



INFLUENZA AND BIOTHREAT DIAGNOSTIC OPPORTUNITIES

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Resilient People. Healthy Communities. A Nation Prepared.

Influenza Diagnostic Opportunities

- **Current Programs**
 - Point-of-Care Diagnostics
 - Flu Subtyping – Seasonal vs Novel/Non-Seasonal
 - Antiviral resistance





The Alere Influenza A & B assay

- Develop an easy to use, CLIA waived, FDA 510(k) cleared Point-of-Care(POC) device that has the ability to detect and differentiate seasonal and non-seasonal influenza A & B viruses
- Molecular assay: nested isothermal amplification, CLIA-waived for use in a physician's office
- Rapid results <20 min



InDevR



- Developing a new, **multiplexed influenza diagnostic termed FluChip-8G**
 - **Multiplexed** analysis of viral genes within 4 hours
 - **Genotyping** the assay accurately identifies virus type and subtype, including B lineage (Yamagata or Victoria)
 - **Anti-viral susceptibility**



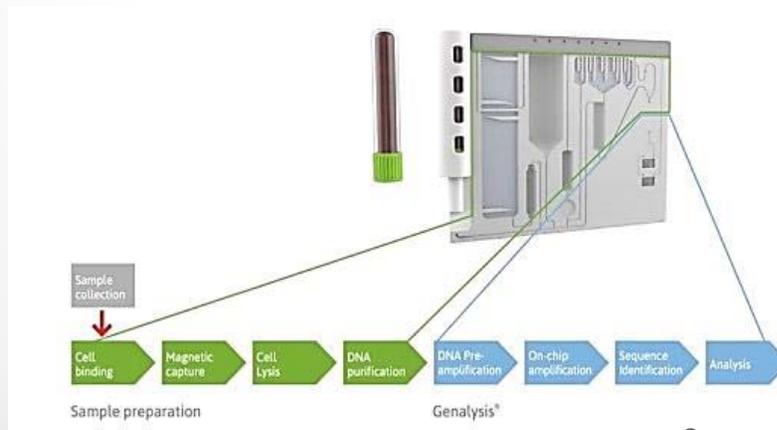
FluChip^{8G}™

ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

DNAe



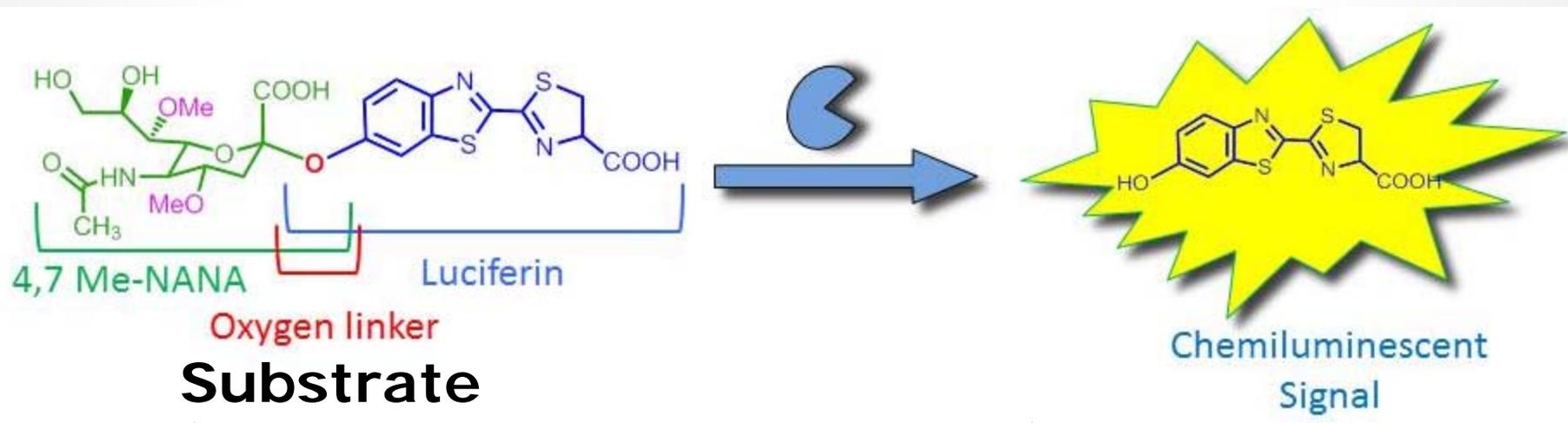
- Develop, validate, and seek FDA clearance for a simplified Next Generation Nucleotide Sequencing Platform
 - Diagnostic identification of pandemic and seasonal influenza
- Pathogen Capture System (PCS)
- Bringing genomic diagnostics to the patient
 - delivering actionable results direct from blood
- Option for Antimicrobial resistance (AMR) testing



Becton, Dickinson and Company



- Neuraminidase-activity Chemiluminescent assay
- Detect Resistance to Neuraminidase Inhibitors
- Directly from clinical samples in less than 30 minutes
- Fills a gap that will improve antiviral monitoring



(Hurt et al., Options IX Conference, 2016)



Areas of Interest - Influenza

BAA-16-100-SOL-0002 AOI #3

- 3.1 Specimen collection materials & methods
- 3.2 Sequencing methods – Clinical Lab
- 3.3 Antiviral drug resistant influenza virus detection
- 3.4 Prognostic marker(s) of influenza infection, both symptomatic and pre-symptomatic
- 3.5 Home use or point-of-care Influenza diagnostics tests
- 3.6 Studies to demonstrate the treatment impact of Influenza diagnostics



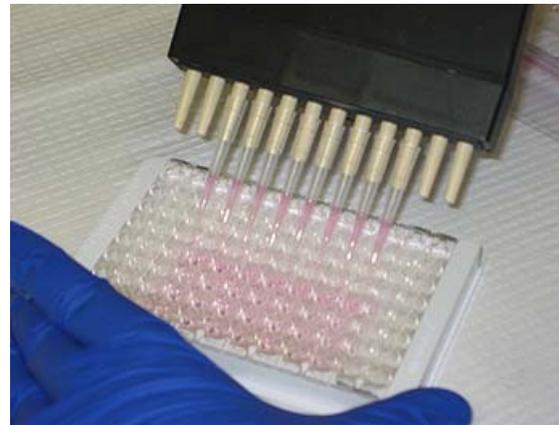
Biothreat Diagnostic Opportunities

- **Current Programs**
 - Zika Diagnostics and Blood Screening for Zika virus
 - Anthrax Diagnostics
 - Ebola Diagnostics
 - Burkholderia Diagnostics



InBios

- Zika Detect IgM Capture ELISA
 - Detection of Zika IgM antibodies in human serum
 - Capture Format, utilizes CDC produced Virus Like Particles
 - Target engineered to reduce/eliminate cross-reactivity
 - 4-4.5 hours assay, no overnight incubation
- EUA issued 17SEP2016
- 510(k) Zika IgM



InBios

*Innovative Diagnostics for
Infectious Diseases*

DiaSorin



- LIAISON ZIKA VIRUS IgM and IgG automated immunoassays
 - LIAISON® XL is a fully automated chemiluminescence analyzer, performing complete sample processing
 - EUA filing for Zika IgM/IgG ELISA
 - 510(k) Validation



OraSure – Ebola & Zika

- The OraQuick Ebola assay
 - Easy to use Lateral flow hand held device
 - CLIA-waived for use in a POC-field setting
 - Rapid results <30 min
 - Whole Blood or Oral Fluid Samples
- The OraQuick Zika assay
 - Easy to use Lateral flow hand held device
 - CLIA-waived for use in a POC field setting
 - Rapid results <30 min
 - Whole Blood, serum, plasma, Oral Fluid Samples, and possible semen and urine
 - EUA Zika Test for IgM WB
 - Feasibility assessment of IgM OF, IgM/IgG, and IgM/Ag protoypes

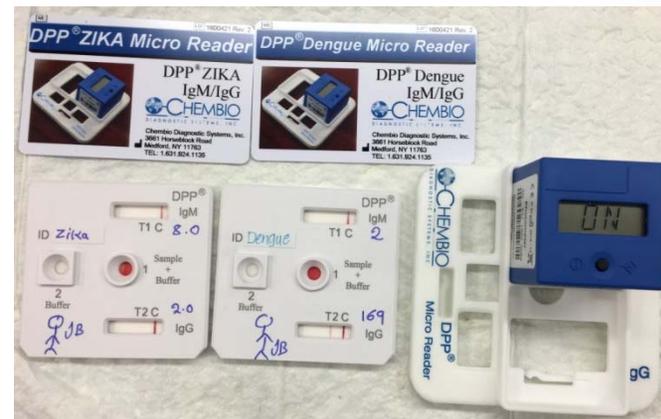
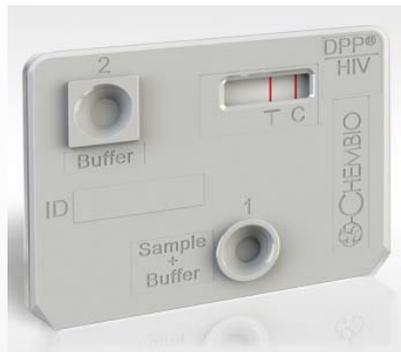


OraQuick® Rapid Antigen Test
EBOLA



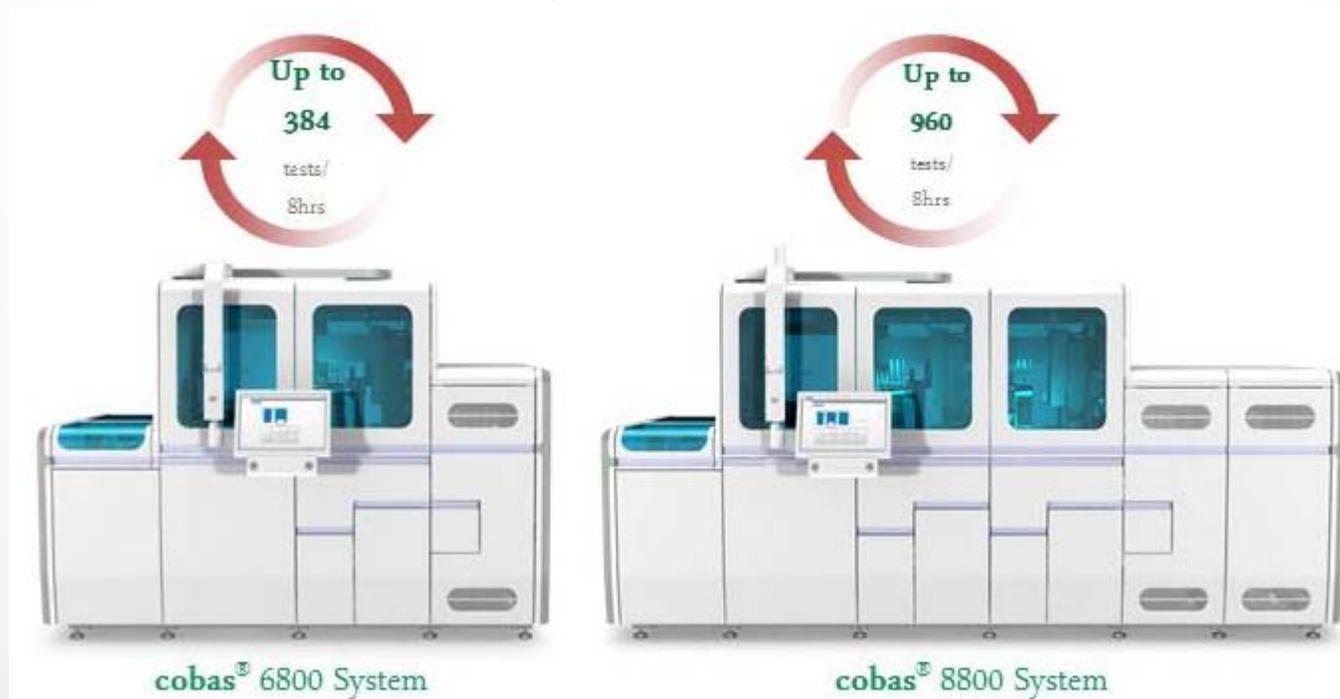
Chembio Diagnostic Systems, Inc. Zika Diagnostics

- POC Zika Assay using the Dual Path Platform (DPP®) Technology
 - Easy to use Lateral flow hand held device
 - CLIA-waived for use in a POC or field setting
 - Rapid results <30 min
 - Whole Blood, serum, plasma
- EUA/510(k)/CLIA waiver – Zika IgM/IgG



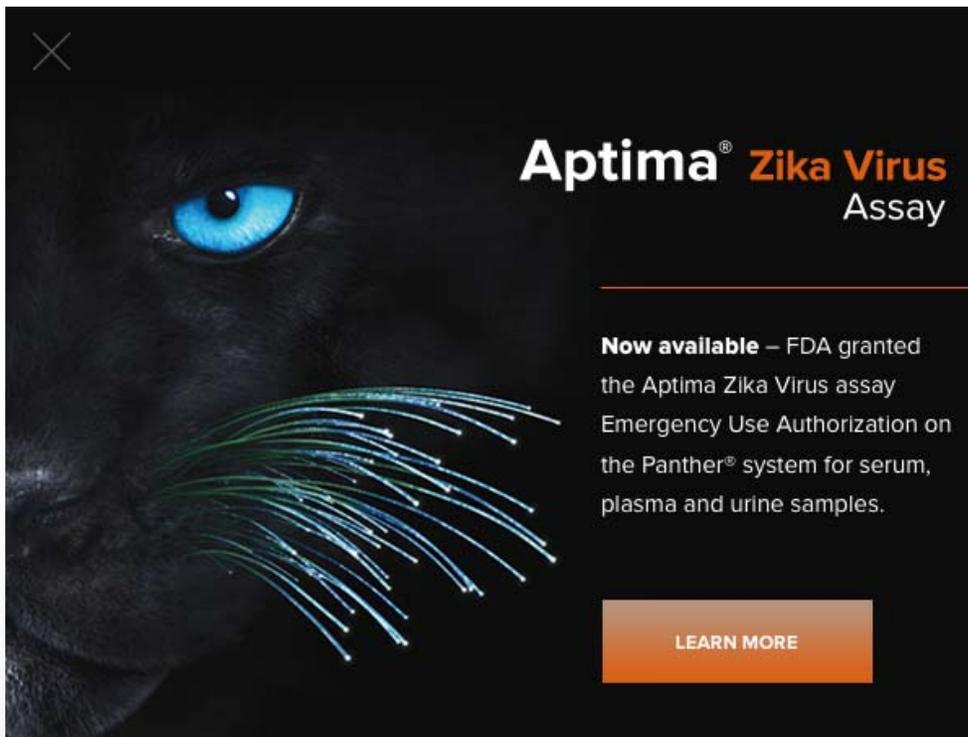
Roche – Blood Screening

- Support the requirements of a Biologics License Application (BLA) of an investigational use blood screening assay – cobas® ZIKA for use with the cobas 6800/8800 system.



Hologic – Blood Screening

- To support and build GMP-level ZIKV assay reagents and conduct a pivotal clinical trial and BLA submission.



Aptima[®] Zika Virus Assay

Now available – FDA granted the Aptima Zika Virus assay Emergency Use Authorization on the Panther[®] system for serum, plasma and urine samples.

[LEARN MORE](#)

MRI Global

- MRI-Global - MRIGlobal Dx's mission is to enable the commercialization of diagnostics for improved patient outcomes. MRIGlobal Dx provides laboratory services for CLIA-certified laboratories and *in vitro* diagnostics developers.
- Develop an FDA cleared *in vitro* diagnostic assay for the detection of *Bacillus anthracis*, validated for use on the Applied Biosystems® 7500 Fast Dx

SRI International

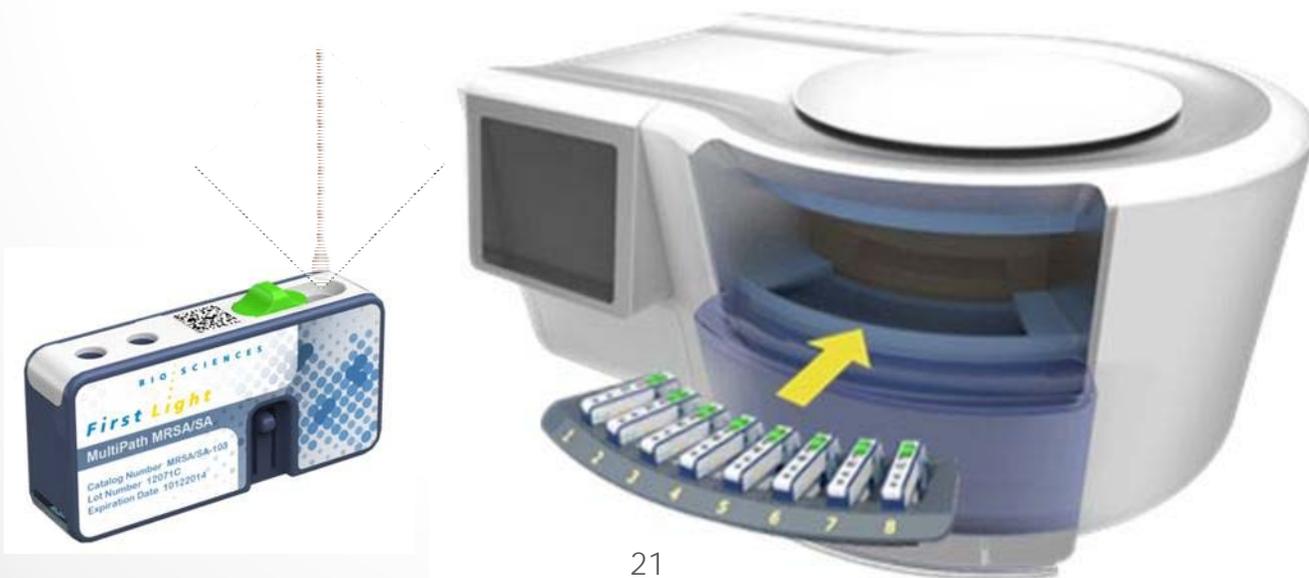
- Anthrax Diagnostics
 - Development of a Rapid, Point-of-Care Anthrax Diagnostic Assay System for the protein targets specific for *B. anthracis*, including LF, LTx, and PGA.
- Burkholderia Diagnostics
 - Biomarker Characterization and Confirmation for Rapid Clinical Diagnosis of: *Burkholderia pseudomallei*, *Burkholderia mallei*, and *Yersinia pestis*.



First Light Biosciences



- Anthrax Diagnostics
 - Development of a Rapid, Point-of-Care Anthrax Diagnostic Assay System for the protein targets specific for *B. anthracis*, including LF, LTx, and PGA
 - Direct from blood
- Early in infection and to determine the correct antibiotic therapy – AMR testing





NanoMR (Acquired by DNAe)

- Pathogen Capture System (PCS)
 - 10 mL whole blood
 - automated workstation
 - concentrations as low as 1 CFU/mL.
- The final output of the PCS is a volume of purified pathogen DNA that can be used for downstream identification (ID) analysis



Areas of Interest-Biothreats

BAA-16-100-SOL-00001 AOI #6

- 6.4 Anthrax diagnostic assay system
- 6.5 Anthrax lateral flow Lethal Factor immunoassay - USG developed antibodies
- 6.6 Hardware platform development
- 6.7 Knowledge Development - "Bio-threat Agent of Interest"
- 6.9 Zika Virus Infection Diagnostics & Blood Screening

