

Abstract

MRIGlobal is a not-for-profit organization that delivers R&D operational technology solutions and management for academia, government and industry, with the mission of enabling scientific innovation and diagnostics for global health, biosurveillance and diagnostics. Founded in 1944, MRIGlobal has built a reputation for innovation, technical excellence, and problem solving. We have the necessary scientific staff, relationships, laboratory space (including BSL-2 and BSL-3 and enhanced BSL-3+), and instrumentation to execute and manage all aspects of the research, development, and validation (i.e. 510k) services needed by customers seeking R&D support in the areas of genomics, transcriptomics, point-of-care diagnostics, wearable systems, and microbial-host relationships, among many others. Recent programs include work in bioinformatics systems, host-pathogen interaction studies, whole genome sequencing, pathogen genomics standardization, and infectious disease genomics for clinical diagnostics. MRIGlobal's current integrated Quality Management System is registered to the standards of ISO 9001:2008 and incorporates ISO 17025:2005 Code of Federal Regulations (CFR) rules that define the FDA and EPA GLP standards.

<p>Global Health Security</p> <p>Supporting public health, advancing product development from lab to</p>	<p>National Security and Defense</p> <p>Breakthrough research and development, test and evaluation of emerging technologies, and operations and management of</p>	<p>Energy and Environment</p> <p>Refining the best options in renewable, alternative, fossil energy,</p>
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Who is MRIGlobal

"We are a solutions provider with the facilities and expertise to assist in R&D, all the way to 510K submission"

Our Mission is simple...

- Perform critical functions in supporting national priorities in public health
- Advance product development from lab to marketplace
- Deliver new detection and diagnostic tools and devices world-wide



Containerized Bio-Containment

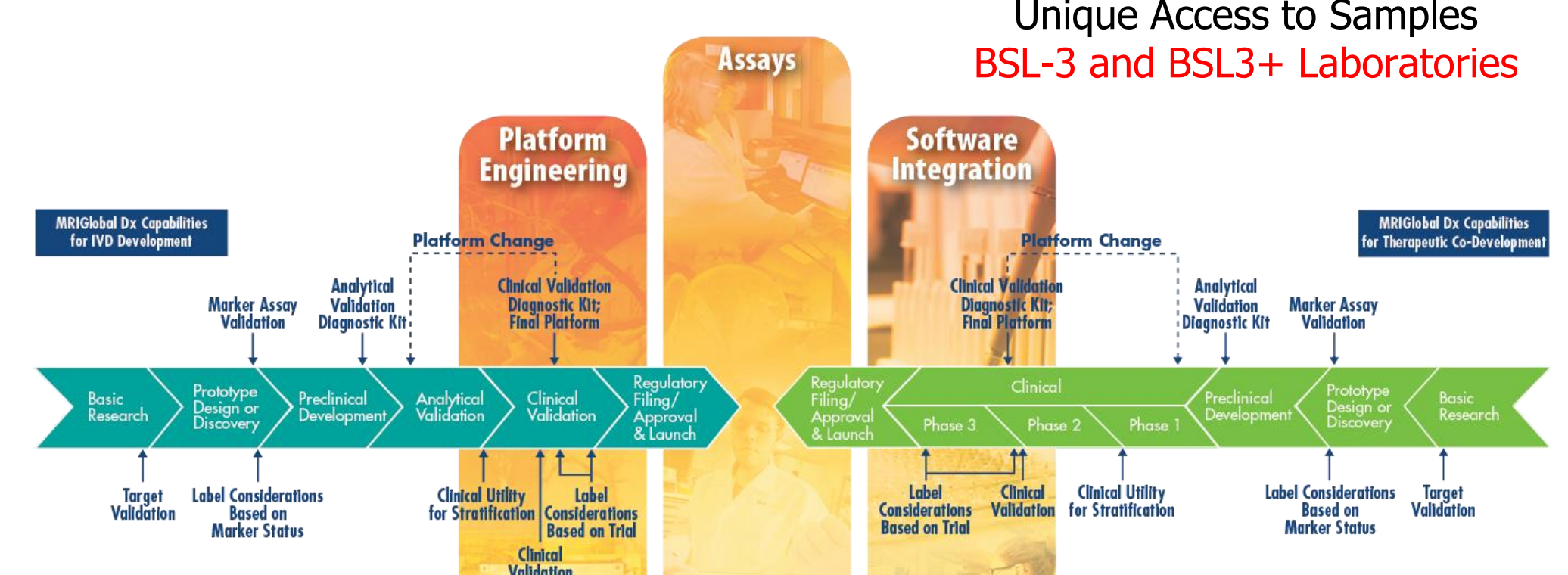


Patient transport container for safe evacuation of people infected with highly contagious diseases (e.g., Ebola)

Capabilities

- Bio-Detection**
- Disease Outbreak Response
 - Plant Biomarker Discovery Program
 - Food Safety and Agriculture
 - Mobile Modular Labs and Lab Operations
 - Biosafety and Security
 - Global Engagement Program
 - Genomics
 - Engineering

- Diagnostics**
- Nucleic Acid Sample Prep and Isolation
 - PCR Test, Evaluation, Validation Services (TEVS)
 - Product Development Solutions
 - Diagnostic Product Test and Evaluation Services
 - CLIA (CAP accredited) Laboratory Services
 - Influenza Virus Research Program
 - Next Generation Sequencing
 - Assay Design, Verification, and Validation Services
 - Unique Access to Samples
 - BSL-3 and BSL3+ Laboratories**



System Design & Testing

- Chemical Analysis
- System Modeling –
- Computational Physics
- Testing & Evaluation
- Systems Integration
- Rapid Response
- Engineering
- Facility & Asset Development
- Explosives Expertise

- PCR
- Sequencing and Next Gen Sequencing
- Microbiology
- Immuno-assays
- Mass Spectrometry
- CLIA & BSL3 Laboratories
- Sample Prep

Examples of Ongoing Programs

Next Gen Sequencing (NGS)

Consortium for Microbial Forensics and Genomics (μFORGE)

- MRIGlobal led the DHS-funded Consortium for Microbial Forensics and Genomics (μFORGE)
- The consortium's purpose was to prepare **high quality genome sequences** of various **human, animal, and plant pathogens** to support microbial forensics, biosurveillance and public health
- Established strict quality guidelines, optimized library prep methods, and utilized a range of sequencing platforms to produce high quality genomes for submission to NCBI
 - Sequencing chemistries employed included **Illumina, PacBio, and Oxford Nanopore** sequencing
 - 147 pathogen genomes** were sequenced and submitted to NCBI, including some species without any existing reference sequences

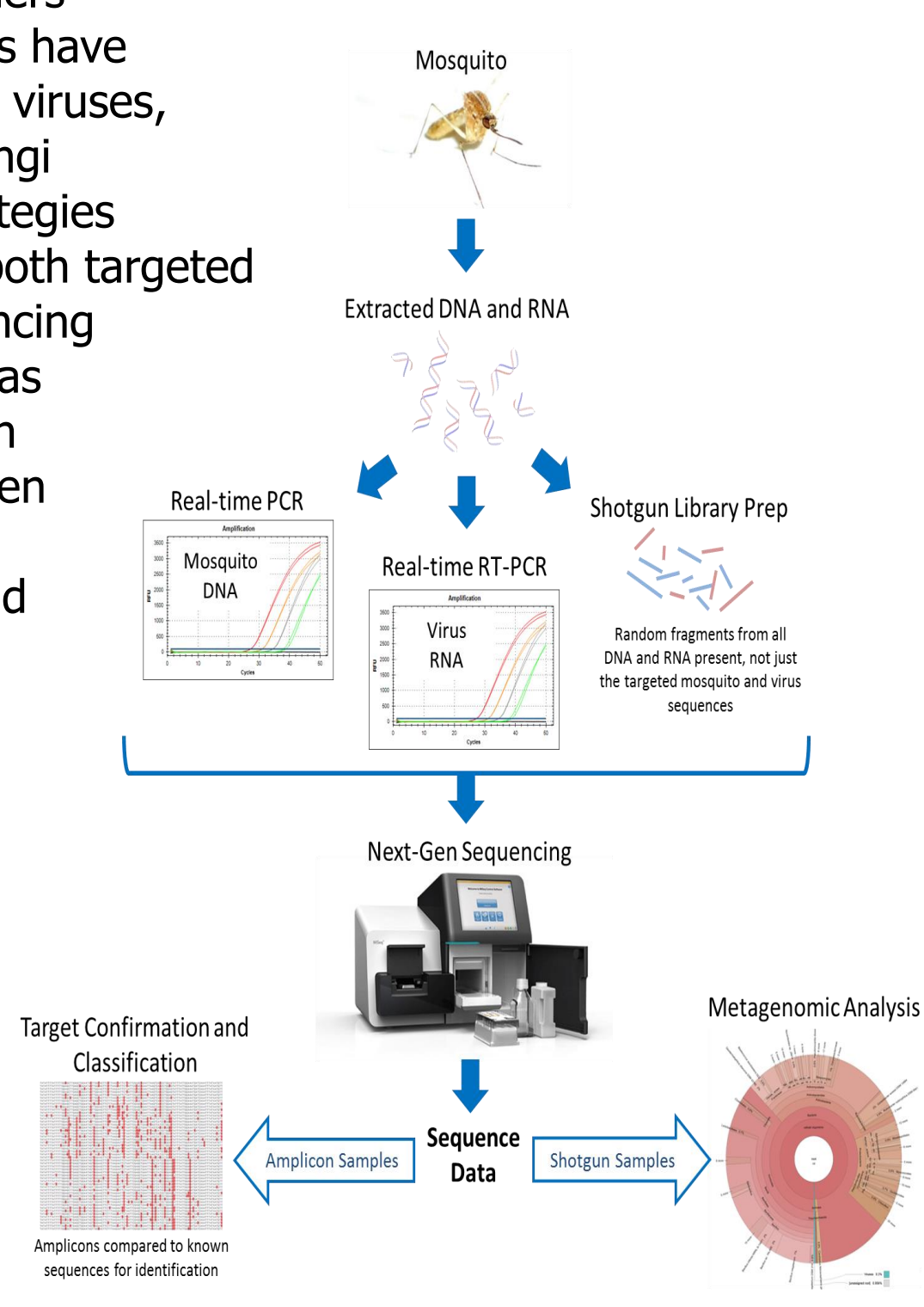


NGS in support of Clinical Trials

- MRIGlobal conducted Next Generation, whole genome sequencing in support of **discrepant sample analysis** for clinical performance testing of a commercial customer's diagnostic device
- MRIGlobal developed an analysis pipeline for **species-level classification of unknown bacterial and yeast isolates**
- Verified the accuracy of the developed analysis pipeline in the laboratory and *in silico*
 - Laboratory evaluations included 95 clinically relevant and related organisms representing **89 different species from 21 genera**
 - In silico* evaluations included 89 SRA samples representing 68 species from 27 different genera
- In addition, MRIGlobal has **sequenced and identified over 300 clinical isolates** using the developed pipeline

Detection of Pathogens in Complex Biological and Environmental Backgrounds

- MRIGlobal has developed specialized sample prep workflows and customized bioinformatics solutions for a number of customers seeking detection of pathogens directly from complex matrices without time-consuming isolation and culturing
- Sample types have included blood, plasma, serum, tissue, swabs, insects, soil, dirty wipes, filter collection devices, and others
- Pathogen targets have included various viruses, bacteria, and fungi
- Sequencing strategies have included both targeted amplicon sequencing panels, as well as agnostic shotgun sequencing, often following host/background depletion or pathogen enrichment



Wearable Systems

Whole Body Monitoring System

Delivering an integrated system certified for secure transmission of accurate, real-time health (heart rate, temperature, respiration rate, pulse oximetry [SpO2]) and GPS data via satellite or cellular. The system leverages the robust capability of a commercially available, clinically validated, FDA approved wearable sensor, while maintaining a flexible system architecture to allow for insertion of developing technologies (and/or different form factors) if/when appropriate. The integrated system operational and performance capabilities include:

- Proven clinical grade health data ensuring reliability across operational conditions (e.g. resting to active states, body composition, ethnicities, sweat).
- Low-risk FDA approved COTS sensor with heart rate, respiration rate, and skin temp. available now; core temp. and SpO2 slated for 2017-2018 release.
- Sensor location flexibility as it can be worn in locations other than chest.
- Disposable and reusable versions of sensor commercially available.
- Compatible MediBioSense vitals watch (CE-Mark Iia approved) available to Program now (commercially in late 2017) allowing greater flexibility.
- Local data processing capability negating need for continual connectivity.
- AES-encrypted communications module with tracker/network status LED indicators and on-board distress button running customized user programmable software (deployable on other devices if desired).
- Automatic reconnection in the event of network drop-out.
- Non-intrusive, wear-and-forget system (no impact to armor, ears are free) operable in excess of 24-hrs with data transmittal every minute (adjustable).

VitalPatch®

- FDA-Approved
- Commercially Available

Comms Module

- BLE to VitalPatch®
- Sat/Cellular to network

MRIGlobal Team Expertise

- Systems integration
- Encrypted communication platforms development
- Agnostic technology assessment

MRIGlobal

- Wearable sensor clinical expertise (e.g., Ebola in W. Africa)
- Wearable sensors application to health management

Scrrips Translational Science Institute

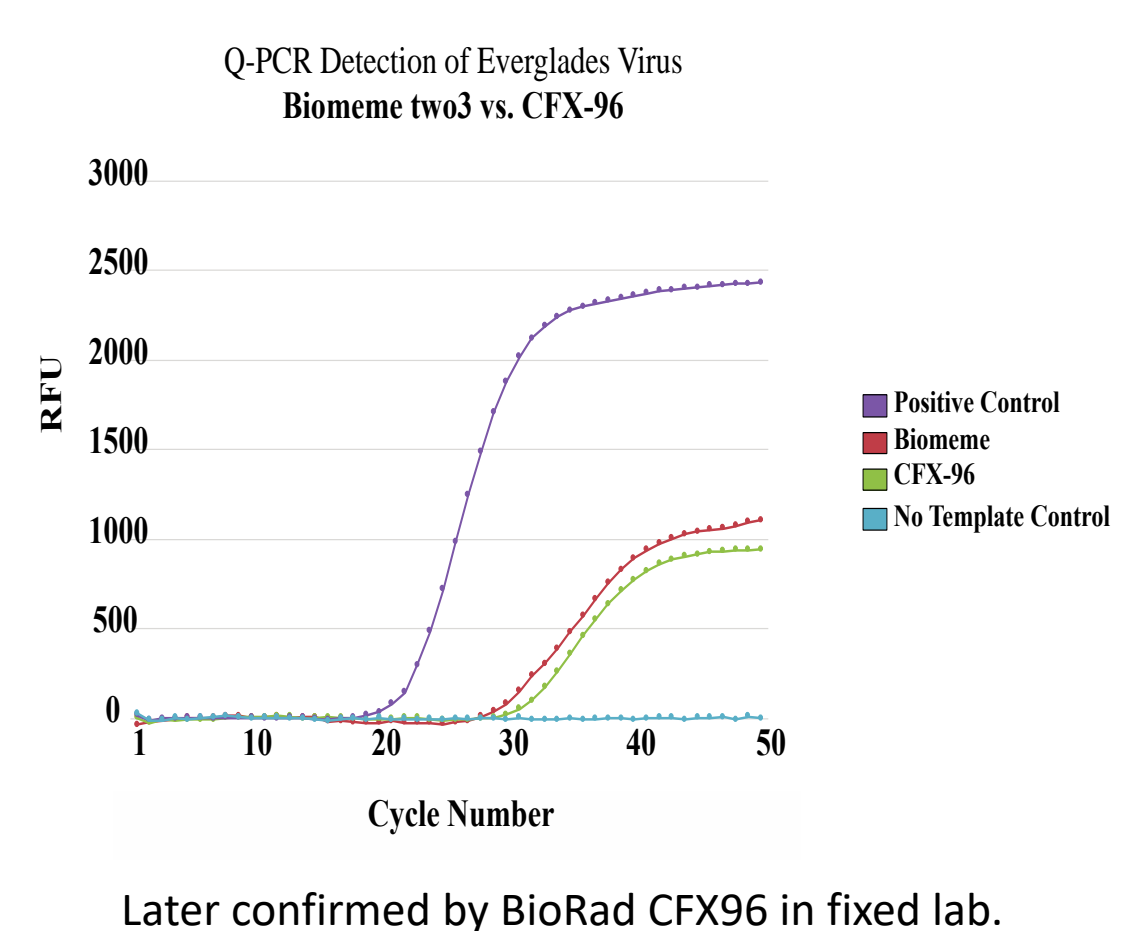
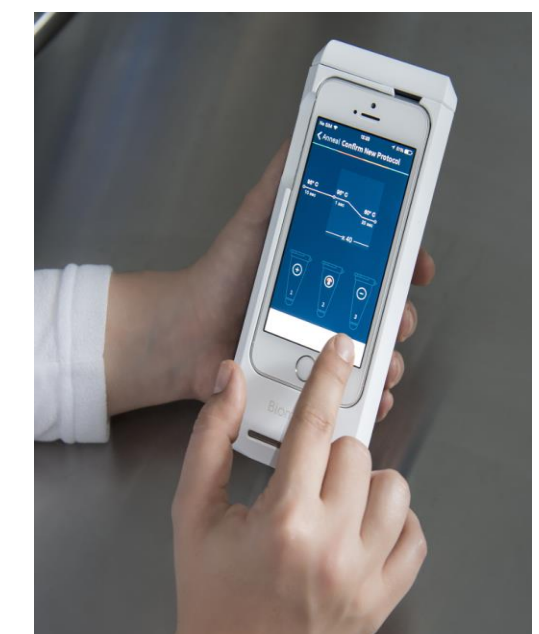
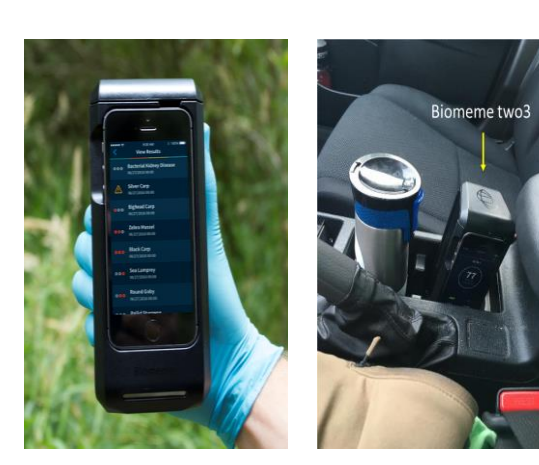
- Wearable sensor developer
- Commercially available FDA & CE-Mark approved vitals sensor
- Health data processing software

MediBioSense

Point-of-Care (POC)

Assay Development for the Biomeme Handheld PCR Platform

- MRIGlobal is currently developing multiplexed real-time PCR assays for biosurveillance and diagnostic use on Biomeme handheld PCR platforms
- Both the extraction reagents and lyophilized assays are room-temperature stable, making the system ideal for use in remote or low-tech POC scenarios
- The Biomeme PCR platforms are small, lightweight, battery-powered, and smartphone-operated, with WiFi and Bluetooth capabilities to easily view and transfer results



Quality and Regulatory Framework

- GLP, cGMP
- Quality System Regulation (QSR)
- ISO 9001, ISO 34, ISO 17025
- CLIA (CAP-accredited)
- ISO 15189 Compliant
- Successful (A+) audit history with FDA, CAP, ISO, DoD, CDC, EPA, DHS, and USDA



Contact information

Jonathan Jacobs, Ph.D.
Senior Advisor, Global Health Surveillance & Diagnostics

MRIGlobal
65 W. Watkins Mill Rd.
Gaithersburg, MD 20879

T: 240.361.4014
E: jjacobs@mriglobal.org