CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

Next generation rapid POC test

Rapid Tests for Earlier Treatment™

DPP Febrile illness assay

Javan Esfandiari
Chief Science & Technology Officer

Lima/Peru May, 14, 2015

Forward-Looking Statements

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those statements include statements regarding the intent, belief or current expectations of Chembio and its management. Such statements reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to, Chembio's ability to develop, manufacture, market and finance new products and the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Other factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

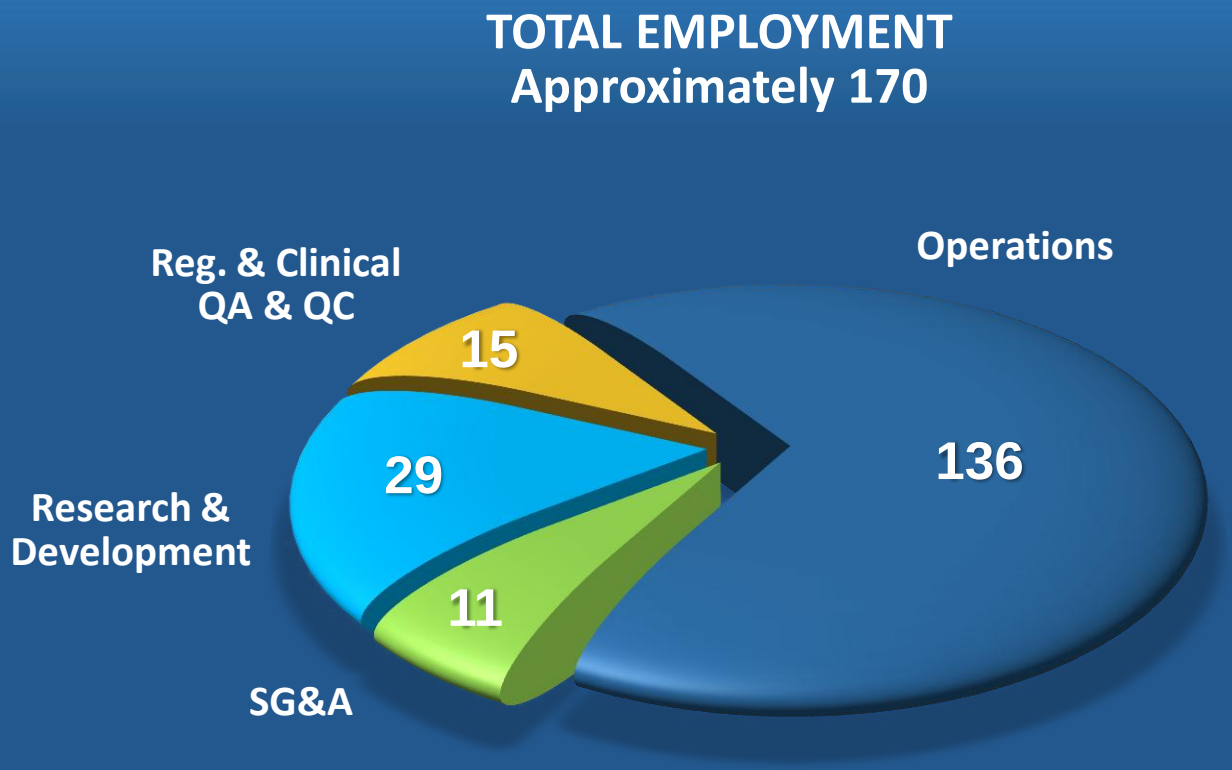
Our Vision & Mission

We enable longer and healthier living through detection and monitoring of serious diseases.

Our mission is to be a leader in the development and commercialization of diagnostic solutions. We are dedicated to delivering high-quality products that provide ease of use, rapid and accurate results at the point-of-care (POC). As a global company, we are committed to innovation and the highest quality standards.

Organization & Facility

- FDA & USDA-Approved Development & Manufacturing Facility
- All Company Operations in 60000 Sq. Ft. Leased Facility in Medford & Holbrook, NY



Global POC Diagnostics Company

NORTH AMERICA

- Established U.S. Sales & Marketing (June '14)
- DPP® HIV 1/2 FDA Approved, CLIA Waiver pending
- Funded Research: CDC, DOD, NIH (2013)

EUROPE

- Achieved CE mark for SURECHECK® HIV (July '13)
- Achieved CE mark for HIV STATPAK®, (March '14)
- Pending CE mark for DPP® HIV and DPP® HIV/Syphilis Assays

ASIA

- Established License, Technical Transfer, Contract Manufacturing, Distribution Agreement (Feb. '14)

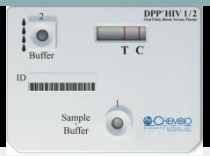
LATIN AMERICA

- Strong OEM Partnerships (e.g., FIOCRUZ, Labtest)
- Branded products sold to NGOs, private distributors

MERA (Middle East, Russia, Africa)

- Sales channel: NGO-direct & through distributors
- Procurements primarily funded by PEPFAR, Global Fund, and WHO

CHEMBIO Rapid HIV Tests
FDA Approved and/or on WHO, USAID Waiver List

	SURE CHECK® HIV 1/2	HIV 1/2 STAT-PAK®	HIV 1/2 STAT PAK® DIPSTICK	DPP® HIV 1/2 Assay (Oral Fluid/Blood)	DPP® HIV-Syphilis Assay
					
Regulatory Approvals & Listings	FDA/CLIA-Waived Approved; CE Mark Approved; USAID Waiver; WHO Bulk Proc. List	FDA/CLIA-Waived Approved; CE Mark Approved; USAID Waiver; WHO prequalified	USAID Waiver; WHO Prequalified	FDA/CLIA–Waived Approved; USAID Waiver; WHO Pending; CE Mark Pending	USAID-waived; WHO, FDA, CE Mark approvals pending
Technology	Lateral Flow - Unique Unitized, Capillary Tip Closed System	Lateral Flow	Lateral Flow	Dual Path Platform (DPP®)	Dual Path Platform (DPP®)
Sensitivity	FDA 99.7% (HIV-1) FDA 100% (HIV-2)	FDA 99.7% (HIV-1) FDA 100% (HIV-2)	WHO 100%	USAID 100 % Oral Fluid	HIV/Syphilis (CDC) 99.53/98.8
Specificity	FDA 99.9%	FDA 99.9%	WHO 99.7%	USAID 99.8 % Oral Fluid	HIV/Syphilis (CDC) 99.47/99.4
Features					
Sample Types	**All Blood Matrices**	**All Blood Matrices**	**All Blood Matrices**	**Oral Fluid All Blood Matrices**	**All Blood Matrices**
True IgG Control	Y	Y	Y	Y	Y
Sample Size (in microliters)	2.5	5	5	10 blood	10
HIV-2	Y	Y	Y	Y	Y

Chembio POC tests serve a diverse, regulated global market

- Chembio's manufacturing (cGMP) is in full compliance with regulatory requirements
- FDA: 3 approved PMAs
- USDA: 2 Produt Manufacturing Licences
- ISO13485 registered
- Audited routinely by various regulatory agencies:
  - CBER Inspected (21 CFR, 210, 211, 600's, & 820)
    - Three of Twenty-four PMAs currently active with FDA CBER belong to Chembio
  - CDRH Inspected (21 CFR 820)
  - CVB Inspected (9 CFR 115)
  - NB inspected (ISO:13485)
  - WHO inspected
  - USDA inspected
  - CE/ LNE inspected

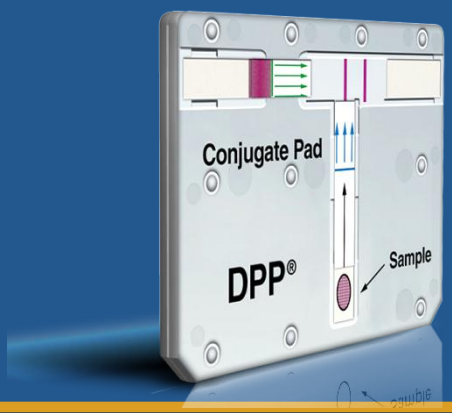
Comprehensive Manufacturing Capabilities

- High Volume Manufacturing: >14M units produced / year
  - 5 reel-to-reel dispensing system, two reel-to-reel lamination, 4 Packaging Lines , Automated Vial Filling Equipment, Barrel Assembly
  - Temperature & Humidity controlled Production Areas
  - Lean & Six Sigma Methodology employed to drive efficiencies, cost reduction and quality
- Engineering Capabilities:
  - >100 years combined experience in Equipment Qualification & Process Validation
- New Warehouse (19K ft^2):
  - Temperature Control
  - Walk in refrigerator storage (2-8oC)
- Strong Operational Management Team experienced in Quality Systems

Chembio's "Dual Path Platform" (DPP®) Technology

- Patented technology
- Allows improved sensitivity compared to Lateral Flow Technology
- Enables multiple test results via a single blood sample (e.g., HIV-Syphilis Combo Assay)
- Offers application within Infectious Disease and potential for a number of other indications

Mechanism → **Results**



Screening Tests

Confirmatory/Multiplex Tests

CHEMBIO

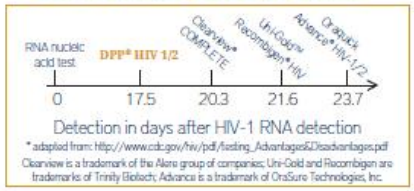
NOW CLIA WAIVED

NEXT GENERATION DPP™

DPP® HIV 1/2 Assay

- Oral fluid and blood rapid HIV test
- Excellent sensitivity and specificity[1]
- Ready-to-use reagents
- Technology prevents issues with "over collection" of oral fluid
- Open kit controls stability 24 months
  - 50 control runs per vial

DPP® HIV 1/2: Earlier Detection Than Leading POC HIV Tests*



* adapted from: http://www.cdc.gov/hiv/pdf/testing_Advantages&Disadvantages.pdf

Clearview is a trademark of the Alere group of companies; Uni-Gold and Recombigen are trademarks of Trinity Biotech; Advance is a trademark of OraSure Technologies, Inc.

Oral Fluid and Blood Assay

Soft Foam Tip

DPP® SampleTainer® specimen collection bottle:
A safe, closed system for handling potentially infectious blood and oral fluid samples.

CHEMBIO
DIAGNOSTIC SYSTEMS, INC.
Rapid Tests for Earlier Treatment™

Manufactured in the USA

FDA approved
CLIA waived for oral fluid, fingerstick and venous whole blood

[1] Sensitivity: 99.9% Whole Blood/Plasma/Serum; 99.8% Fingerstick; 98.9%* Oral Fluid
Specificity: 100% Fingerstick; 99.9% Oral Fluid/Whole Blood/Plasma/Serum

* 98.9% (953/964), 7 false negative individuals were previous known test positives on Highly Active Anti-Retroviral Therapy (HAART). An Individual infected with HIV who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.

The world's most accurate

HIV Self Test

Reliable Discreet Convenient

>99.7% ACCURATE

BUY NOW

The only CE marked HIV Self Test

Simple Accurate Approved

HIV is just three letters... not a sentence

BUY NOW

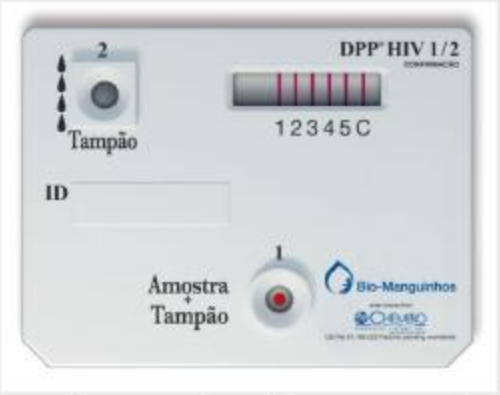
CHEMBIO

Ongoing Collaboration with Brazilian MOH Affiliate Complemented by New Agreement with Labtest

Instituto de Tecnologia em Imunobiológicos
Bio-Manguinhos

Labtest

CHEMBIO



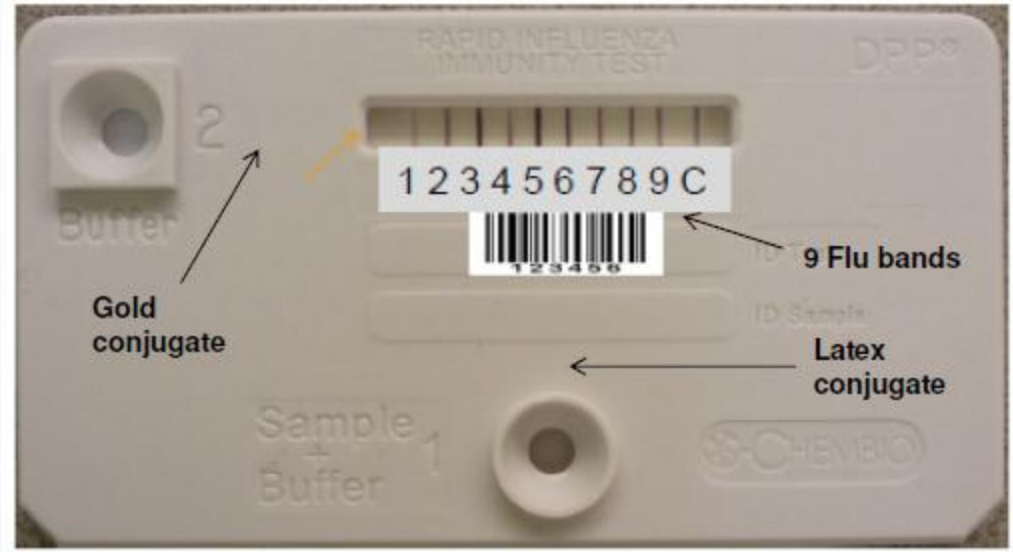
List of product technology transfer to Brazil:

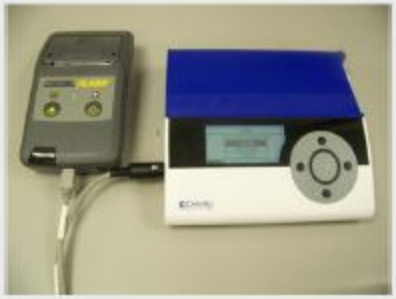
1. HIV1/2 Stat-Pak (lateral flow)
2. DPP® HIV 1/2 (Oral Fluid/Blood)
3. DPP® HIV 1/2 Confirmatory
4. DPP® Syphilis Trep
5. DPP® Syphilis Trep&N.Trep
6. DPP® Leishmania (Human&Canine)
7. DPP® Leptospira

New products:

1. DPP® HIV-Syphilis
2. DPP® Chagas (Screen&Confirm)
3. DPP® Torch

DPP® Rapid Influenza Immunity Test





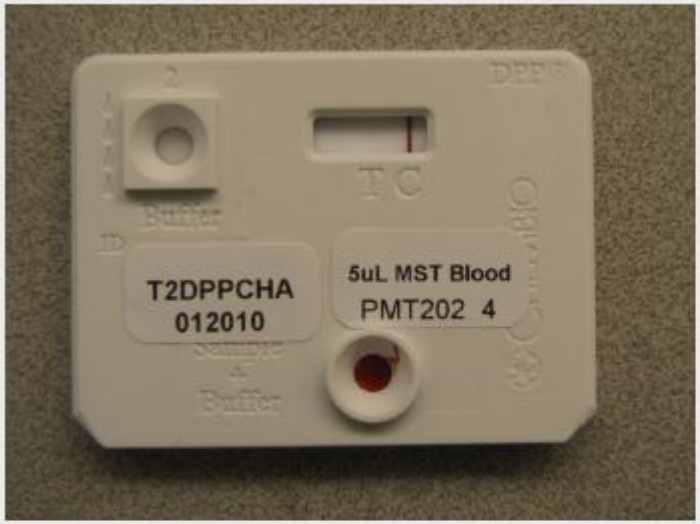
Innovation to solve complex issue:

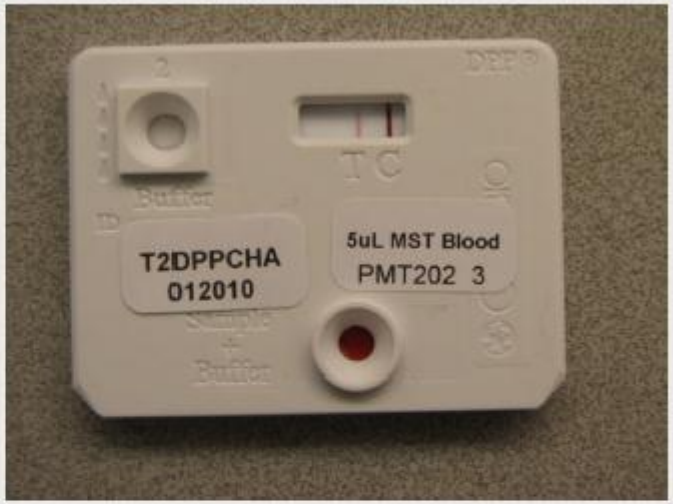
1. Multiplexing up to 9 different Influenza antigens in POC format with 20 ul fingerstick blood with reader
2. Incorporate latex conjugate with FLU antigen to block cross reactivity between different FLU strains and improve sensitivity and specificity of assay

Funded by US. Agency

Patent Pending

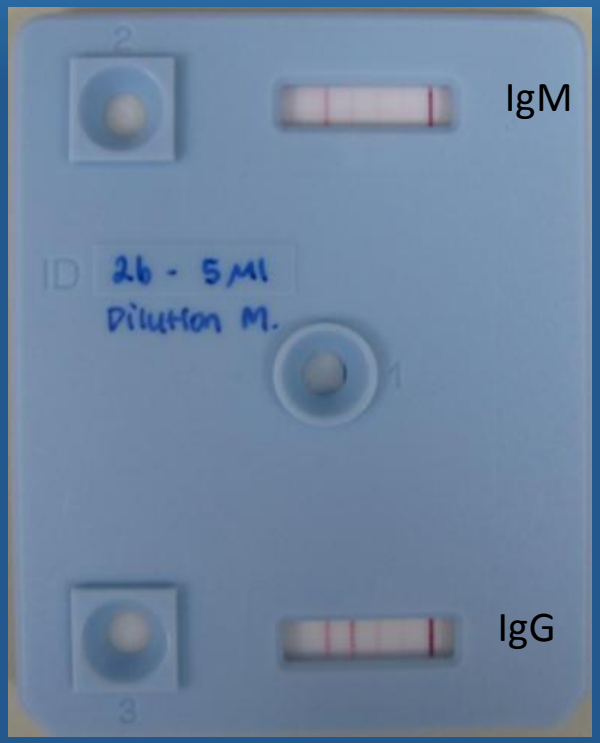
DPP Chagas Screen and Confirmatory Assay

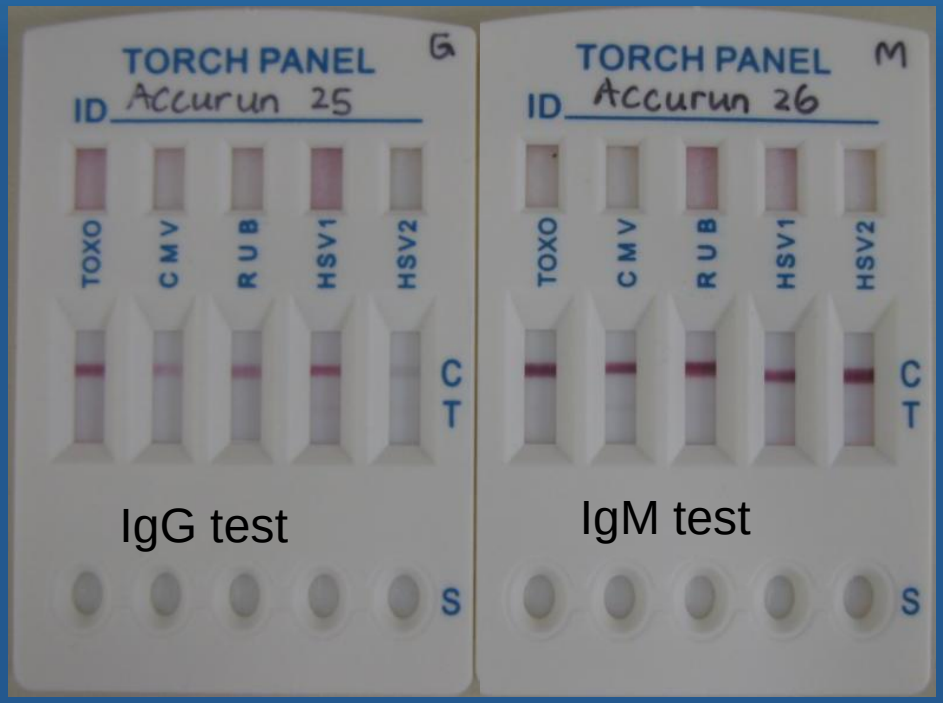




Chagas Stat-Pak

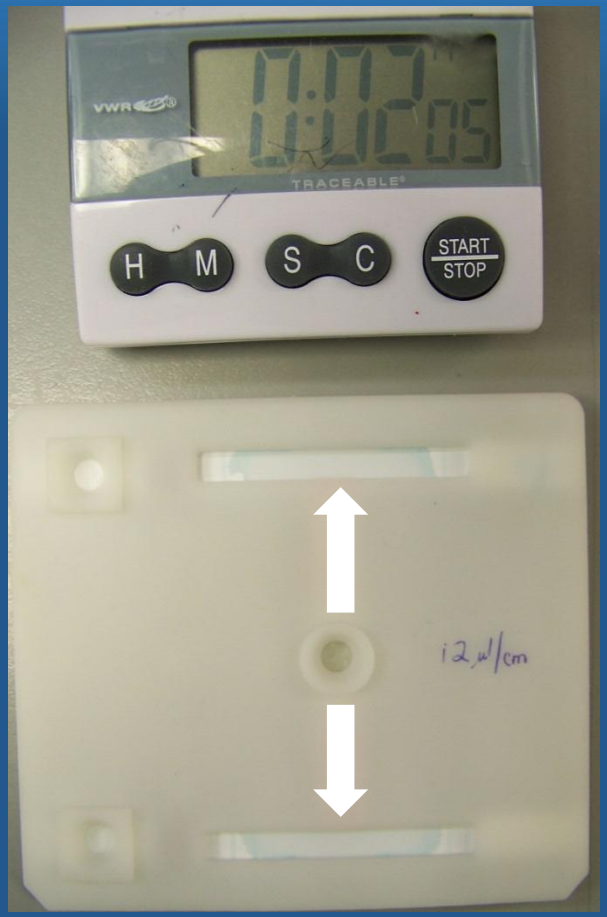
DPP® Torch IgG/IgM Assay vs. Competitor's LF Assay

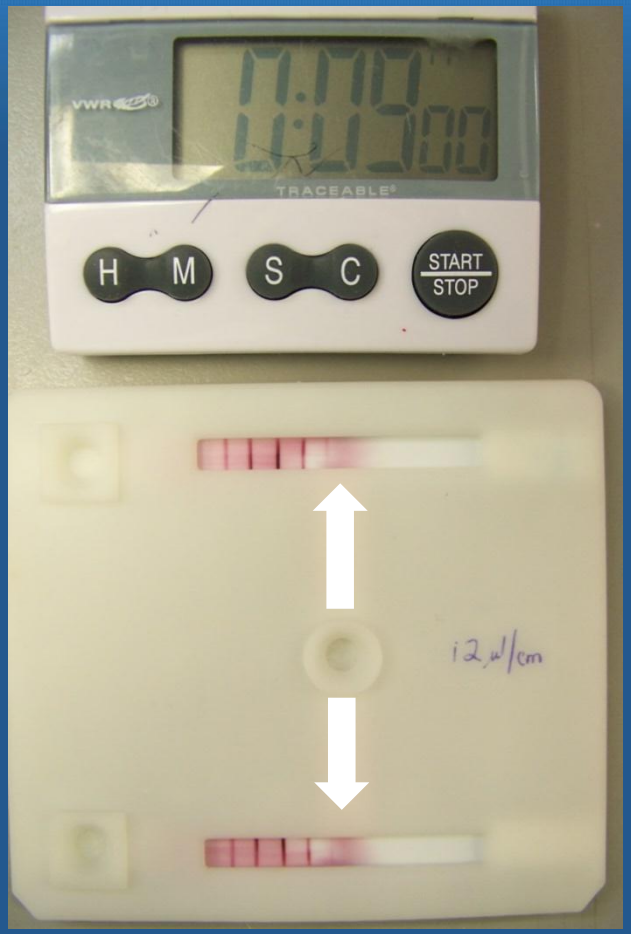




D-DDP with one blood sample (10 ul) v LF 10x 20ul=200 ul

DPP Results Multiplex 18 tests line + 2 control lines
5-50 ul Serum/blood for screening of IgG/IgM or IgE
Possible combination of antibody and antigen detection
Allergy, Autoimmune, tropical panel,Veterinary……





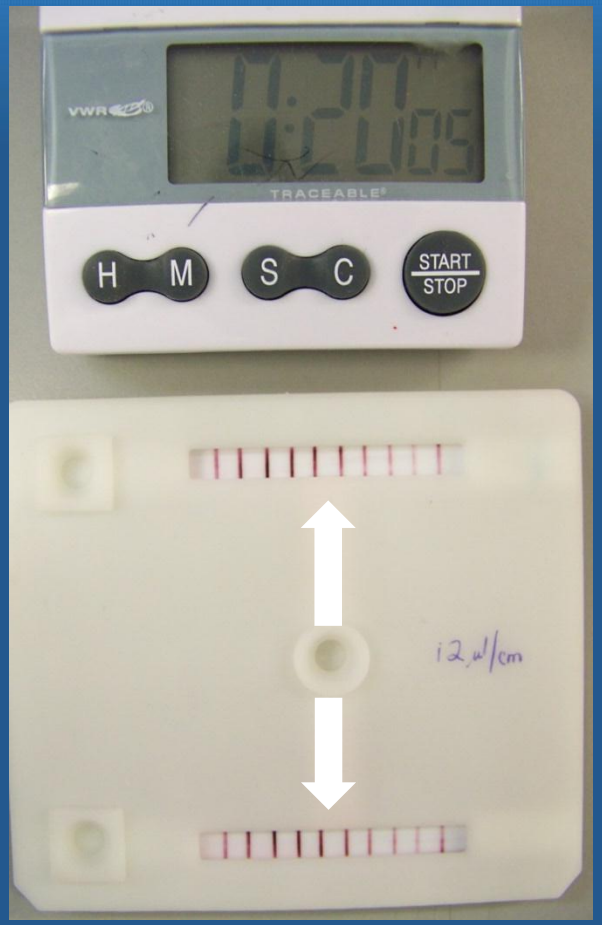


Table 5-02. Common causes of fever, by geographic area

GEOGRAPHIC AREA	COMMON TROPICAL DISEASE CAUSING FEVER	OTHER INFECTIONS CAUSING OUTBREAKS OR CLUSTERS IN TRAVELERS
Caribbean	Dengue, malaria (Haiti)	Acute histoplasmosis, leptospirosis
Central America	Dengue, malaria (primarily *Plasmodium vivax*)	Leptospirosis, histoplasmosis, coccidioidomycosis
South America	Dengue, malaria (primarily *P. vivax*)	Bartonellosis, leptospirosis, histoplasmosis
South-central Asia	Dengue, enteric fever, malaria (primarily non-falciparum)	Chikungunya virus infection
Southeast Asia	Dengue, malaria (primarily non-falciparum)	Chikungunya virus infection, leptospirosis
Sub-Saharan Africa	Malaria (primarily *P. falciparum*), tickborne rickettsiae, acute schistosomiasis, filariasis	African trypanosomiasis

http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-5-post-travel-evaluation/fever-in-returned-travelers#3184

Table 5-03. Common infections, by incubation period

DISEASE	USUAL INCUBATION PERIOD (RANGE)	DISTRIBUTION
Incubation <14 days		
Chikungunya	2–4 days (1–14 days)	Tropics, subtropics (Eastern Hemisphere)
Dengue	4–8 days (3–14 days)	Topics, subtropics
Encephalitis, arboviral (Japanese encephalitis, tickborne encephalitis, West Nile virus, other)	3–14 days (1–20 days)	Specific agents vary by region
Enteric fever	7–18 days (3–60 days)	Especially in Indian subcontinent
Acute HIV	10–28 days (10 days to 6 weeks)	Worldwide
Influenza	1–3 days	Worldwide, can also be acquired en route
Legionellosis	5–6 days (2–10 days)	Widespread
Leptospirosis	7–12 days (2–26 days)	Widespread, most common in tropical areas
Malaria, *Plasmodium falciparum*	6–30 days (almost always within 3 months of travel; occasionally longer)	Tropics, subtropics
Malaria, *P. vivax*	8 days to 12 months (occasionally longer)	Widespread in tropics and subtropics
Spotted-fever rickettsiae	Few days to 2–3 weeks	Causative species vary by region
Incubation 14 Days to 6 Weeks		
Encephalitis, arboviral; enteric fever; acute HIV; leptospirosis; malaria	See above incubation periods for relevant diseases	See above distribution for relevant diseases
Amebic liver abscess	Weeks to months	Most common in developing countries
Hepatitis A	28–30 days (15–50 days)	Most common in developing countries
Hepatitis E	26–42 days (2–9 weeks)	Widespread
Acute schistosomiasis (Katayama syndrome)	4–8 weeks	Most common in sub-Saharan Africa
Incubation >6 weeks		
Amebic liver abscess, hepatitis E, malaria, acute schistosomiasis	See above incubation periods for relevant diseases	See above distribution for relevant diseases
Hepatitis B	90 days (60–150 days)	Widespread
Leishmaniasis, visceral	2–10 months (10 days to years)	Asia, Africa, Latin America, southern Europe, and the Middle East
Tuberculosis	Primary, weeks; reactivation, years	Global distribution, rates and levels of resistance vary widely

Table 5-04. Common clinical findings and associated infections

COMMON CLINICAL FINDINGS	INFECTIONS TO CONSIDER AFTER TROPICAL TRAVEL
Fever and rash	Dengue, chikungunya, rickettsial infections, enteric fever (skin lesions may be sparse or absent), acute HIV infection, measles
Fever and abdominal pain	Enteric fever, amebic liver abscess
Undifferentiated fever and normal or low white blood cell count	Dengue, malaria, rickettsial infection, enteric fever, chikungunya
Fever and hemorrhage	Viral hemorrhagic fevers (dengue and others), meningococcemia, leptospirosis, rickettsial infections
Fever and eosinophilia	Acute schistosomiasis, drug hypersensitivity reaction, fascioliasis and other parasitic infections (rare)
Fever and pulmonary infiltrates	Common bacterial and viral pathogens, legionellosis, acute schistosomiasis, Q fever, leptospirosis
Fever and altered mental status	Cerebral malaria, viral or bacterial meningoencephalitis, African trypanosomiasis, scrub typhus
Mononucleosis syndrome	Epstein–Barr virus, cytomegalovirus, toxoplasmosis, acute HIV
Fever persisting >2 weeks	Malaria, enteric fever, Epstein–Barr virus, cytomegalovirus, toxoplasmosis, acute HIV, acute schistosomiasis, brucellosis, tuberculosis, Q fever, visceral leishmaniasis (rare)
Fever with onset >6 weeks after travel	*Plasmodium vivax* or *ovale* malaria, acute hepatitis (B, C, or E), tuberculosis, amebic liver abscess

Severe Acute Systemic Febrile Illness, SASFI

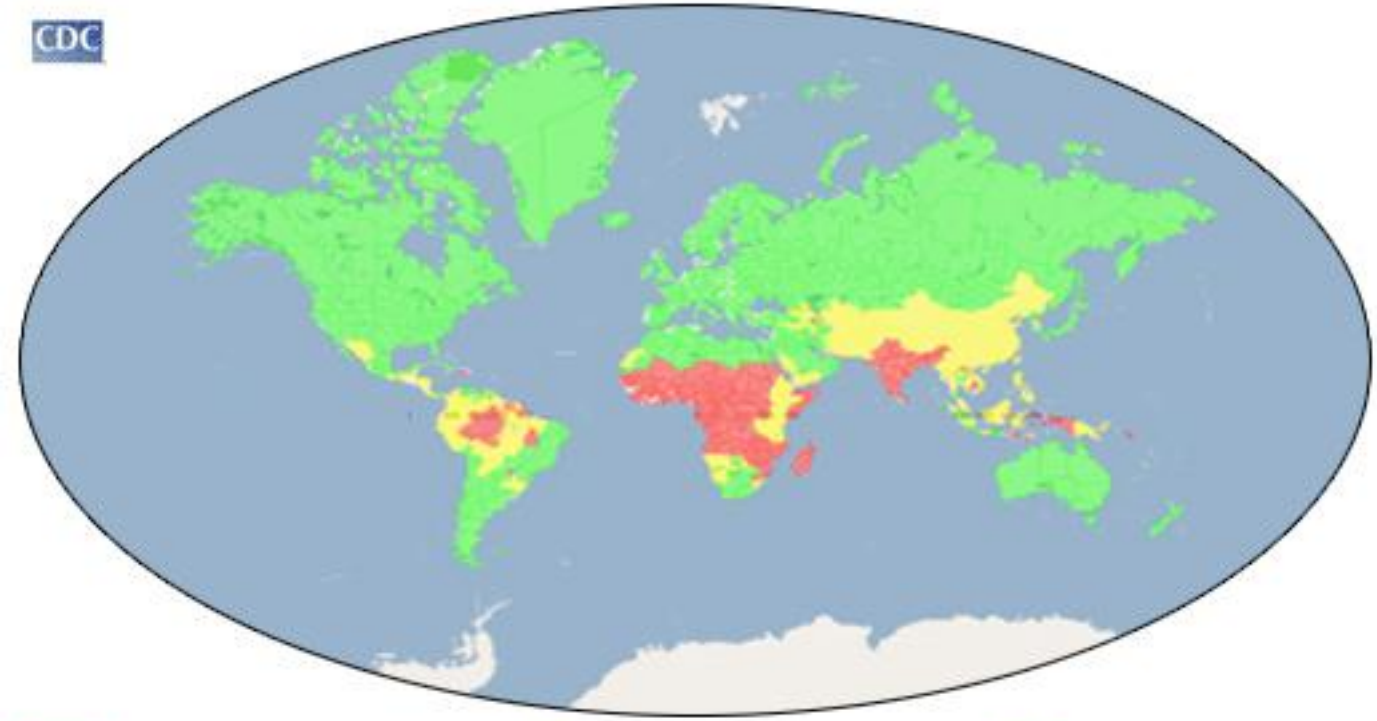
- Dengue
- Malaria (*P. falciparum*)
- Melioidosis (*B. pseudomaelli)*
- Plague (*Y. pestis*)
- Anthrax
- Lassa fever
- Leptospirosis
- Rickettsial disease
- Typhoid
- Chikungunya
- Q-fever
- Meningococcal
- Pneumococcus
- CCHF

Disease State Summary of Scores

	Detectable in Blood	Predictable/ reliable	SASFI	Available reagents/materials	Use in Medical Differential	Cost/Time for evaluation	Clinical Impact	Total Score 4=highest 1=lowest
Malaria	4	4	4	4	4	4	4	28
Dengue	4	4	4	4	3.5	4	2.5	26
Burkholderia	2.5	3	4	3.5	3.5	4	4	24.5
Typhoid	3	3.5	4	4	3	3	3.5	24
Chikungunya	3.5	3	4	4	3	3.5	3	24
Leptospirosis	2.5	4	4	2	4	2	4	22.5
Rickettsia	3	3	4	3	3.5	2	3.5	22
Plague	2.5	2.5	4	4	2	4	2	21
Pneumococcal	2.5	3	4	2	3	2.5	2.5	20.5
Q-Fever	2.5	3	4	3	3	1	3.5	20
Meningococcal	2	3	4	2	3	2.5	3.5	20
Anthrax	2	2	4	4	2	4	1	19
Lassa	3.5	3	4	3.5	2	1	1	18
CCHF	3	2.5	4	1.5	2	1	2.5	16.5

Malaria Worldwide

In 2012, an estimated 627,000 people died of malaria—most were young children in sub-Saharan Africa. Within the last decade, increasing numbers of partners and resources have rapidly increased malaria control efforts. This scale-up of interventions has saved 3.3 million lives globally and cut malaria mortality by 45%, leading to hopes and plans for elimination and ultimately eradication. CDC brings its technical expertise to support these efforts with its collaborative work in many malaria-endemic countries and regions.



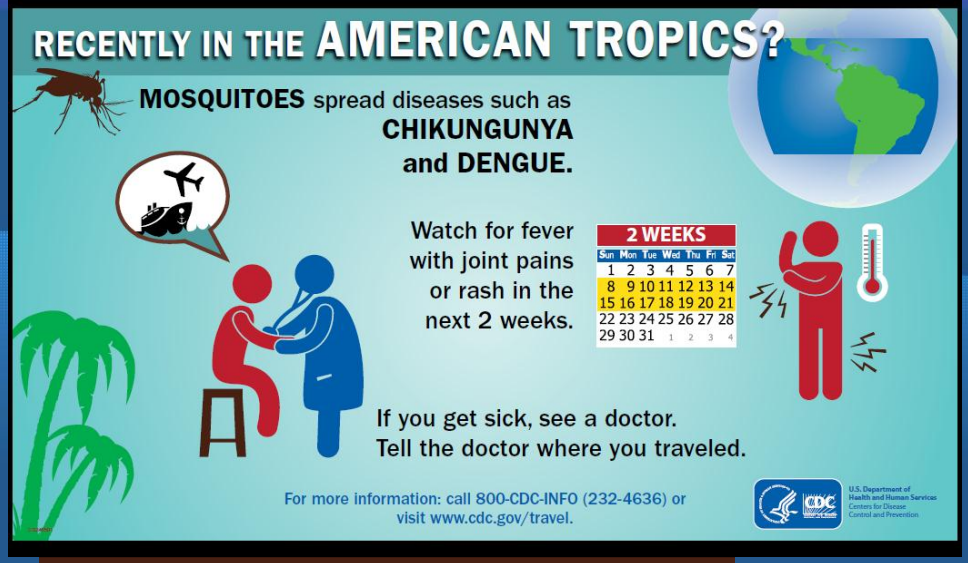
http://www.cdc.gov/malaria/malaria_worldwide/index.html

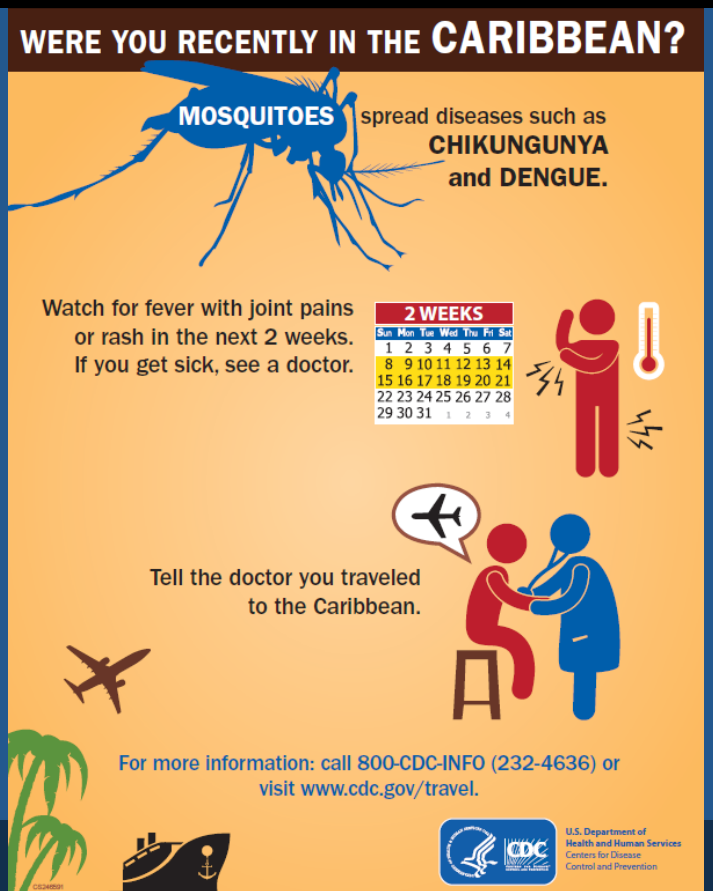
Today about 2.5 billion people, or 40% of the world's population, live in areas where there is a risk of Dengue Transmission. WHO estimates that 50-100 MM infections occur yearly.

Increasing Concern About Dengue and Chikungunya in the United States

Chikungunya was introduced into the Caribbean in late 2013. Through September 5, 2014, more than 650,000 clinical cases of chikungunya have been reported throughout the Caribbean and Americas. This includes more than 750 travel-associated cases of individuals who were infected while abroad and became ill after returning to the United States. Importation of chikungunya has led to at least eight locally acquired chikungunya cases in Florida. Up-to-date information on the number of chikungunya cases in the Americasand in the United States are available.

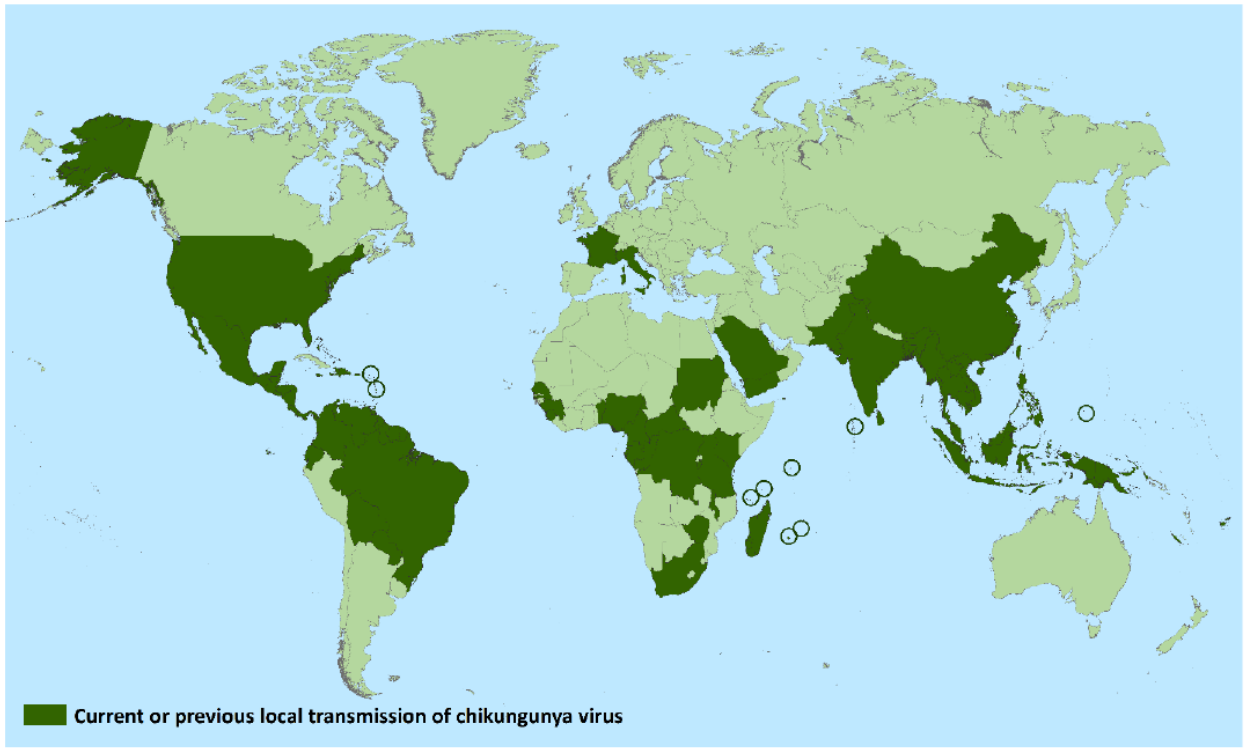
Because dengue is endemic in all areas of the Caribbean and Americas that have ongoing chikungunya outbreaks, both dengue and chikungunya should be included on the differential diagnosis of patients returning from these areas with acute febrile illness.





Preparedness and Response for
Chikungunya Virus
Introduction in the Americas

http://www.cdc.gov/chikungunya/



http://www.medscape.com/view
article/831523

Co-operation with CDC for field studies in May 2015

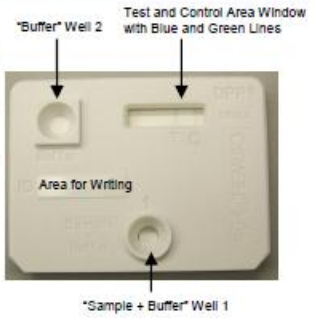
CHEMBIO DIAGNOSTIC SYSTEMS, INC.

Quick Reference Instructions

DPP® Ebola Antigen Assay: Fingerstick Whole Blood Test Procedure

- Gather the material you will need
- Cover your work space with a clean, disposable absorbent workplace cover
- Put on your disposable gloves
- **Let the test reach room temperature** (between 18-30°C or 64-86°F) before opening the pouch

Step 1. Remove the DPP® Ebola Antigen test device from its pouch.



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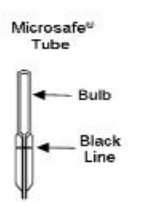
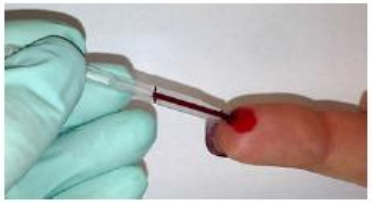
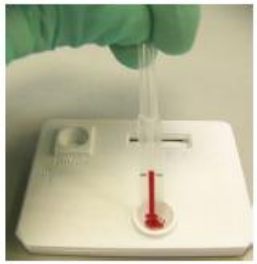




Step 2. Obtain a fingertip blood sample according to normal laboratory practices. After pricking the finger, wipe away the first drop and sample from the second drop. Without squeezing the bulb, hold the Microsafe® Tube in a horizontal position and touch the tip of the tube to the blood sample. Capillary action will draw the sample to the black fill line. Be sure the tube is completely filled to the black line and there are no air bubbles.

2

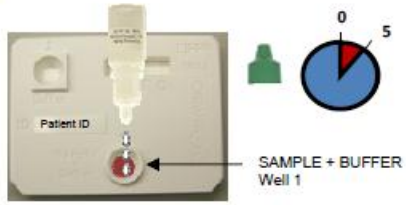


Step 3. Holding the Microsafe Tube vertically over the Sample + Buffer Well 1, squeeze the bulb to release the sample into the well. Immediately continue to **Step 4.**

IN THE EVENT THAT THE SAMPLE DOES NOT COME OUT OF THE TUBE, hold the tube vertically and slide a finger over the vent hole near the black mark. Then line up the Microsafe Tube tip with Well 1 and squeeze the bulb.

3

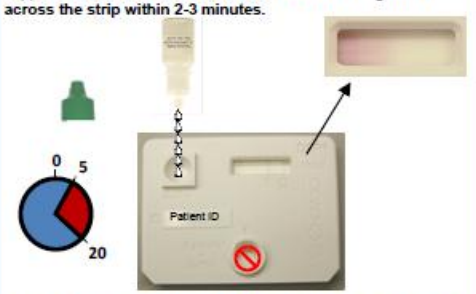
Step 4. Remove (unscrew) the green cap on the DPP Ebola Buffer EB5 Bottle. Invert the bottle and hold it vertically (not at an angle) over the SAMPLE + BUFFER Well 1. Slowly add 3 drops (55 µL) into the SAMPLE + BUFFER Well 1. Start the timer.



Wait 5 minutes. The blue and green colored lines should have disappeared from the rectangular TEST and CONTROL window. If not, discard the test device and repeat the procedure with a new DPP test device.

4

Step 5. Add 6 drops (150µL) of DPP Ebola Buffer EB5 (green cap) to BUFFER Well 2. **A reddish color should begin to flow across the strip within 2-3 minutes.**



Read the test result 10 to 15 minutes after the addition of the DPP Ebola Buffer to BUFFER Well 2. DO NOT read result after 20 minutes from the start of test (Start of test = addition of sample with buffer to well #1).

Refer to the INTERPRETATION OF RESULTS section to determine the test results

5

For Research Use Only.
May 2015

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DPP® Febrile Illness Test: Quick Reference Instructions for Point-Of-Care Testing

Antigen detection (Parasite, Virus and Bacteria) funded by US. Agency

1) ADD SAMPLE BUFFER TO VIAL

Using the supplied DPP® Febrile Illness Sample Dilution Buffer (red cap), deliver 2 drops of solution into the supplied sample vial.

2) COLLECT BLOOD SAMPLE

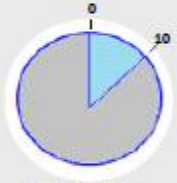
Prick finger and wipe away the first drop. Hold the Microsafe® Tube in a horizontal position and touch the tip of the tube to the blood sample. Capillary action will draw the sample to the black fill line.

3) ADD SAMPLE TO SAMPLE VIAL

Squeeze the bulb of the Microsafe® tube to deliver the sample into the sample vial containing the sample diluent. Close the sample vial and mix contents by lightly tapping the outer walls of the vial in a constant motion for 15 seconds.

4) DELIVER SAMPLE MIXTURE TO SAMPLE + BUFFER WELL

Remove the DPP® Febrile Illness Test from its pouch. Ensure a desiccant is present. Examine device for defects (line breaks or scratches). If free from defects, label assay with patient information.



Wait 10 minutes.

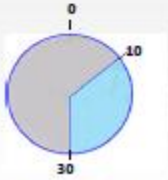
Squeeze the upper bulb of the transfer pipet and insert it into the sample vial containing the diluted sample mixture. Depress bulb to allow the sample to fill the pipet. Deliver the sample mixture into the Sample + Buffer well (Well #1) by squeezing the upper bulb. Incubate for 10 minutes at room temperature.

5) ADD RUNNING BUFFER TO BUFFER WELL

At 10 minutes, ensure the printed lines in the test area window are no longer visible, then add 4 drops of DPP® Running Buffer to the Buffer well (Well #2).

6) READ ASSAY RESULTS

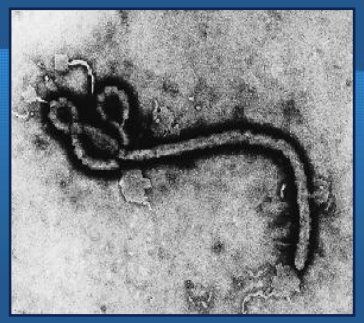
At 20 minutes from the addition of Running Buffer to the Buffer well (Well #2), insert the DPP® Febrile Illness Assay into the supplied Deki™ Reader device. Read device according to the Deki™ Reader instruction manual.

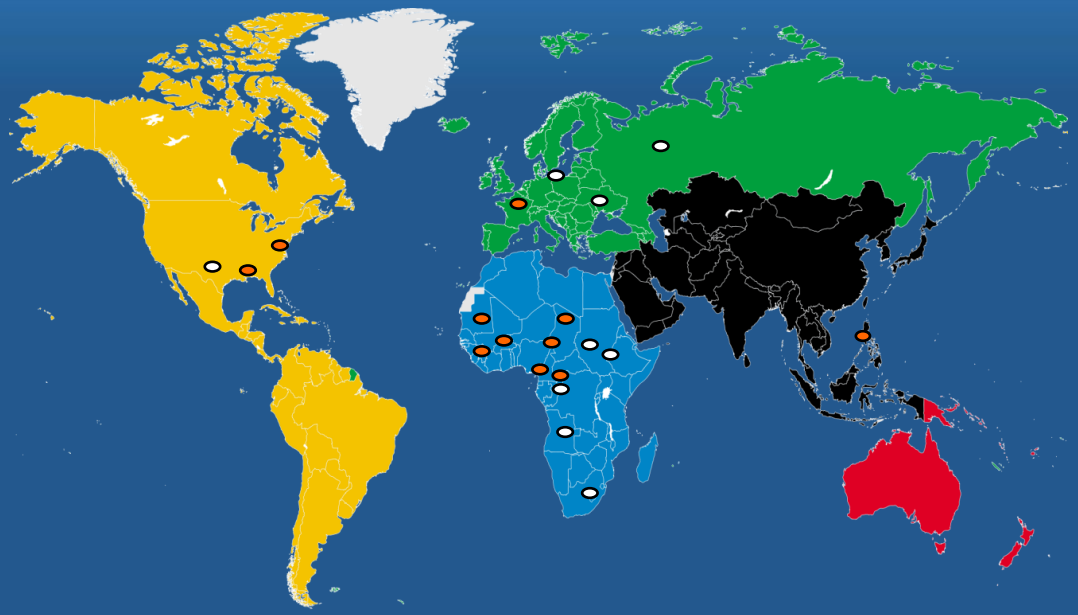


Wait 20 minutes.

Results displayed on reader & stored in a secure cloud database

Filoviridae





Marburg virus
Ebola virus

Reservoir (Fruit bats?)

Apes, Monkeys, Swine

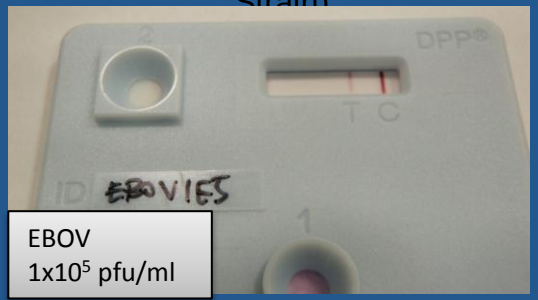
Human

Fever, Malaise, Diarrhea, Hemorrha

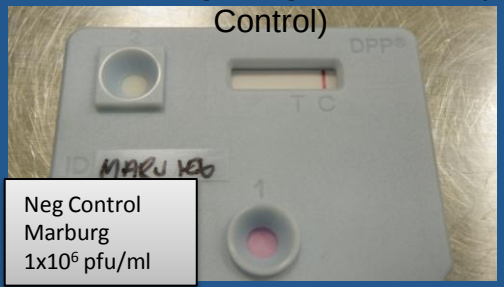
Ebola DPP® Detection: Ebola Virus

Performance site: BSL4 lab PHA Health Canada (Dr. Gary Kobinger)

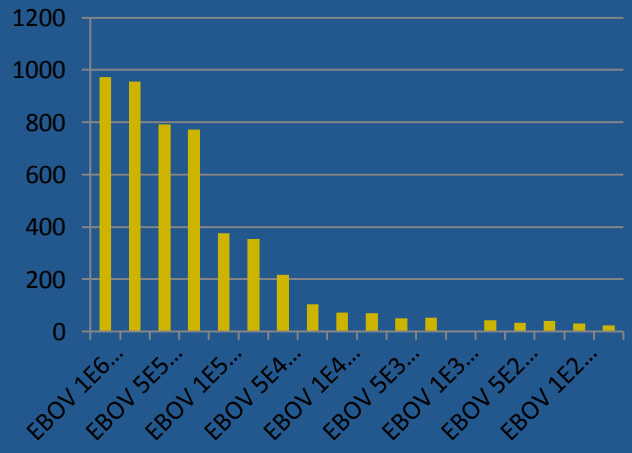
Ebola DPP® Testing using Live EBOV (Guinea Strain)



Ebola DPP® Testing using Live MARV (Negative Control)



DPP® Test quantitated using DPP® rea



EBOLA DPP® is specific for EBOV and detects down to 5000 pfu/ml of Ebola virus Guinea Strain. This corresponds to 500 pfu per test

integrated therapeutics

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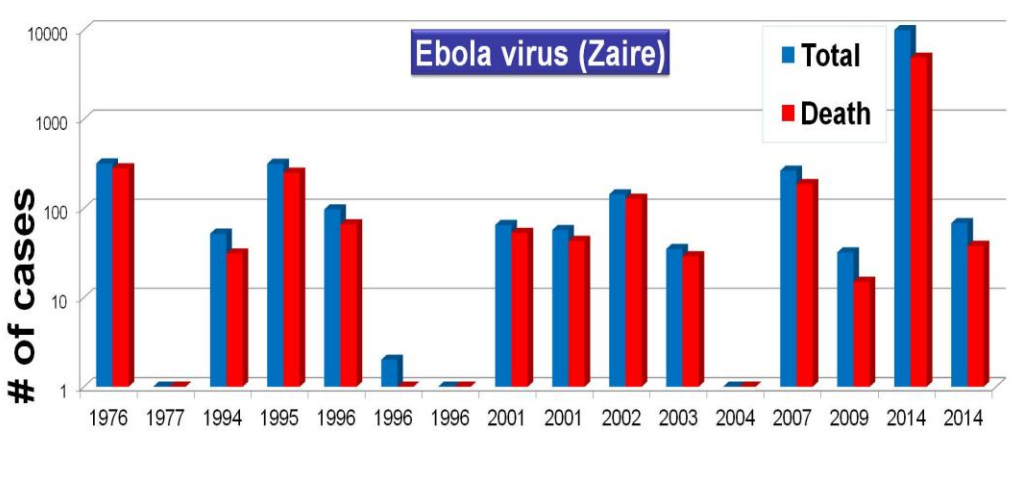
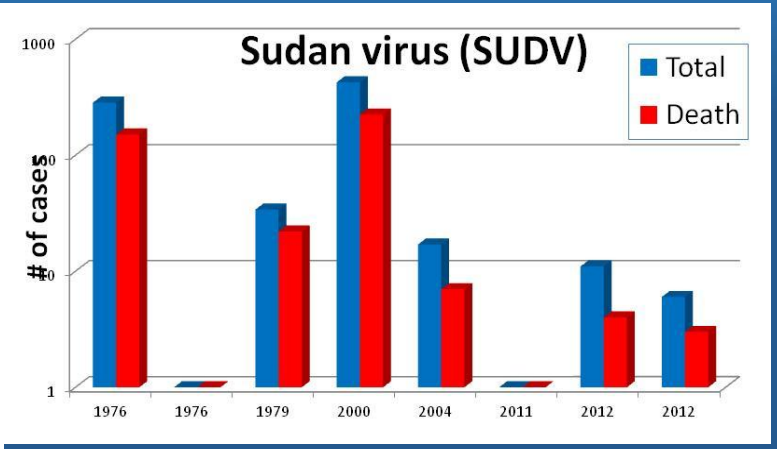
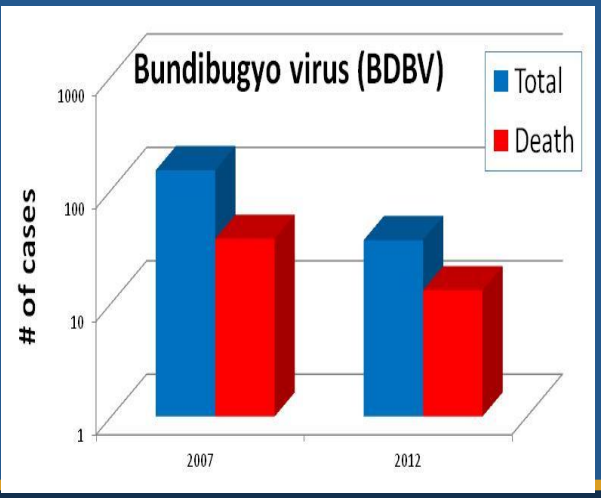
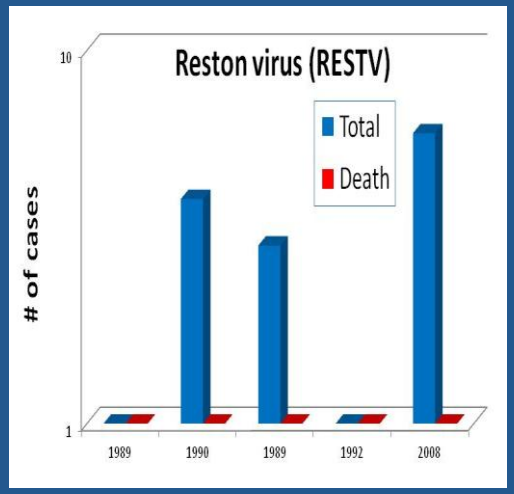
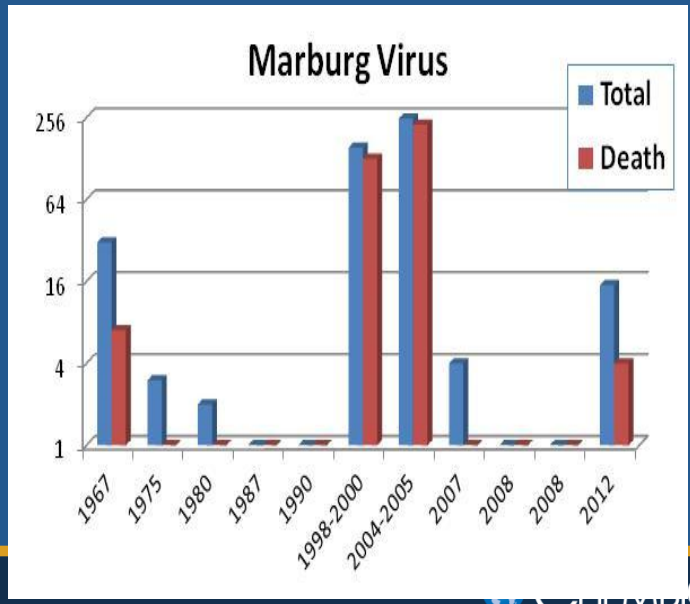
It is not only Ebola Virus





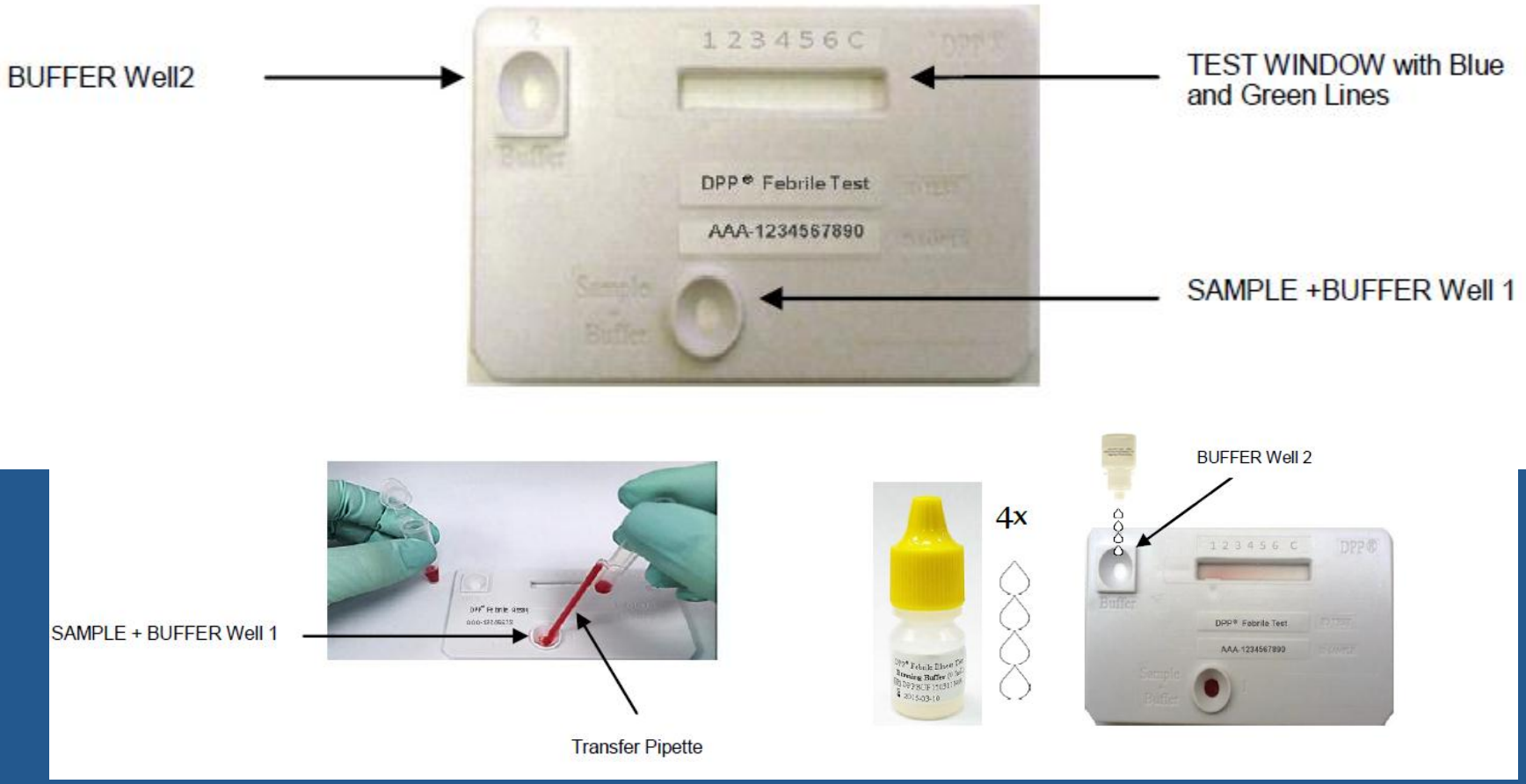






A Semi-Quantitative Test Kit for the Detection of Ebola Glycoprotein specific to Ebola virus (EBOV), HRP-II specific to *P. falciparum* and pLDH Pan specific to *P.* species, NS1 specific to Dengue, CPS specific to *Burkholderia pseudomallei* , and F1 specific to *Yersinia pestis* antigens in Fingerstick Whole Blood

Figure 6



WHO Panel Dilution Series

WHO Panel Group	Parasites	SD Malaria Ag P.f/P.v Test	Chembio Malaria Pf/Pan Test	
			Visual Result	Reader Result
FC27/A3	400	3	3	617
	200	2	3	413
	100	2	2	327
	50	1	2	186
	25	1	1	109
	12.5	1	1	66
	6.25	N2	1	61
	3.125	N1	1	58
	1.6	N1	N2	25
PH1	400	2	1	128
	200	1	1	104
	100	N1	1	65
	50	N1	1	45
	25	N1	1	43
	12.5	N1	N2	34
Benin I	400	3	3	675
	200	3	3	553
	100	3	3	394
	50	2	2	229
	25	1	2	161
	12.5	1	1	102
	6.25	1	1	58
	3.125	N2	1	44
	1.6		1	49
	0.8	NA	N2	21
Santa Lucia	400	2	2	219
	200	1	1	132
	100	1	1	78
	50	N2	1	54
	25	N1	N1	0
	12.5	N1	N1	0
	6.25	N1	N1	16
Nigeria XII	400	3	3	448
	200	3	3	352
	100	2	2	257
	50	2	1	134
	25	N2	1	90
	12.5	N2	N2	35
	6.25	N1	1	50
	3.125	N1	1	51
	1.6	N1	1	43
	0.8	NA	N2	19

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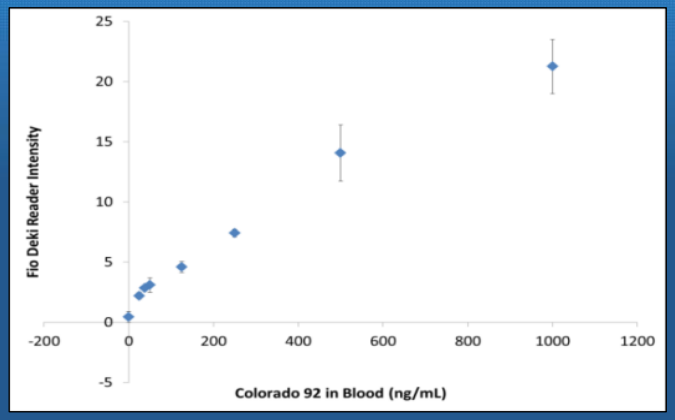
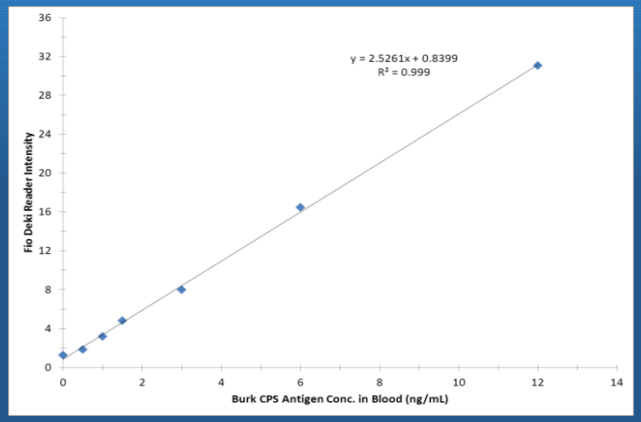
DPP® Febrile Illness Assay – Limit of Detection



Dose Response Profile of *Yersinia pestis* Assay in Blood LOD ~ 25ng/mL in Blood

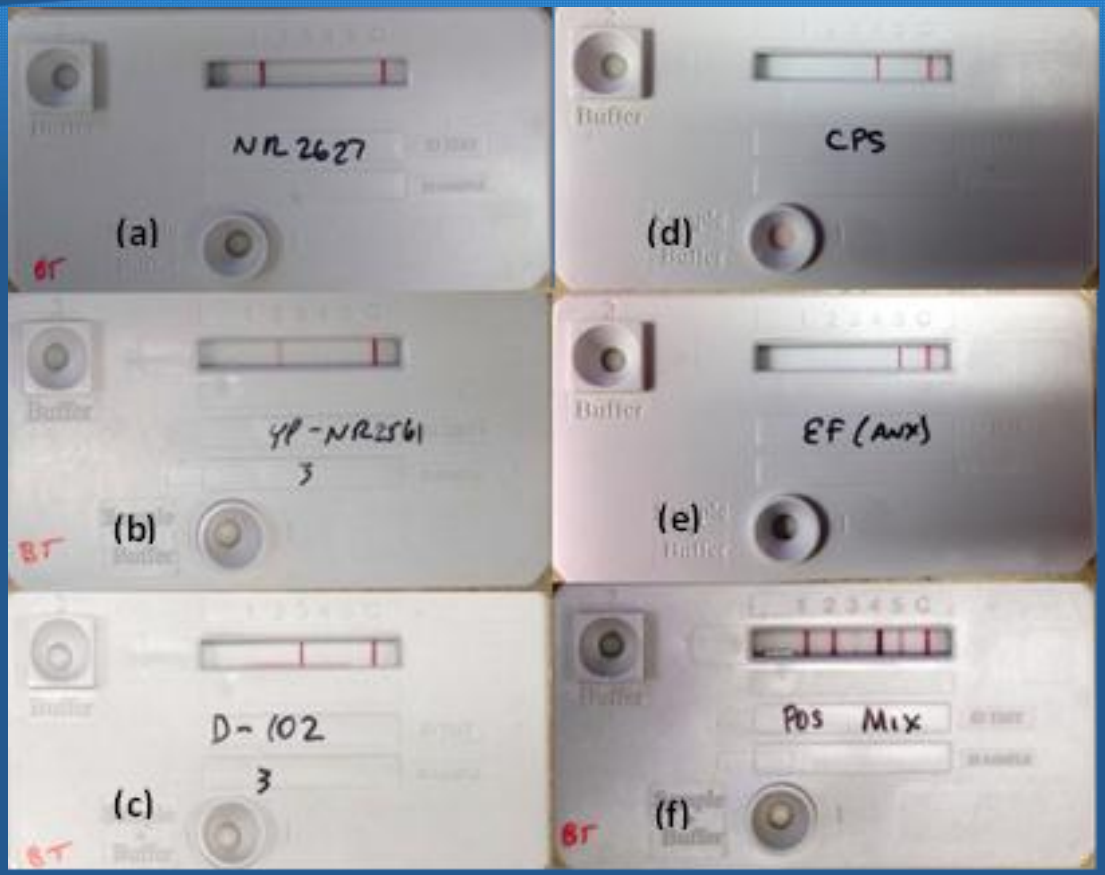


Performance of *B. pseudomallei* Assayd ~ 05-12ng/mL in Blood

Multiplexed DTRA Marker	Antigen		Limit of Detection (LOD)	
			Biosafety II (NRL)	Biosafety III
Dengue	Strain 1		30 ng/mL	
	Strain 2		15 ng/mL	
	Strain 3		70 ng/mL	
	Strain 4		70 ng/mL	
Burkholderia pseudomallei	CPS antigen		500 pg/mL	3.8×10^4 cfu/ml**
Yersinia pestis	F1 antigen	Colarado-92 strain	1×10^5 cfu/ml**	5×10^5 cfu/ml**

LOD studies for Multiplex DPP® Febrile Illness Test. Exclusivity panel of 10 agents evidenced no reactivity for test (no false-positive). *Tests carried out in U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), **exclusivity panel of six agents at 200x of the LOD showed no response during tests carried out in Naval Medical Research Center (NMRC0.

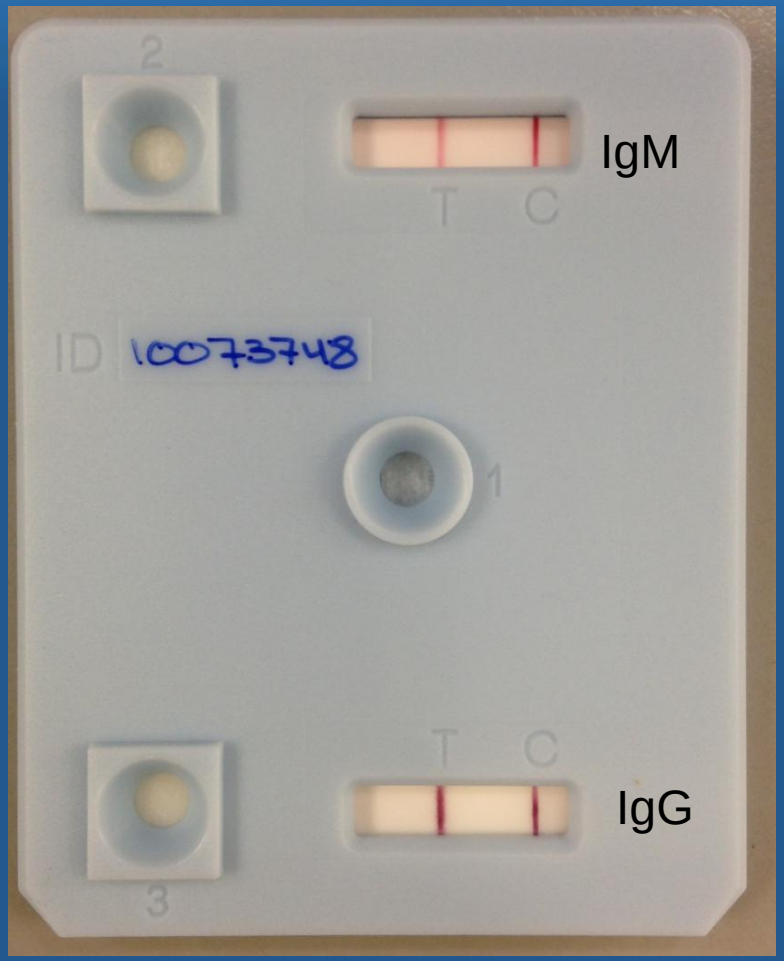
Prototype DPP® Biothreat Assay



Prototype DPP multiplex Biothreat device shows successful detection among all test lines. Test line combination is: 1) *F. tularensis* (LPS) 2) *Y. pestis* (F1) 3) Dengue fever (NS1) 4) *B. pseudomallei* 5) *B. anthracis* (EF). All test lines were assayed individually with their respective antigens (a, b, c, d, & e for Tularensis, plague, Dengue, Melioidosis and Anthrax respectively) as well as with a mixture of all antigens (e). When assayed individually the marker in question was easily identifiable as positive while the other test lines showed no intensity. We do not see any cross reactivity issues with the biological test prototype. The positive mix sample shows that the prototype is capable of detection along all markers simultaneously.

DPP® Chikungunya IgM / IgG Assay

Testing with **Chikungunya Positive Sample**;
Product Code DS-903; Donor ID # **BD217710**



Batch # 10073748					
DDPP IgM			**DDPP IgG**		
Visual		**Reader**	**Visual**		**Reader**
Test	Control	**Test**	**Test**	Control	**Test**
3	3	**6950**	**3**	3	**10931**

Sera Care Data- Reference lab; Quest Diagnostics

Markers tested	Inspection Method	Interpretation	Dilution
CHIKUNG	IFA	POS	1280
CHIKUNM	IFA	POS	160

DPP Leptospira IgG/IgM

Accuracy of a Dual Path Platform (DPP) Assay for the Rapid Point-of-Care Diagnosis of Human Leptospirosis

Scott A. Nabity[1,2], Guilherme S. Ribeiro[2,3]*, Carolina Lessa Aquino[4], Daniele Takahashi[2], Alcinéia Oliveira Damião[2], André H. O. Gonçalves[2], Demócrito B. Miranda-Filho[5], Rena Greenwald[6], Javan Esfandiari[6], Konstantin P. Lyashchenko[6], Mitermayer G. Reis[2], Marco A. Medeiros[4], Albert I. Ko[2,7]

1 Duke University School of Medicine, Durham, North Carolina, United States of America, **2** Centro de Pesquisa de Gonçalo Moniz, Fundação Oswaldo Cruz, Salvador, Brazil, **3** Instituto de Saúde Coletiva, Universidade Federal da Bahia, Salvador, Brazil, **4** Bio-Manguinhos, Fundação Oswaldo Cruz, Rio de Janeiro, Brazil, **5** Departamento de Medicina Clínica, Universidade de Pernambuco, Recife, Brazil, **6** Chembio Diagnostic Systems, Medford, New York, United States of America, **7** Yale University Schools of Public Health and Medicine, New Haven, Connecticut, United States of America

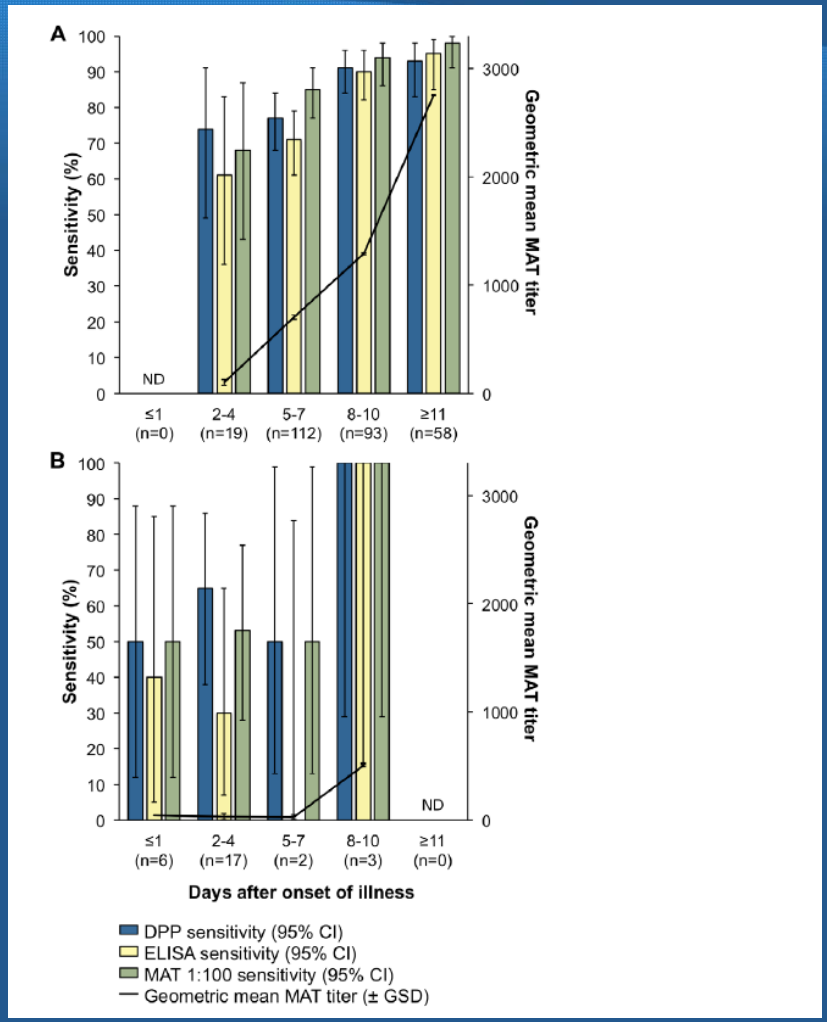
Abstract

Background: Diagnosis of leptospirosis by the gold standard serologic assay, the microscopic agglutination test (MAT), requires paired sera and is not widely available. We developed a rapid assay using immunodominant *Leptospira* immunoglobulin-like (Lig) proteins in a Dual Path Platform (DPP). This study aimed to evaluate the assay's diagnostic performance in the setting of urban transmission.

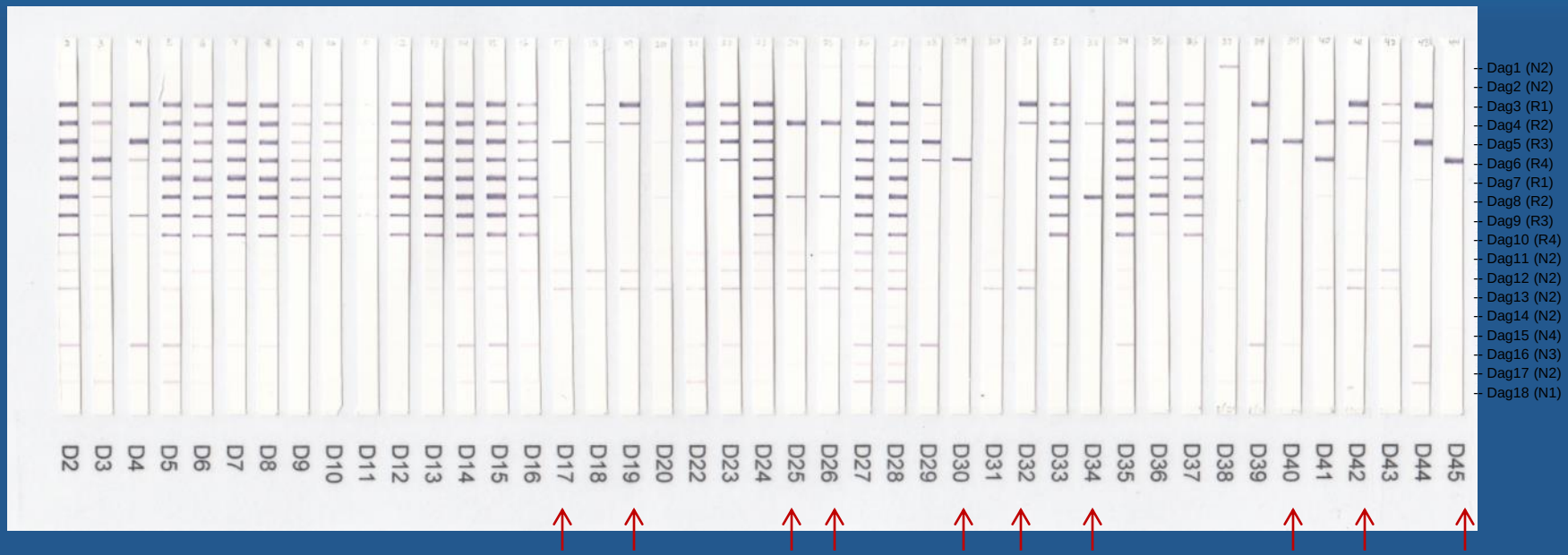
Methodology: We determined test sensitivity using 446 acute and convalescent sera from MAT-confirmed case-patients with severe or mild leptospirosis in Brazil. We assessed test specificity using 677 sera from the following groups: healthy residents of a Brazilian slum with endemic transmission, febrile outpatients from the same slum, healthy blood donors, and patients with dengue, hepatitis A, and syphilis. Three operators independently interpreted visual results without knowing specimen status.

Results: The overall sensitivity for paired sera was 100% and 73% for severe and mild disease, respectively. In the acute phase, the assay achieved a sensitivity of 85% and 64% for severe and mild leptospirosis, respectively. Within seven days of illness onset, the assay achieved a sensitivity of 77% for severe disease and 60% for mild leptospirosis. Sensitivity of the DPP assay was similar to that for IgM-ELISA and increased with both duration of symptoms (chi-square regression $P = 0.002$) and agglutinating titer (Spearman $\rho = 0.24$, $P < 0.001$). Specificity was ≥93% for dengue, hepatitis A, syphilis, febrile outpatients, and blood donors, while it was 86% for healthy slum residents. Inter-operator agreement ranged from very good to excellent (kappa: 0.82–0.94) and test-to-test reproducibility was also high (kappa: 0.89).

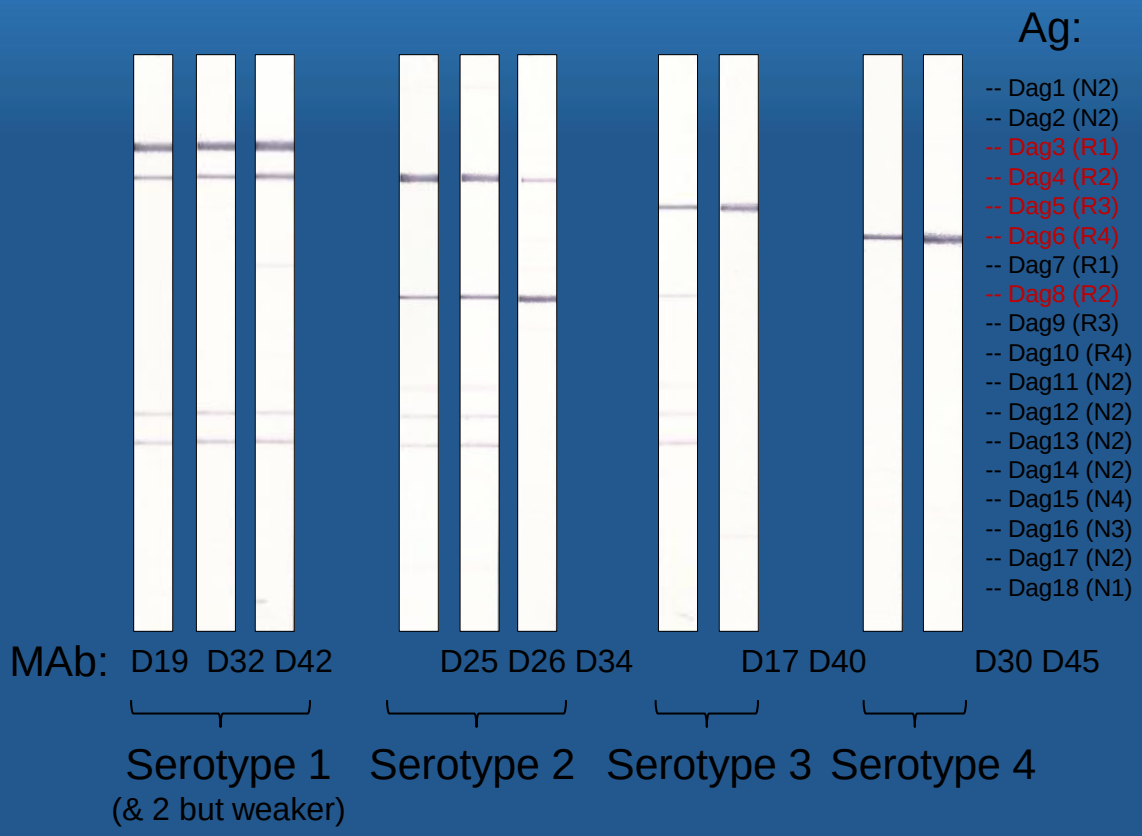
Conclusions: The DPP assay performed acceptably well for diagnosis of severe acute clinical leptospirosis and can be easily implemented in hospitals and health posts where leptospirosis is a major public health problem. However, test accuracy may need improvement for mild disease and early stage leptospirosis, particularly in regions with high transmission.



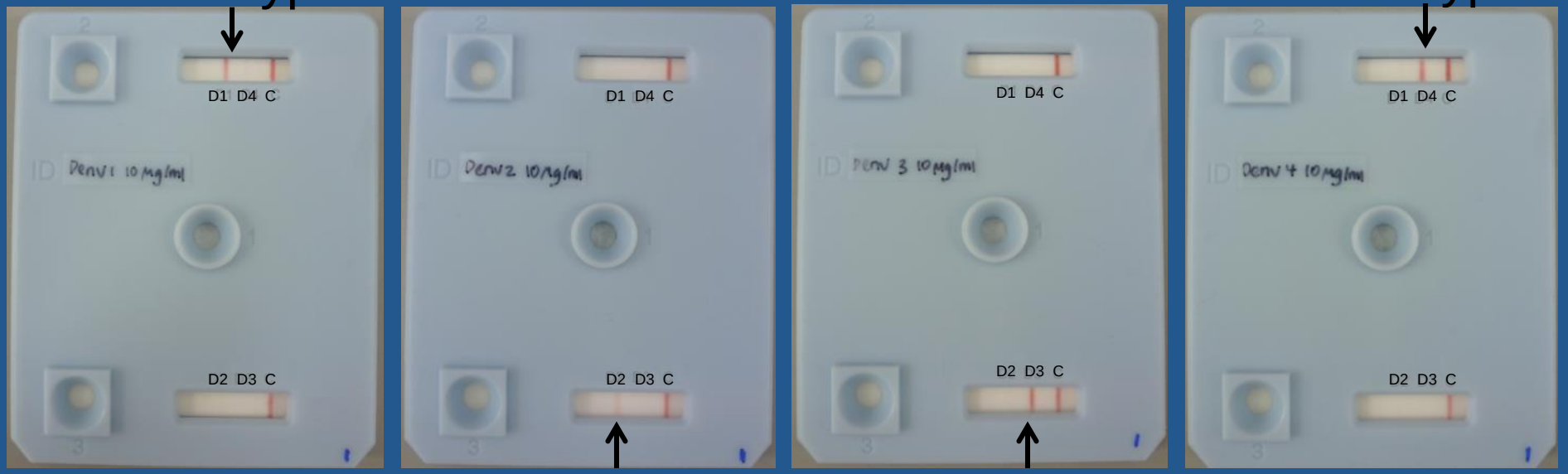
MAPIA for Dengue NS1 Antibody Seroselectivity Screening



Dengue Seroselectivity on MAPIA



DPP Dengue Serotyping Assay

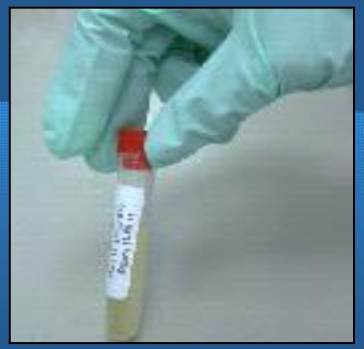


DDPP® Dengue Antibody Detection Assay: Quick Reference Instructions for Laboratory Settings Testing — For *IN VITRO* diagnostic use

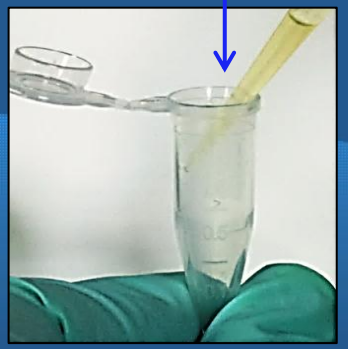
1) SPECIMEN COLLECTION : SERUM or PLASMA only

7 drops

250 µL Sample Buffer

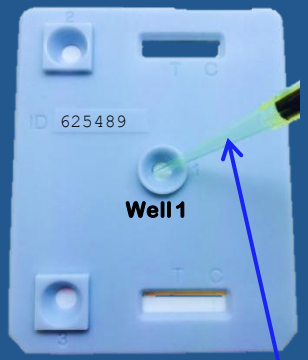


10 µL sample



Pipette up and down 3x to mix

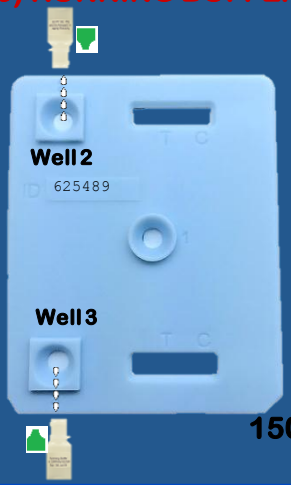
2) SAMPLE + BUFFER DELIVERY INTO WELL 1



175 µL sample

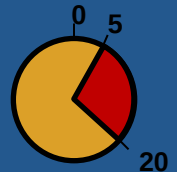
Wait 5 minutes

3) RUNNING BUFFER DELIVERY INTO WELL 2 AND 3



4 drops

150 µL Running Buffer

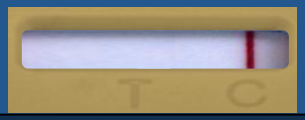


Read results

4) RESULT INTERPRETATION

ADEQUATE LIGHTING REQUIRED

NON-REACTIVE



REACTIVE

INVALID

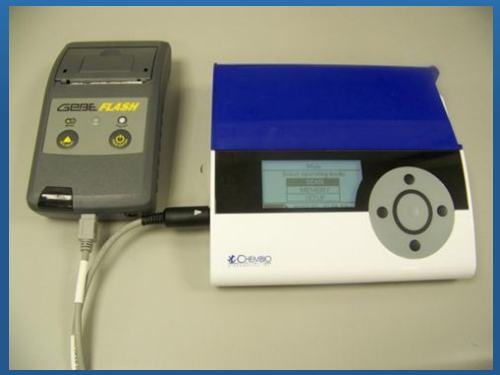
For problems or questions, please contact Chembio Diagnostic Systems Customer Services at 631-924-1135 x112

CHEMBIO

Update DPP reader

1. Micro reader+RFID

2. Desktop reader

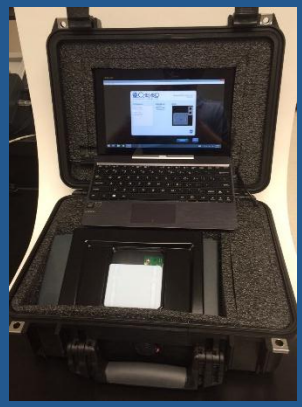


3. Phone/Cloud based reader

4. Desktop reader with printer

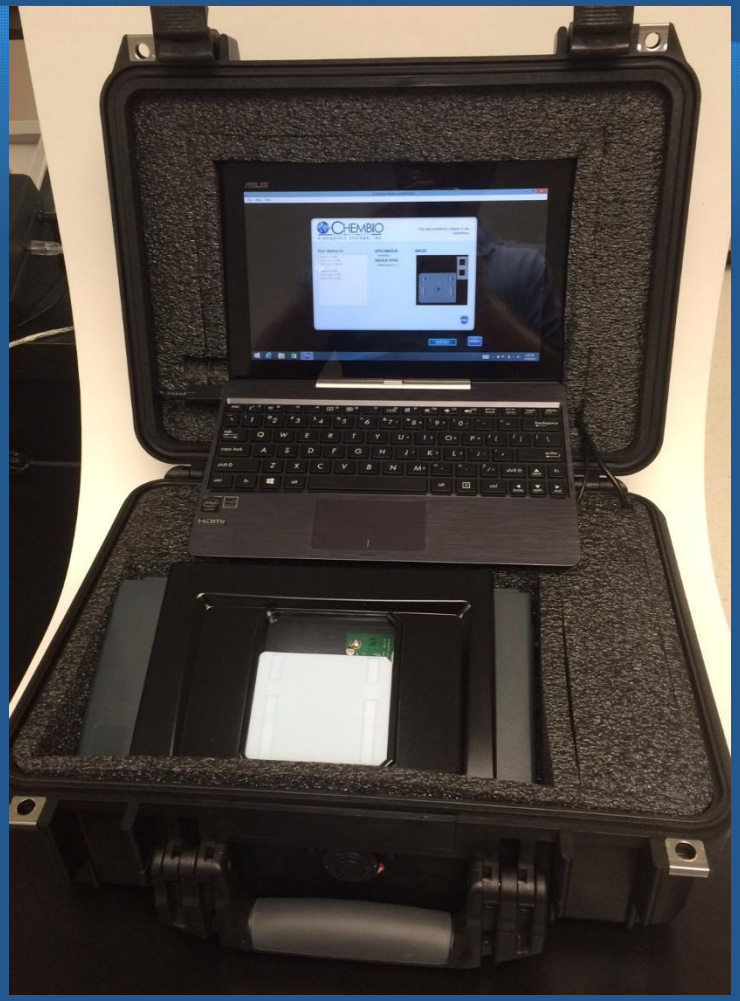
6. Cell phone reader

7. Scanner reader +laptop

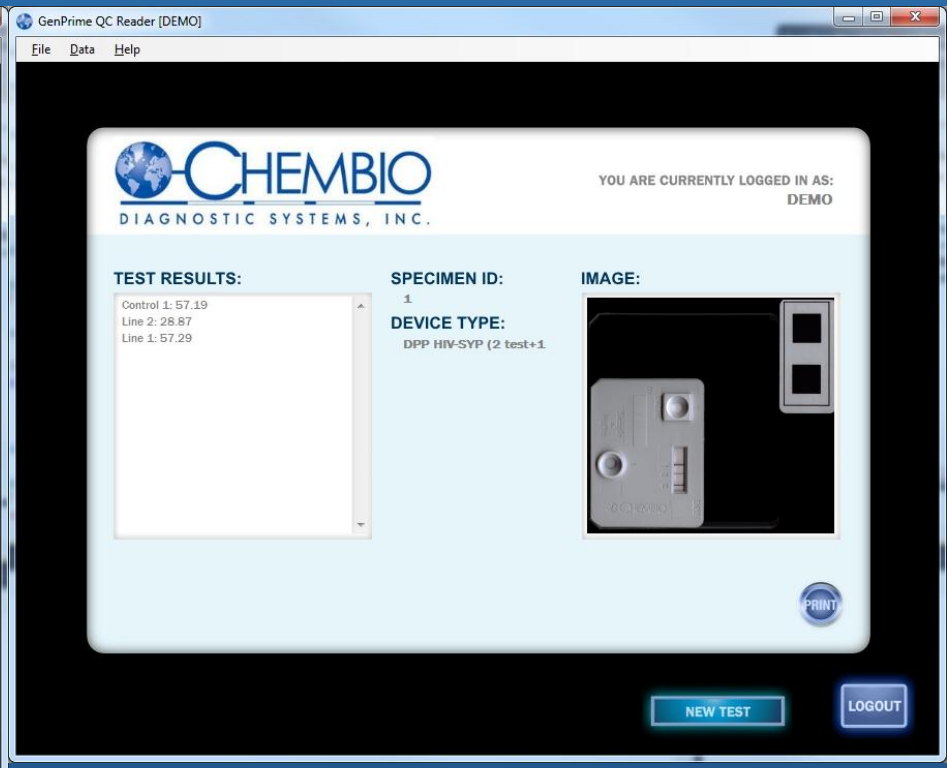


DPP Reader V4 mobile with Laptop

- Ruggedized
- Portable
- Drop resistant
- Touch screen
- Removable keyboard

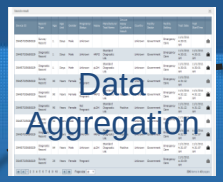



GenPrime QC Reader
File Data Help
CHEMBIO
DIAGNOSTIC SYSTEMS, INC.
USER ID: DEMO
FOR DEMONSTRATION PURPOSES ONLY
LOGIN


GenPrime QC Reader [DEMO]
File Data Help
CHEMBIO
DIAGNOSTIC SYSTEMS, INC.
YOU ARE CURRENTLY LOGGED IN AS:
DEMO
TEST RESULTS:
Control 1: 57.19
Line 2: 28.87
Line 1: 57.29
SPECIMEN ID:
1
DEVICE TYPE:
DPP HIV-SYP (2 test+1
IMAGE:
PRINT
NEW TEST
LOGOUT

Global Public Health: Two Big Problems

Clinical Workflow



Data Aggregation

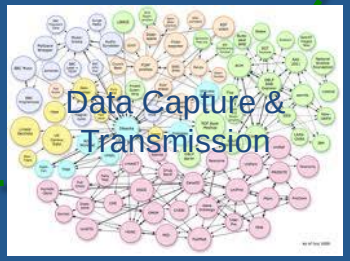
Health Workers

Health Program Managers

Diagnostic Testing

One Unified Solution

Monitoring, Evaluation, & Reporting



Health Worker Guidance

Care Delivery

- Inadequate diagnostic accuracy
- Inadequate clinical work-up & therapy
- Inadequate data capture & data flow

Care Management

- $100BNs in spending not evidence-based
- Costly, low-reliability data collection
- Poor health worker monitoring & direction

CHEMBIO

THANK YOU!

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PLoS NEGLECTED TROPICAL DISEASES

Design, Development and Evaluation of rK28-Based Point-of-Care Tests for Improving Rapid Diagnosis of Visceral Leishmaniasis

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Abstract

Background: Visceral leishmaniasis (VL) is diagnosed by microscopic confirmation of the parasite in bone marrow, spleen or lymph node aspirates. These procedures are unsuitable for rapid diagnosis of VL in field settings. The development of rK39-based rapid diagnostic tests (RDT) revolutionized diagnosis of VL by offering high sensitivity and specificity in detecting disease in the Indian subcontinent; however, these tests have been less reliable in the African subcontinent (sensitivity range of 75–85%, specificity of 70–92%). We have addressed limitations of the rK39 with a new synthetic polyprotein, rK28, followed by development and evaluation of two new rK28-based RDT prototype platforms.

Methodology/Principal Findings: Evaluation of 62 VL-confirmed sera from Sudan provided sensitivities of 96.8% and 93.6% (95% CI = K28: 88.83–99.61%; K39: 84.30–98.21%) and specificities of 96.2% and 92.4% (95% CI = K28: 90.53–98.95%; K39: 85.54–96.65%) for rK28 and rK39, respectively. Of greater interest was the observation that individual VL sera with low rK39 reactivity often had much higher rK28 reactivity. This characteristic of the fusion protein was exploited in the development of rK28 rapid tests, which may prove to be crucial in detecting VL among patients with low rK39 antibody levels. Evaluation of two prototype lateral flow-based rK28 rapid tests on 53 VL patients in Sudan and 73 VL patients in Bangladesh provided promisingly high sensitivities (95.9% [95% CI = 88.46–99.1 in Sudan and 98.1% [95% CI = 89.93–99.95%] in Bangladesh) compared to the rK39 RDT (sensitivities of 86.3% [95% CI = 76.25–93.23%] in Sudan and 88.7% [95% CI = 76.97–95.73%] in Bangladesh).

Conclusions/Significance: Our study compares the diagnostic accuracy of rK39 and rK28 in detecting active VL cases and our findings indicate that rK28 polyprotein has great potential as a serodiagnostic tool. A new rK28-based RDT will prove to be a valuable asset in simplifying VL disease confirmation at the point-of-care.

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Comparison of two immunochromatographic assays and the indirect immunofluorscence antibody test for diagnosis of *Trypanosoma cruzi* infection in dogs in south central Louisiana

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ABSTRACT

Two rapid tests evaluated in dogs considered to be of high risk of infection with the Chagas parasite *Trypanosoma cruzi* using two immunochromatographic assays: Trypanosoma Detect™ for canine, InBios, Seattle, WA and CHAGAS STAT-PAK™ assay, Chembio Diagnostic Systems, Medford, NY, in south central Louisiana. For this purpose a serological survey was carried out in a total of 122 dogs and a serum bank was created. These 122 animals were first tested by IFAT that was used as the standard test. From the serum bank 50 samples were tested using the two rapid Chagas assays and results compared to the standard test IFAT. The serological survey using IFAT showed a prevalence of *T. cruzi* infection in 22.1% of the tested dogs. In the immunochromatographic assays, 13 and 11 animals were positive on rapid assay: Trypanosoma Detect™ for canine, InBios and CHAGAS STAT-PAK™, Chembio Diagnostic Systems, respectively compared to 11 positive by IFAT. These two immunochromatographic tests have shown high susceptibility and specificity compared to our standard method IFAT. The rapid, easy and accurate screening assays used in conjunction with confirmatory tests, would be an excellent tool for veterinarians to diagnose *T. cruzi* infection. Early detection of *T. cruzi* infection may prevent complications through an effective treatment. Greater awareness by veterinarians of the risk, clinical findings, history along with diagnostic methods will contribute greatly to an understanding of the true prevalence of Chagas disease in dogs in Louisiana.

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Chagas' disease diagnosis: a multicentric evaluation of Chagas Stat-Pak, a rapid immunochromatographic assay with recombinant proteins of *Trypanosoma cruzi*

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Abstract

A rapid serologic test for diagnosis of *T. cruzi* infection (Chagas Stat Pak) was developed using recombinant proteins in an immunochromatographic assay. This cassette format test was evaluated first in blind with a panel of 393 coded serum samples. The Chagas Stat-Pak identified 197 infected (98.5% sensitivity) and 183 non-infected individuals (94.8% specificity). A second evaluation was performed with 352 sera from four Latin America countries tested independently in each country, showing a sensitivity of 100% and specificity of 98.6%. A third set of tests comparing sera with plasma and eluates from filter paper as well as serum preserved in 50% glycerol did show identical results as those obtained with serum. This rapid test (15 min) uses one device per sample, does not require refrigeration nor a laboratory structure or specialized skills to be performed, accepts different types of samples and may be stored for long periods of time for result checking and documentation. These attributes together with the high sensitivity and specificity demonstrated herein, make this test a suitable tool for field studies, small laboratories and emergencies at blood banks in the countryside of endemic areas.

DPP Leprosy

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Selection of Antigens and Development of Prototype Tests for Point-of-Care Leprosy Diagnosis▽†

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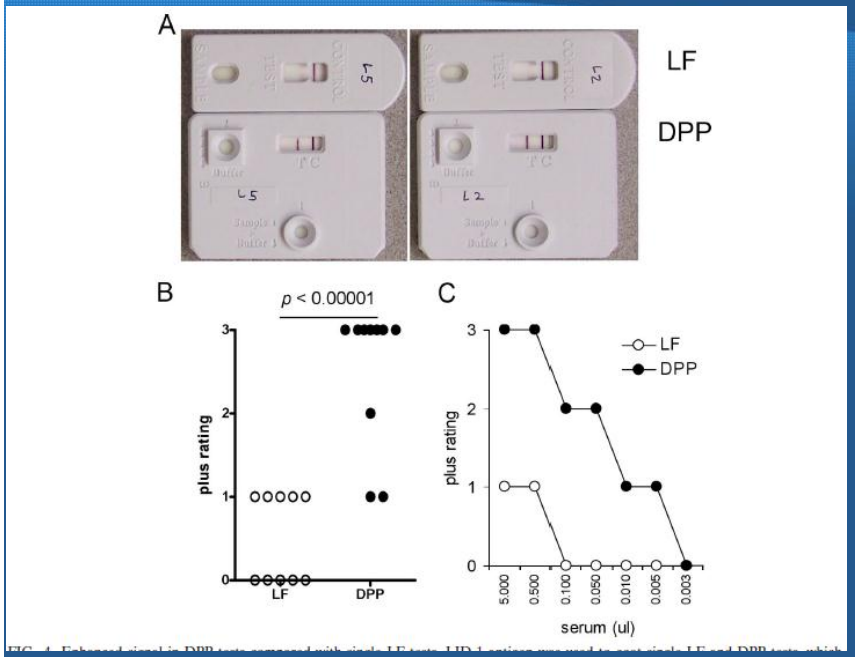
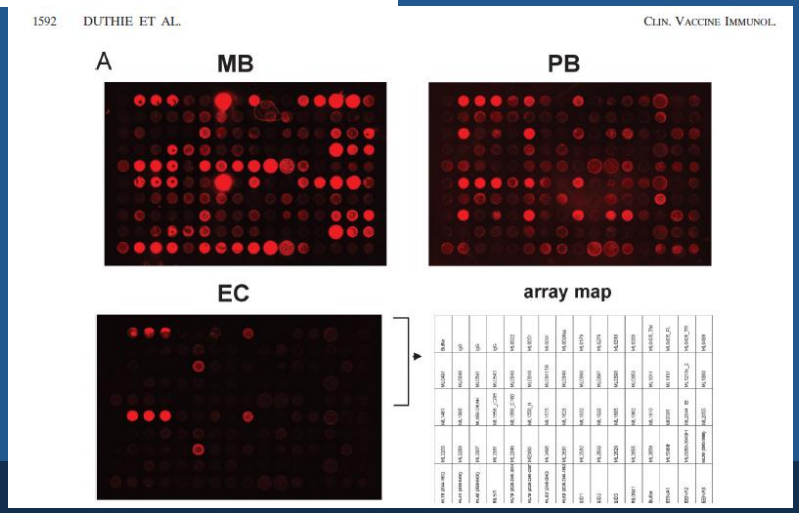
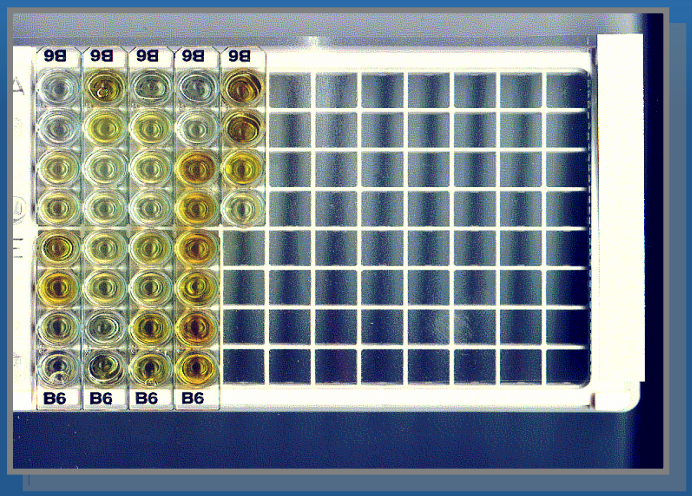
Leprosy can be a devastating chronic infection that causes nerve function impairment and associated disfigurement. Despite the recent reduction in the number of registered worldwide leprosy cases as a result of the widespread use of multidrug therapy, the number of new cases detected each year remains relatively stable. The diagnosis of leprosy is currently based on the appearance of clinical signs and requires expert clinical, as well as labor-intensive and time-consuming laboratory or histological, evaluation. For the purpose of developing an effective, simple, rapid, and low-cost diagnostic alternative, we have analyzed the serologic antibody response to identify *Mycobacterium leprae* proteins that are recognized by leprosy patients. More than 100 recombinant antigens were analyzed in a protein array format to select those with discriminatory properties for leprosy diagnosis. As expected, multibacillary leprosy patients recognized more antigens with stronger antibody responses than paucibacillary leprosy patients. Our data indicate, however, that multibacillary patients can be distinguished from paucibacillary patients, and both of these groups can be segregated from endemic control groups. We went on to confirm the diagnostic properties of antigens ML0405 and ML2331 and the LID-1 fusion construct of these two proteins by enzyme-linked immunosorbent assay. We then demonstrated the performance of these antigens in rapid test formats with a goal of developing a point-of-care diagnostic test. A serological diagnostic test capable of identifying and allowing treatment of leprosy could reduce transmission, prevent functional disabilities and stigmatizing deformities, and facilitate leprosy eradication.





Diagnóstico para Leptospirose

ELISA

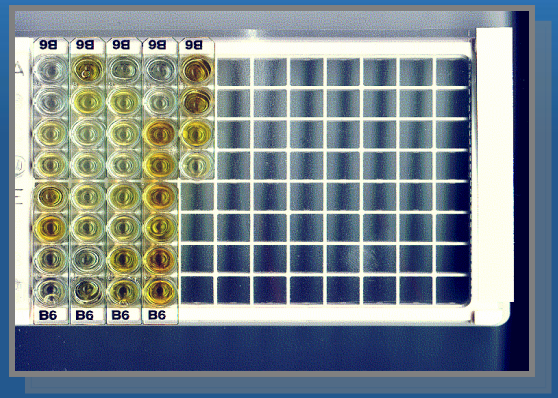


TR DPP® Leptospirose – Bio-Manguinhos (Aguardando registro)

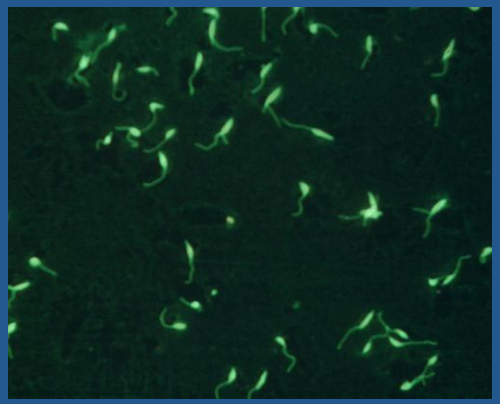
- ✓ Fácil manipulação;
- ✓ Resultado rápido;
- ✓ Confiável;
- ✓ Uso Ambulatorial, laboratorial e em campo;
- ✓ Diagnóstico rápido e precoce da leptospirose. Fundamental para o sucesso do tratamento.

Diagnóstico para Leishmaniose Visceral Canina

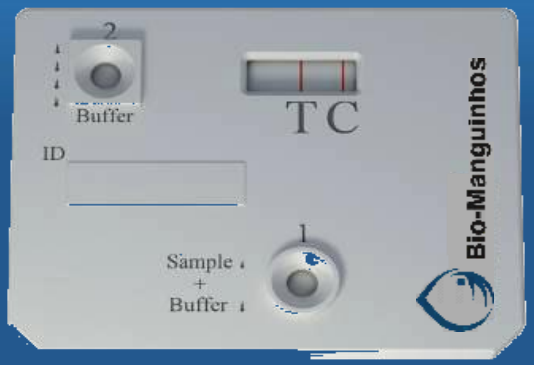
ELISA



IFI



TR DPP® LVC – Bio-Manguinhos
(Março de 2011)



✓ Fácil manipulação;

✓ Resultado rápido;

✓ Confiável;

✓ Uso Ambulatorial, laboratorial e em campo;

✓ Resultado imediato permitindo definir o destino do animal.