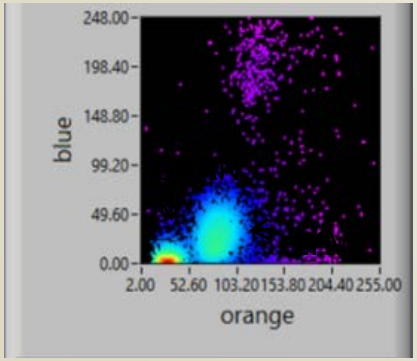
rHEALTH X Capabilities

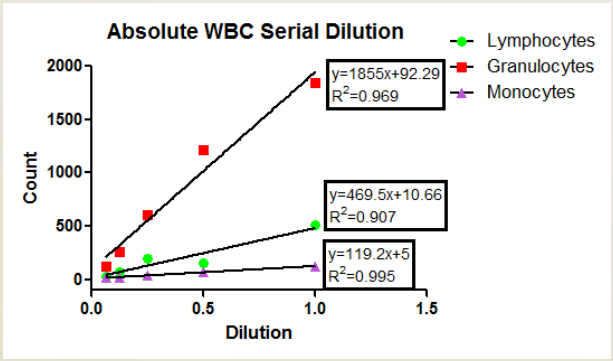
Optical block
405 nm, 532 nm lasers
3 single photon counters

Optical Block Performance



WBC 3-Part Diff





- 3-part counts
- Differential antibody staining

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.