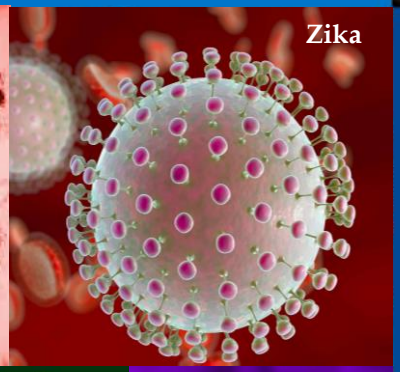
DCLS

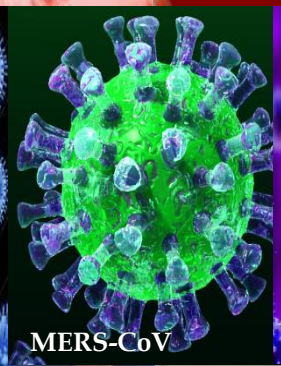
Division of

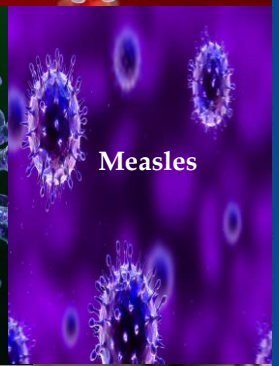
Consolidated Laboratory Services

DGS

DEPARTMENT OF GENERAL SERVICES







Emerging Infectious Disease Testing at DCLS: Preparedness and Response

LaToya A. Griffin-Thomas, Ph.D.
Lead Scientist – Bioterrorism/Special Pathogens Response Coordinator

2019 Ebola Virus and Emerging Disease Summit
October 28, 2019

Objectives

1. Provide an overview of DCLS' testing services and role in public health
2. Review selected emerging, highly infectious diseases of significant public health concern
3. Discuss DCLS' "ready" state of preparedness and response capabilities
4. Discuss DCLS' response efforts to high-consequence, infectious pathogens
5. Discuss DCLS' outreach initiatives to clinical laboratory partners as part of emergency response plans

DCLS

- Serves as the public health, environmental, agriculture and consumer protection laboratory for the Commonwealth of Virginia
- Serves hundreds of local, state and federal agencies
- Conducts over 9 million tests per year with over 650 different analytes
- Operate a statewide courier that provides routine and emergency transportation for specimens from over 200 locations to DCLS
- Comprehensive testing services include:
  - Neonatal screening
  - Immunology/Virology
  - Molecular biology
  - Microbiology
  - Mycology
  - Drug testing
  - Food and water adulteration
  - Metal and pesticide analyses
  - Radiochemistry
  - Motor fuels and commodities
  - Comprehensive chemical analyses

Primary Goal: Protecting the Public's Health

LRN-Biothreat Testing Capabilities

Bacterial:

- *Bacillus anthracis* (Anthrax)
- *Brucella spp.* (Brucellosis)
- *Burkholderia mallei* (Glanders)
- *Burkholderia pseudomall*ei (Melioidosis)
- *Clostridium botulinum* (Botulism)
- *Coxiella burnetii* (Q-fever)
- *Francisella tularensis* (Tularemia)
- *Yersinia pestis* (Plague)

Viral:

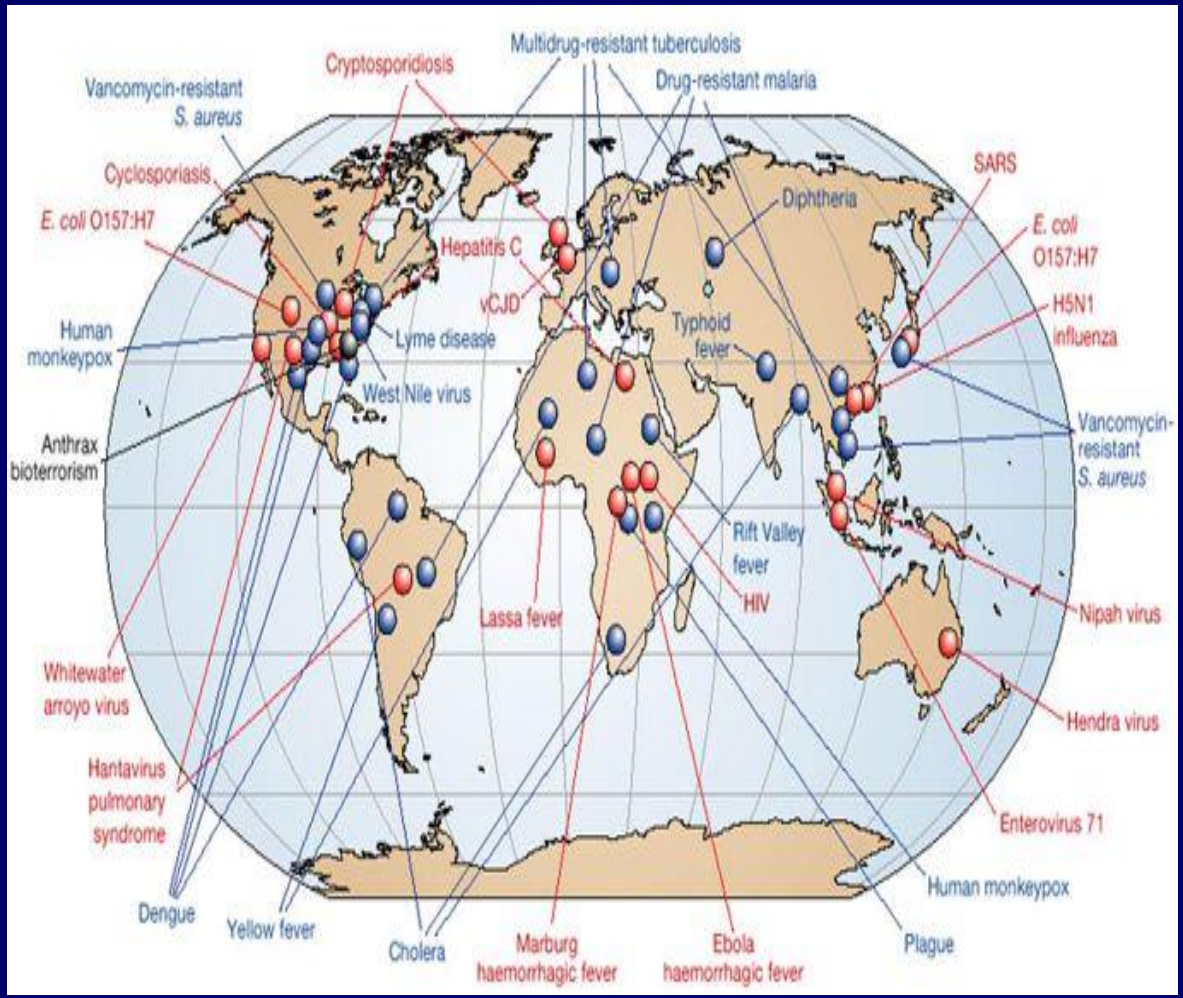
- Non-variola orthopoxvirus (Vaccinia virus)
- Orthopoxvirus (Monkeypox, Cowpox)
- Varicella Zoster Virus (Chickenpox)
- Variola virus (Smallpox)

Toxin:

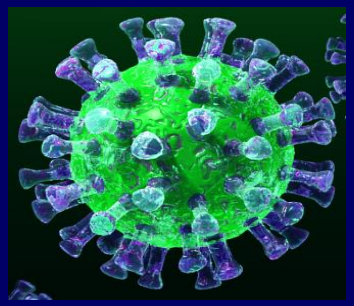
- *Clostridium botulinum* and neurotoxins (Botulism)
- Ricin toxin (Ricin poisoning)

Newly-Emerging Pathogens

- **2013**: Middle Eastern Respiratory Syndrome - Novel Coronavirus (MERS-CoV)
- **2014**: Ebola Virus (Ebola Virus Disease)
- **2016**: Zika virus (Zika virus infection)



Newly-Emerging Respiratory Threat: MERS-CoV

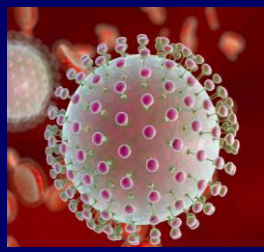


- Disease was first reported in Saudi Arabia, September 2012
- First known case was actually identified in Jordan, April 2012
- Highly contagious, inhalation transmission
- Symptoms (fever, cough, shortness of breath) are comparable to other respiratory illnesses (e.g. flu)
- Can cause acute respiratory distress syndrome (ARDS)
  - 30-40% fatality rate.
- Novel to the US (exotic)
  - Two imported cases identified in the US in 2014 (Indiana, Florida)
  - Healthcare providers that lived and worked in Saudi Arabia

Newly-Emerging Blood-Borne Threat: Ebola Virus

- First discovered in 1976 near the Ebola River, Democratic Republic of Congo
  - Group of viruses within the *Ebolavirus* genus
- Rare and deadly disease, affecting non-human primates and people
- Transmitted from person to person via direct contact with bodily fluids via broken skin or mucous membrane exposure
  - Widespread outbreaks in African countries (2014, 2018)
- Symptoms include fever, severe headache, muscle pain, fatigue, diarrhea, vomiting, abdominal pain, and unexplained hemorrhaging
  - Similar to other illnesses (flu, malaria, enteric pathogen infection)
- Novel to the US (exotic):
  - One fatal case in 2014 (Dallas, TX)
  - Two Dallas, TX nurses who treated the fatal case patient
  - One physician (New York) infected while treating patients in West Africa

Newly-Emerging Vector-Borne Threat: Zika Virus



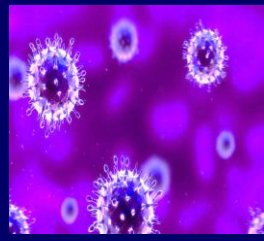
- Flavivirus, first isolated in the Zika Forest in Uganda in 1947
  - Other flaviviruses: West Nile, Yellow Fever, Dengue, Japanese Encephalitis
- Known to cause outbreaks in areas of Africa and Asia.
  - Continuous spread of Zika virus since 2007 has resulted in Zika virus spread to the Americas
  - 2014 – 2016 outbreak in South America (Brazil)
- Modes of transmission include bites by *Aedes* species of mosquitoes (primary), sexual intercourse, blood transfusions, laboratory exposure and maternal-fetal
- Mild illness that rarely causes death, but now known to cause severe fetal birth defects when pregnant women become infected
  - Common symptoms (fever, rash, joint pain, conjunctivitis) similar to Dengue fever but 80% of infected persons are asymptomatic
- Novel to the US (exotic):
  - Local transmissions identified 2016 – 2017, Florida (220 cases) and Texas (11 cases)

Re-Emerging Pathogen Threats

VACCINE - PREVENTABLE:

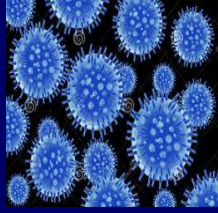
- Rubeola virus (Measles)
- Influenza viruses (Flu)
  - Highly Pathogenic Avian Influenza Virus (HPAIV)
  - Influenza A variant (H3N2v)
  - Novel influenza strain

Vaccine-Preventable Threat: Measles Virus



- Causes a highly contagious disease transmitted via infectious aerosols (breathing, coughing, sneezing)
- Remains a common disease in most parts of the world but most cases in the US are from international travel
- Symptoms (rash, high fever, cough, runny nose, red/watery eyes) are comparable to other respiratory illnesses (e.g. flu)
  - Other symptoms: ear infection, diarrhea, pneumonia, brain swelling
  - While rare, measles can cause death
  - Illness can be severe in infants and persons with weakened immune systems
- Not novel to the US:
  - Measles vaccine was developed in the 1960s – CDC declared measles eliminated from the US in 2000
  - Outbreaks in the US have occurred, with case counts in 2019 (n=1,250) surpassing case counts from as far back as 2010
    - Unvaccinated populations
    - Imported cases

Vaccine-Preventable Threat: Influenza Virus



- A highly contagious, respiratory illness caused by influenza viruses (strains A-D)
  - History of causing pandemics and wide-spread outbreaks (Influenza A)
- Transmitted via infectious droplets when talking, coughing or sneezing
- Illness can be mild to severe, and could result in hospitalization or death for some vulnerable populations
  - Symptoms present suddenly: fever, cough, sore throat, runny nose, muscle/body aches, headaches, fatigue, vomiting or diarrhea
- Not novel to the US - flu vaccine has been utilized in the US since the 1940s and outbreaks occur annually across the US
- Continued threat in the US, as frequent and random genetic changes in flu viruses lead to:
  - Ineffective vaccines
  - Novel or variant influenza strain assortments (swine flu)
  - Highly pathogenic strains that have crossed to other species (HPAIV)

How does DCLS respond to diverse pathogen threats?

DCLS' Implementation of New Emergency Testing

Ready State of Preparedness

- 24/7 emergency contacts and services
  - DCLS mobile emergency number
  - Biothreat (BT) and chemical-threat (CT) mobile emergency numbers
  - On-demand, emergency courier
- Trained, competent staff
  - Molecular biology
  - Clinical microbiology
  - Virology/immunology
  - BSL-3 containment
- Critical instrumentation and laboratory facilities:
  - Biosafety Level-3 (BSL-3) containment laboratories
  - High-throughput automated instrumentation
  - Rapid, real-time PCR platforms
- Maintain qualification as the only Laboratory Response Network (LRN) reference laboratory in Virginia
  - Rapid and confirmatory testing of biothreat agents and newly emerging pathogens

Preparation

Step 1: Receive request to implement testing by the CDC and/or the LRN - Collaborate/communicate with VDH partners to address new threat

Step 2: Perform biosafety risk assessments (PPE, laboratory facilities, engineering controls, decontamination, waste disposal)

Step 3: Identify and mitigate biosafety gaps

Step 4: Perform testing needs assessment (reagents, supplies, instrumentation, personnel, IT)

Step 5: Identify and mitigate testing gaps

DCLS Risk Assessment

Biosafety Risk Assessment Meeting

Attendees:
Commonwealth of Virginia
Division of Consolidated Laboratory Services

Biosafety Risk Assessment Meeting Form

Date:
Department of General Service
Richmond, Virgini

Room number(s) for testing:

☐ Scientific Services (SS) in attendance?
☐ Sample Support Services (SSS) in attendance?

Reason for risk assessment meeting?
☐ Project:
☐ Proficiency testing:
☐ New Testing:
☐ Other:

Agent(s) / Risk Group(s) / Biosafety Level:

Procedural hazards

Methods that will be used:
☐ LRN:
☐ FERN:
☐ CDC-dev:
☐ Other (e.g. LDT):

Is there an Exposure Control Plan for the agent(s)?
☐ Yes (attach to risk assessment) ☐ No
If no, print & attach SDS for agent.

Has the Exposure Control Plan(s) been distributed and discussed with all attendees, to include fever watch protocol, signs and symptoms, and incubation period? ☐ Yes ☐ No

Is there a vaccine for the agent(s)?
☐ Yes ☐ No

Is there post exposure prophylaxis for the agent?
☐ Yes ☐ No

Volume of the Agent that will be stored/handled

Agent concentration

Is there a splash potential (large volumes)? ☐ Yes ☐ No
Comments:

Does the procedure have a high potential to generate aerosols? ☐ Yes (indicate below) ☐ No
☐ Vortex ☐ Centrifuge ☐ Stomacher/Homogenizing
☐ Other (please indicate):

Percutaneous hazards? ☐ Yes ☐ No
(e.g., use of glass, syringes, or other sharps)
Comments:

DCLS Risk Assessment

Biosafety level, work practices, and personal protective equipment
Accessioning:

Performed by SSS ☐ or Laboratory staff ☐: ______________________________ (name Group) Biosafety Level: ☐2 ☐3 Work Practices: ☐2 ☐2+ ☐3

Gloves:	**Lab coat:**	**Eye protection:**	**Shoe covers required?**
☐Nitrile ☐Latex ☐Double gloves required in BSC	☐ Cloth ☐ Tyvek suit ☐ Disposable front-closing gown ☐ Disposable back-closing gown	☐ Safety glasses ☐ Goggles ☐ Face shield ☐ PAPR hood, CAPR or head cover	☐ Yes ☐ No

Respirator: ☐ N/A ☐ N-95† ☐ PAPR or CAPR
†Have all staff members wearing an N-95 been medically cleared and fit tested within the previous 12 months? ☐ Yes ☐ No

Processing:

Culture: In BSC? ☐ yes ☐ no Biosafety Level: ☐2 ☐3 Work Practices: ☐2 ☐2+ ☐3 ☐ N/A		**Procedure:** ______________________________ In BSC? ☐ yes ☐ no Biosafety Level: ☐2 ☐3 Work Practices: ☐2 ☐2+ ☐3 ☐ N/A	
Gloves: ☐Nitrile ☐Latex ☐Double gloves required in BSC	**Shoe covers required?** ☐ Yes ☐ No	**Gloves:** ☐Nitrile ☐Latex ☐Double gloves required in BSC	**Shoe covers required?** ☐ Yes ☐ No
Lab coat: ☐ Cloth ☐ Tyvek suit ☐ Disposable front-closing gown ☐ Disposable back-closing gown	**Eye protection:** ☐ Safety glasses ☐ Goggles ☐ Face shield ☐ PAPR hood, CAPR or head cover	**Lab coat:** ☐ Cloth ☐ Tyvek suit ☐ Disposable front-closing gown ☐ Disposable back-closing gown	**Eye protection:** ☐ Safety glasses ☐ Goggles ☐ Face shield ☐ PAPR hood, CAPR or head cover
Respirator: ☐ N/A ☐ N-95† ☐ PAPR or CAPR **†Have all staff members wearing an N-95 been medically cleared and fit tested within the previous 12 months?** ☐ Yes ☐ No		**Respirator:** ☐ N/A ☐ N-95† ☐ PAPR or CAPR **†Have all staff members wearing an N-95 been medically cleared and fit tested within the previous 12 months?** ☐ Yes ☐ No	
Procedure: ______________________________ In BSC? ☐ yes ☐ no Biosafety Level: ☐2 ☐3 Work Practices: ☐2 ☐2+ ☐3 ☐ N/A		**Procedure:** ______________________________ In BSC? ☐ yes ☐ no Biosafety Level: ☐2 ☐3 Work Practices: ☐2 ☐2+ ☐3 ☐ N/A	
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Risk Assessment

DCLS Risk Assessment

Employees involved in the method:	Training requirements:

Activity/Procedure:	Hazard:	Control/Protection:

*Has a DCLS inactivation study been conducted to ensure product is non-viable? ☐Yes ☐No

If no inactivation study has been conducted, explain why:

Comments & Acknowledgements

Biosafety Officer comments:

Additional comments:

Enhanced PPE

- **Standard DCLS BSL-3 PPE:**

- PAPR
- PAPR head cover
- Fluid-impervious, back-closing gown
- Shoe covers
- Gloves
  - Double gloves when working

- **Enhanced DCLS Ebola Testing PPE:**

- PAPR (inside of Tyvek suit)
- Full PAPR hood
- Tyvek suit
- Tyvek boots
- Fluid-impervious, back-closing gown
- Gloves
  - Double gloves when working

Preparation

Step 6: Complete internal validation/verification procedures and testing studies

Step 7: Prepare testing SOPs, worksheets, training checklists

Step 8: Submit of validation/verification data packet to administration for approval

Step 9: Train additional staff to enhance testing workforce

Collaborate/Communicate

Step 10: Outreach to clinical laboratory partners to discuss testing plans, concerns, gaps

Step 11: Prepare and distribute testing guidance documents for Epi and clinical laboratory partners

Step 12: Develop and distribute specimen collection and shipping kits for Epidemiology and laboratory partners

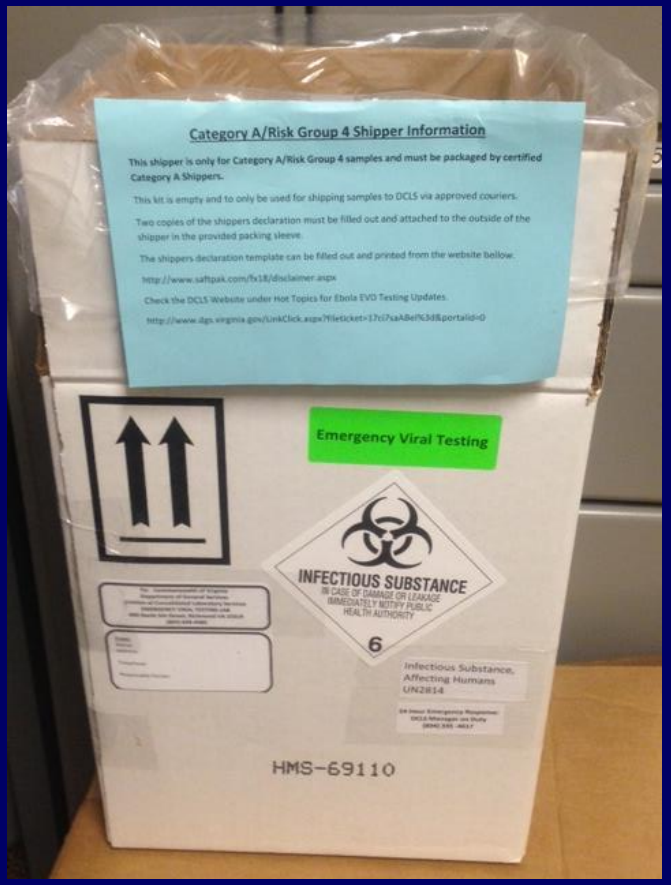
Category A Specimen Collection and Shipping Kits

- Conference call with VA sentinel hospital laboratories to discuss biosafety, specimen collection, packaging & shipping

- Purchased Ebola Category A/UN2814 specimen collection and shipping kits
  - $50 per kit

- Provided 2 complete kits free-of-charge to:
  - 35 VDH Health Districts
  - 5 regional epidemiologists
  - 4 OCME offices
  - Over 100 Virginia hospitals
  - 6 VA Ebola Assessment Centers
  - 2 VA Ebola Treatment Centers

- Provided kits to courier to provide on-demand



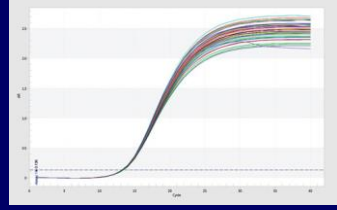
Mitigating Training Gaps at Clinical Laboratories

- Purchased and offered free-of-charge 12 Saf-T-Pak Packaging and Shipping training courses for hospitals
  - $3,200 per course, up to 24 participants
  - Participants have remote access to webinar
  - Training course materials shipped to each participant
  - Packaging/shipping materials provided for hands-on training demonstration

- Thirty-five locations participated
  - Over 70 laboratorians became certified to package and ship Category A/UN2814 packages

- Continued updates on testing instructions and FAQ documents as new guidance was received
  - Blast emails
  - Updates to DCLS website

Test and Report



Step 13: Respond 24/7 to provide emergency testing and report results

Step 14: Update and distribute guidance documents as CDC provides updated guidance

Step 15: Maintain staff training and competency (two times the first year, and annual thereafter)

Step 16: Participate in annual proficiency testing

Response By the Numbers

MERS-CoV Response

- Since implementation in June 2013, DCLS has tested 48 Patients Under Investigation (PUIs) for MERS-CoV
- This includes reflex influenza and/or RVP testing for all 48 cases
- Testing capabilities still are maintained

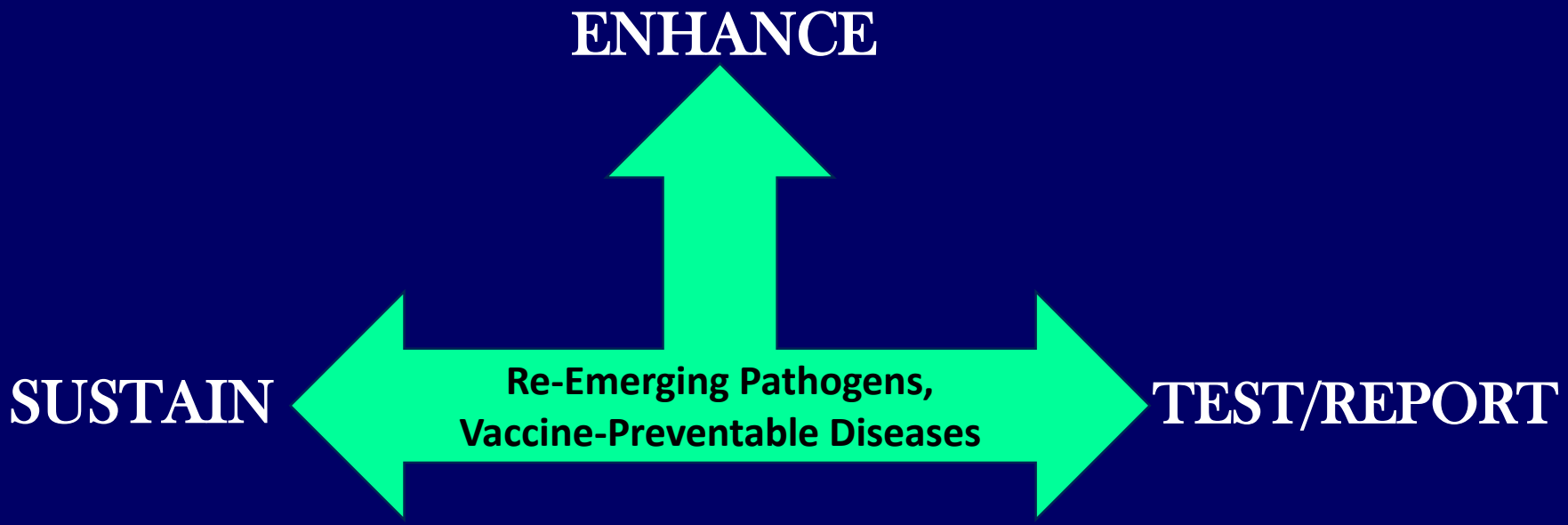
Ebola Virus Response

- Since implementation in August 2014, DCLS has tested 11 Patients Under Investigation (PUIs) for Ebola virus disease
- This includes concurrent malaria testing for all 11 cases
- Testing capabilities are still maintained

Zika Virus Response

- Since implementation in April 2016, DCLS has tested over 4,500 specimens for patients with exposure to Zika virus infection
- DCLS tested over 3,000 mosquito pools for Zika virus in 2016; testing still is performed routinely for those patients meeting criteria for public health testing

DCLS' Core Testing Capacities



Sustain/Enhance: VPD testing

Testing Laboratories	Testing Services
1. Molecular Detection and Characterization (MDC) 2. Immunology/Virology 3. Microbial Reference	Real-Time PCR: • Bordetella spp. (pertussis – IS481, holmesii, parapertussis, pertussis toxin) • Measles virus • Measles vaccine strain assay (coming soon) • Mumps virus • Bacterial meningitis (coming soon) Serology: • Measles IgM and IgG • Mumps IgM and IgG Culture: • Pertussis • Measles virus isolation • Mumps virus isolation

Sustain/Enhance: Respiratory Testing

Testing Laboratories	Molecular, Virus Isolation and FA

1. **Molecular Detection and Characterization (MDC)**
 	
2. **Immunology/Virology**
 	
***Fluorescent Antibody detection**
	• **Influenza A** viruses
	  • Flu A/H3, Flu A/2009 pandemic H1, Flu A/H5, Flu A/H7
	• **Influenza B** virus
	  • Lineage - Yamagata vs. Victorian
	• Respiratory Virus Panel (RVP)
	  • Flu A -H1, -H3 and -H1N1
	  • Flu B
	  • **RSV** -A and –B
	  • **Parainfluenza –1, -2 and -3**
	  • **Adenovirus** –C, and –B/E
	  • Human Rhinovirus
	  • **Human Metapneumovirus**
	• New RVP assay – ePlex
	  (viral and bacterial respiratory pathogens)

Sustain/Enhance: Arbovirus Testing

Testing Laboratories	Molecular and Virus Isolation

1. **Molecular Detection and Characterization (MDC)**
 	
2. **Immunology/Virology**
	• **LRN Trioplex Real-Time PCR assay**:
	  • Zika, Chikungunya and Dengue
	
	• **CDC Zika Virus Real-Time PCR Assay**:
	  • Pan Zika
	  • Asian lineage
	
	• **CDC Dengue Virus Real-Time PCR assay:**
	  • Serotypes 1, 2, 3 and 4
	
	• **WNV Real-Time PCR assay – mosquitoes**
	
	• **IgM MAC ELISA/Microsphere Immunoassay (MIA)**
	  • Zika, Chikungunya and Dengue viruses
	  • West Nile Virus (WNV)
	  • Eastern Equine Encephalitis (EEE) virus
	  • La Crosse Encephalitis (LAC) virus
	  • St. Louis Encephalitis (SLE) virus

Summary

- DCLS offers diverse testing services as the Commonwealth's public health, environmental, agriculture and consumer protection testing laboratory
- DCLS maintains a "ready" state of preparedness to respond to newly-emerging and re-emerging pathogen threats
- DCLS provides 24/7 communication processes, courier service and emergency testing, as needed
- Since 2013, DCLS rapidly implemented testing to respond to MERS-CoV, Ebola virus and Zika virus public health threats
- DCLS maintains a strong biosafety program to ensure all testing, including testing of new, exotic pathogens are performed in the safest manner possible
- DCLS' response to newly emerging pathogens focuses on preparation (assessing and mitigating testing gaps), collaboration/outreach (support to Epi and clinical laboratory partners), testing (providing 24/7 testing services to protect the public's health).
- DCLS sustains and enhances, core testing capabilities in order to respond to a diverse array of pathogenic threats

Contact Information

LaToya A. Griffin-Thomas, Ph.D.
Bioterrorism/Special Pathogens Response Coordinator
Phone: 804-648-4480, ext. 281
Blackberry: 804-385-8057
Email: latoya.griffin-thomas@dgs.virginia.gov

DCLS 24/7 Emergency Mobile Phone: (804) 335-4617
DCLS weblink: www.dgs.state.va.us
(Department of General Services - Division of Consolidated Laboratory Services link)

Questions