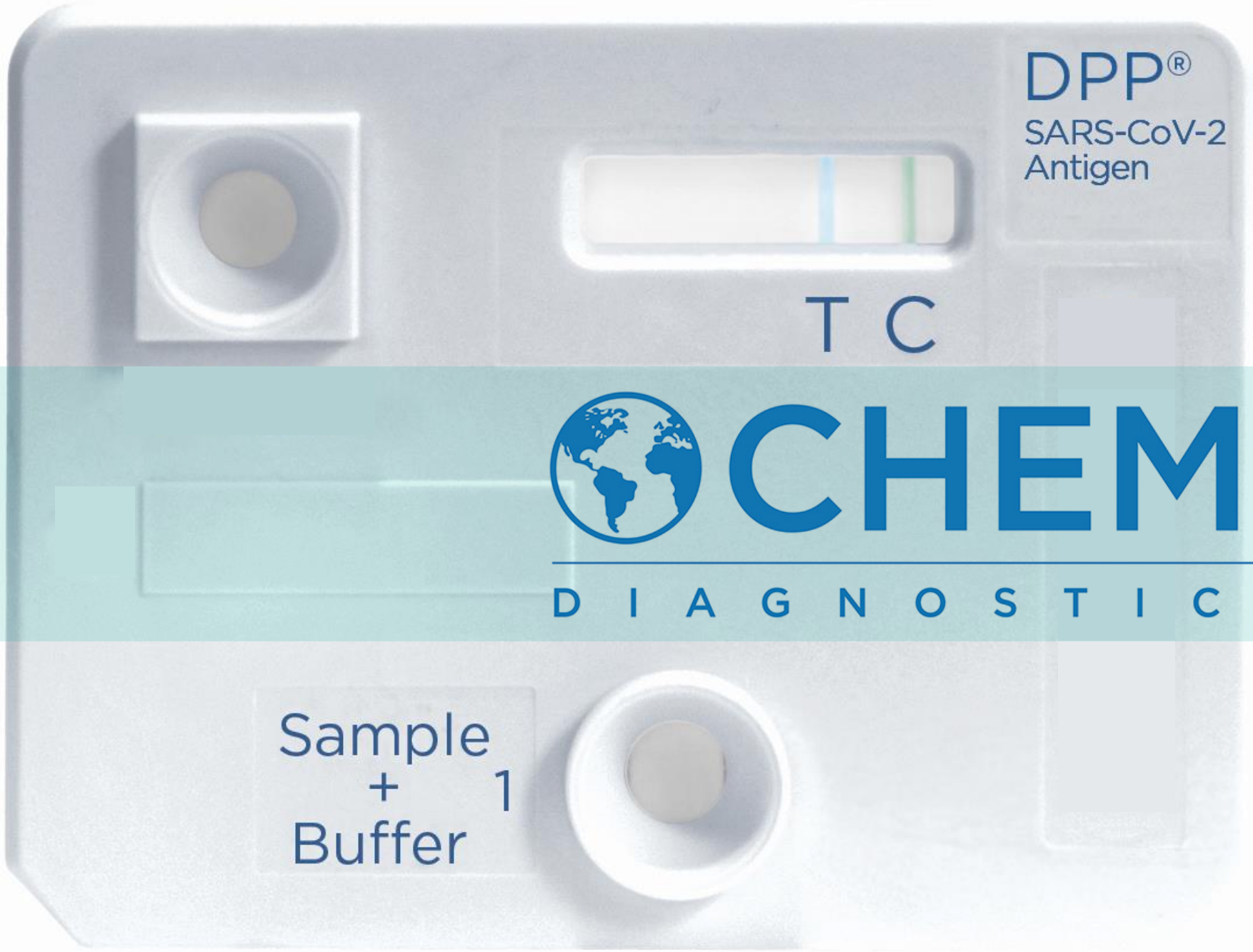



# CHEMBIO DIAGNOSTICS, INC.

(Nasdaq: CEMI)

May 2021

# Safe Harbor Statement

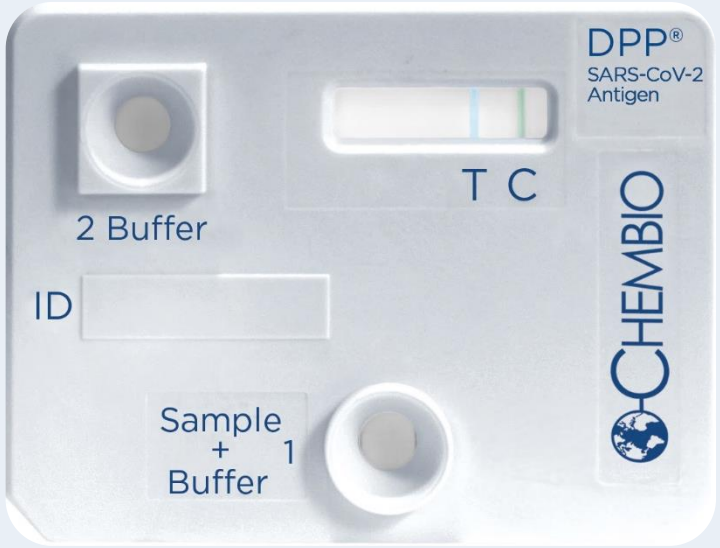
Statements contained in this presentation that are not historical facts may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations of Chembio and its management with respect to the further development of COVID-19 tests. Such statements, which are only expectations, 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 forward-looking statements due to a number of important factors, including, but not limited to the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States and globally: the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals, particularly for its proposed DPP COVID-19 diagnostic tests; Chembio's dependence upon, and limited experience with, COVID-19 diagnostic tests; the highly competitive and rapidly developing market for testing solutions for COVID-19, which includes a number of competing companies with strong relationships with current and potential customers, including governmental authorities, and with significantly greater financial and other resources that are available to Chembio; and the risks of doing business with foreign governmental entities, including geopolitical, international and other challenges as well as potential material adverse effects of tariffs and other changes in U.S. trade policy. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and its subsequent Quarterly Reports on Form 10-Q, particularly under the heading "Risk Factors".

*DPP, STAT-PAK and SURE CHECK are Chembio's registered trademarks. For convenience, these trademarks appear in this presentation without ® symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademarks.*



We deliver high-quality diagnostic tests that provide results in approximately 15 minutes using fingertip blood, nasal swabs and other sample types




# Investment Highlights

- Proprietary DPP technology platform with growing portfolio of broad diagnostic applications
- Scaled commercial team and sales channels to penetrate high growth markets
- Focused on high value testing application and markets to drive ASPs
- Operational initiatives underway to automate U.S. manufacturing and expand U.S. facilities to add capacity, reduce variable costs and drive margin expansion

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= Strong revenue growth with high gross margin potential in line with diagnostic industry

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# Point-of-Care Testing: an Expanding Solution for the Evolving Healthcare System

Delivers rapid results while patients are on site

Enables immediate triage and treatment decisions

Reduces costs and improves outcomes in the modern, decentralized healthcare system

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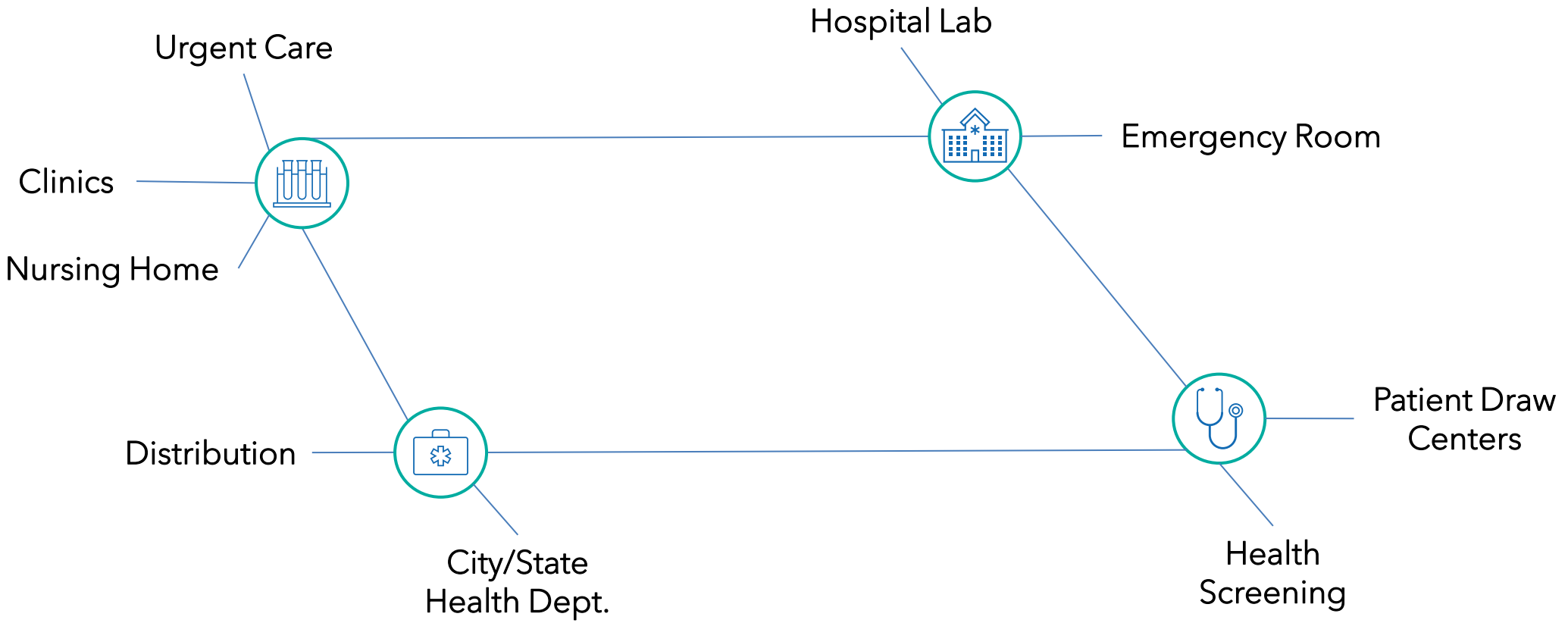
# Proliferation of Point-of-Care Diagnostics

## Expansive Decentralized Customer Opportunity – delivering tests to patients




Source: US Census Bureau.

# Point-of-Care Diagnostics Market

## Large and growing opportunity

>$10 Billion Annual Global Market

Respiratory

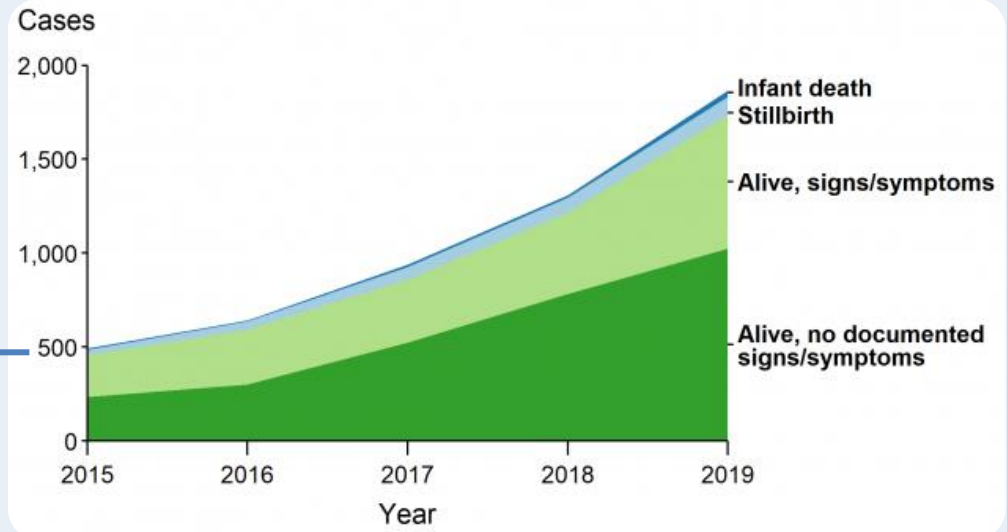
STI

Insect Vector

(Not to scale, relative sizing)

Well positioned across infectious disease

~40% of children born to women with untreated syphilis are stillborn or die as infants




U.S. Congenital Syphilis Reported Cases[1]

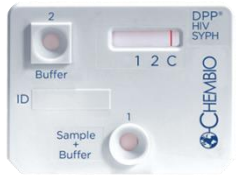
[1] CDC - National Overview - Sexually Transmitted Disease Surveillance, 2019

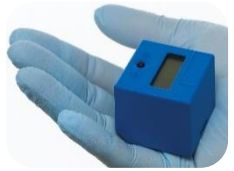
 

# Chembio Comprehensively Addresses Unmet Stakeholder Needs

- ✓ Accurate results
- ✓ Complete diagnostic information: advanced multiplexing, objective, numerical data
- ✓ Removes capital cost barrier

- X Inconsistent results
- X Difficult to interpret results
- X Significant capital outlay



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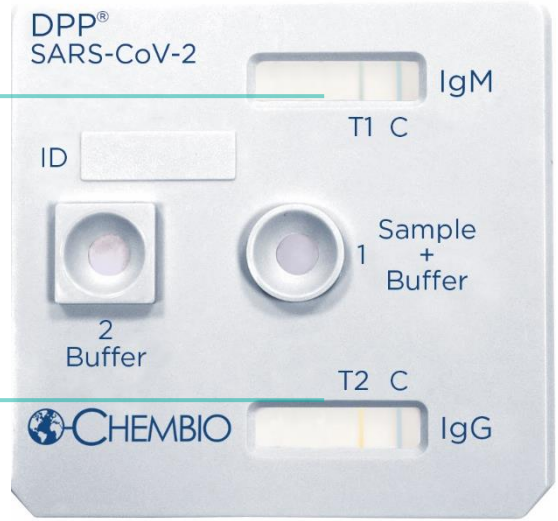
# Patented DPP Technology Platform

## Features

- Simple - Easy to use
- Fast - Results in ~15 minutes
- Reliable - FDA approved, CLIA waived[1]

## Uniqueness

- Enhanced sensitivity and specificity
- Advanced multiplexing capabilities
- Numerical results with DPP Micro Reader within 15 seconds

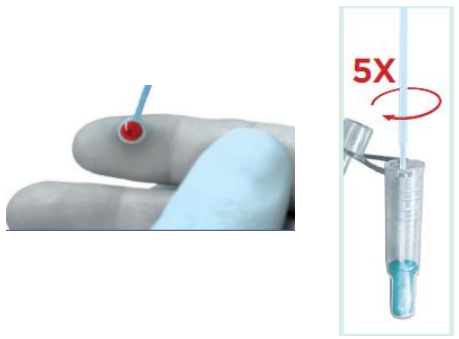



[1] DPP HIV 1/2 Assay – PMA and CLIA Waived
DPP Zika IgM Assay and Micro Reader 1 – 510(k)

# Rapid & Easy: DPP System Workflow

## 1 | Sample Collection




- Collect sample from a fingerstick or nasal swab
- Combine sample with buffer

## 2 | Transfer to Test Cassette


*~5 minutes*

- Transfer to cassette and incubate for ~5 minutes

## 3 | Add Buffer


*~10 - 15 Minutes*

- Add buffer
- Incubate for ~10 - 15 minutes

## 4 | Read Results

*<15 seconds*

- Insert cassette into DPP Micro Reader
- Results delivered within 15 seconds

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# Reader and Tests Enable Recurring Revenue Model

## Any DPP Test…

- HIV-Syphilis
- SARS-CoV-2
- **Expanding Test Menu**
  US-focused, targeting high value biomarkers
  - STI
  - Respiratory
  - Insect vector
  - Gastroenterology

## Expanding base of customers with Micro Readers


## Reorders from broadening menu of single-use tests

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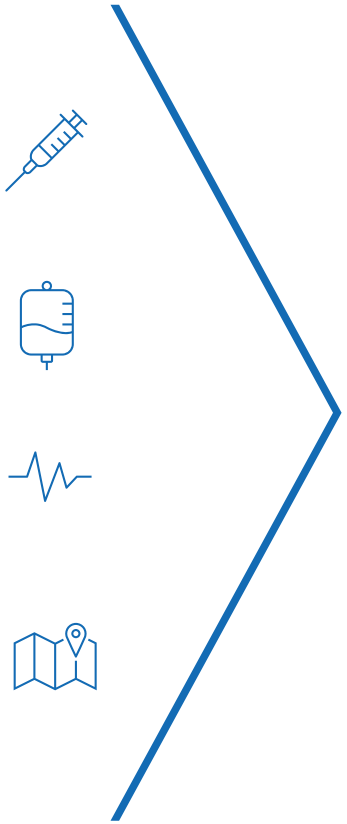
# Development Criteria & Go-to-Market Strategy

1. Rapid diagnosis impacts patient treatment and outcomes
2. Existing diagnostics underserve clinical needs due to performance or availability
3. Regional, demographic or clinically unique opportunities



**Creating high value products** to leverage direct salesforce and distributor network

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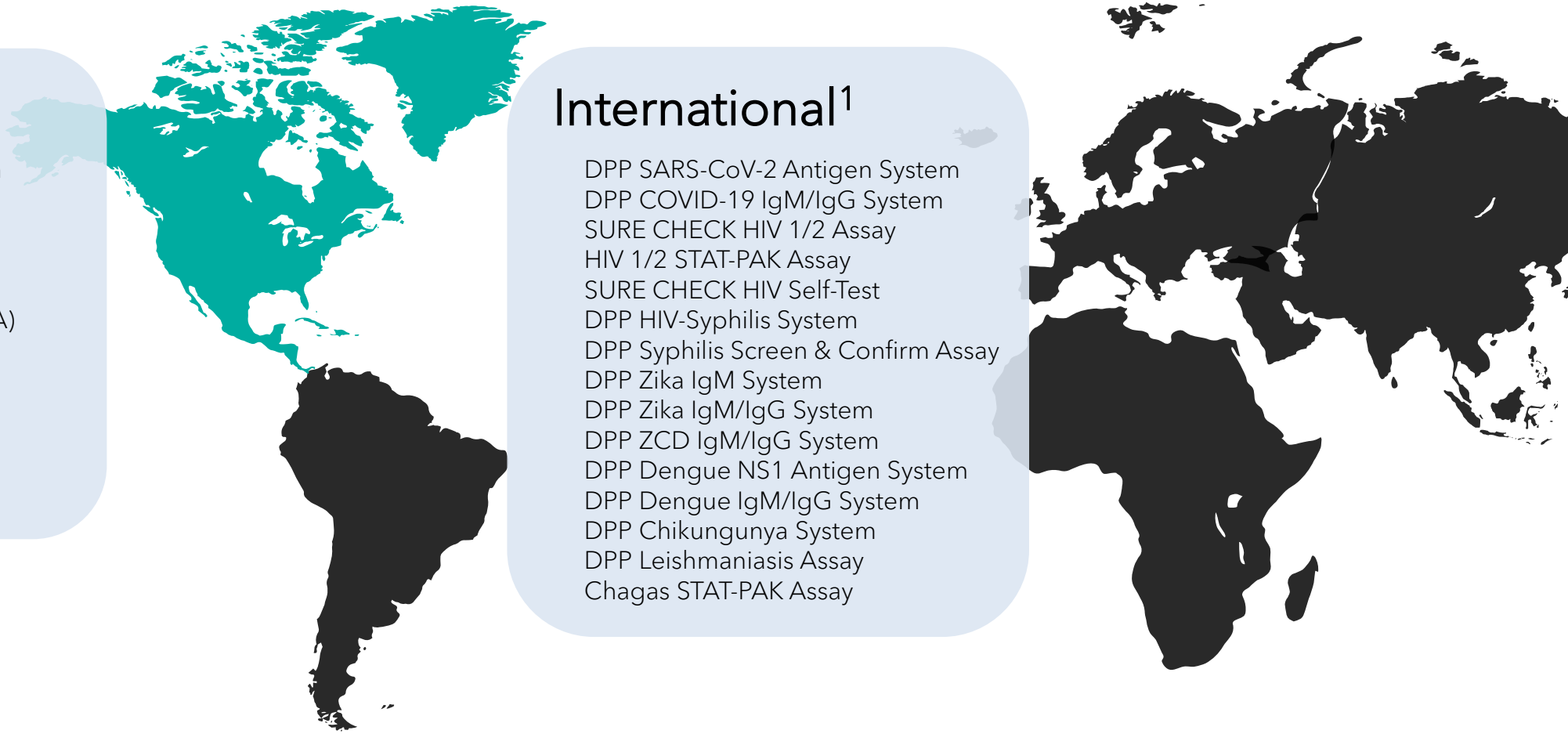
# Proven Track Record of Global Product Approvals

## FDA

DPP HIV-Syphilis System
DPP HIV 1/2
SURE CHECK HIV 1/2
HIV 1/2 STAT-PAK
DPP Zika IgM
DPP Ebola Antigen (EUA)



## International[1]

DPP SARS-CoV-2 Antigen System
DPP COVID-19 IgM/IgG System
SURE CHECK HIV 1/2 Assay
HIV 1/2 STAT-PAK Assay
SURE CHECK HIV Self-Test
DPP HIV-Syphilis System
DPP Syphilis Screen & Confirm Assay
DPP Zika IgM System
DPP Zika IgM/IgG System
DPP ZCD IgM/IgG System
DPP Dengue NS1 Antigen System
DPP Dengue IgM/IgG System
DPP Chikungunya System
DPP Leishmaniasis Assay
Chagas STAT-PAK Assay

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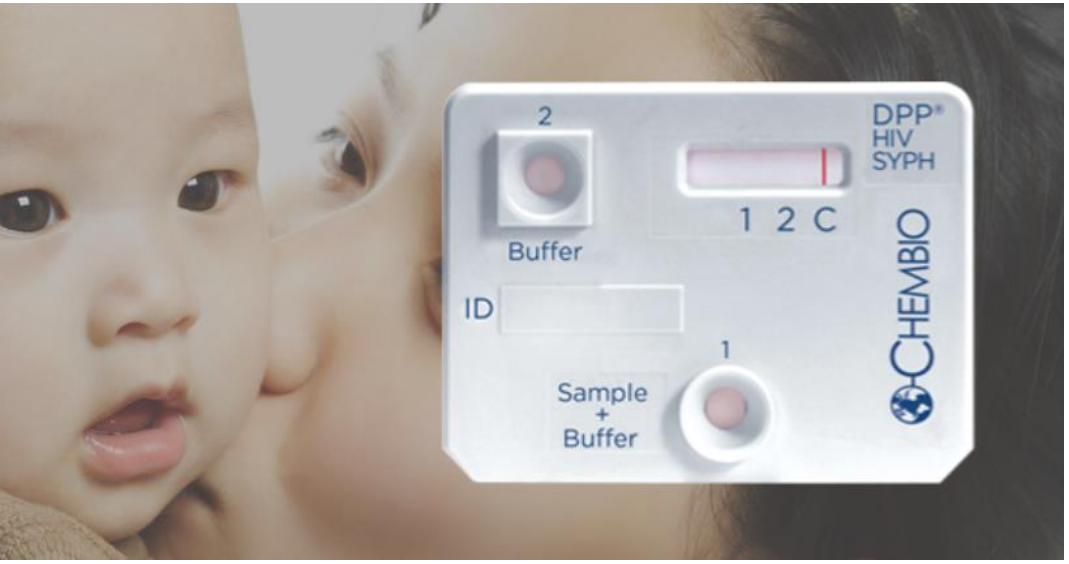
[1] International includes approval from any single or combination of ANVISA, CE Mark, WHO, or others. Sspecific country registrations may be required.

# DPP HIV-Syphilis Illustrates Unmet POC Need

## The First & Only FDA Approved HIV-Syphilis Rapid Test




**Congenital syphilis has increased by 185%**

- Untreated syphilis in pregnant women may result in still birth or infant death in up to 40% of cases
- Active syphilis infections have increased 165% among reproductive-aged women

**Co-infection rates of HIV and syphilis are on the rise**

- Active syphilis infection represents a 2-to-5-fold increased risk of contracting HIV if exposed

**Dual Reimbursement via Separate CPT Codes**

**Current Target Customers** +15,000
physician office labs, hospital labs and clinical labs

**CLIA waiver** submitted to dramatically expand the market

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Source: U.S. Centers for Disease Control and Prevention. From 2014 to 2018, among those who acquired the disease during the four years before delivery can lead to infection of the fetus in up to 80% of cases.

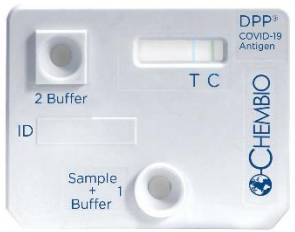
 

# BARDA Awards Totaling $13.3 Million

*Two awards to develop and pursue regulatory approval for DPP COVID-19 Tests*

## DPP SARS-CoV-2 Antigen System

- Develop and pursue EUA
- Pursue 510(k) Clearance




## DPP Respiratory Panel

SARS-CoV-2, Flu A, Flu B

- Develop and pursue EUA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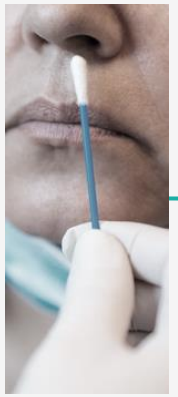
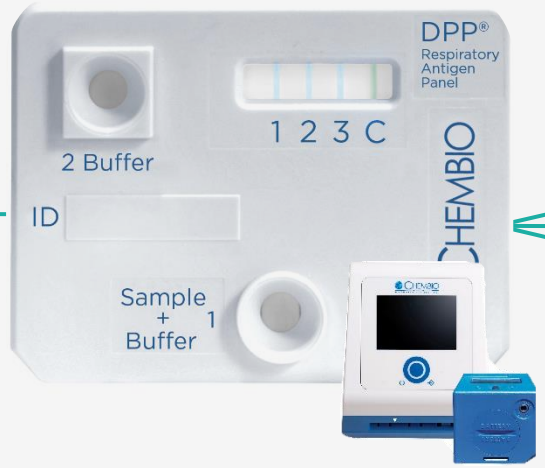
# DPP Respiratory Antigen Panel

- DPP's advanced multiplexing capability enables simultaneous, discrete, and differential detection of the most prevalent cocirculating respiratory pathogens that cause similar symptoms
- 20-minute detection enables more efficient patient management and therapy selection while preserving critical resources

## One Sample



## One Test




## Three Results

- SARS-CoV-2
- Influenza A
- Influenza B

*Under development, supported by BARDA contract number 75A50120C00138*

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# Corporate Priorities

## Operational:

- Create a corporate culture driven by profitability
- Expand manufacturing automation capability

## Product & Commercial:

- Leverage scaled U.S. marketing, sales management, salesforce, distribution management and customer service professionals
- Expand the current base business and relationships with the launch DPP HIV-Syphilis in the U.S. and achieving CLIA waiver
- Continue progress on COVID-19 product development objectives under BARDA awards

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# Operational Capabilities

## Enhanced Through Automation

Fully-Automated Assembly & Packaging Lines


**Intelligent** Improves inspection and quality control via vision-guided, robotic operation

**Flexible** Allows assembly of various configurations of tests on a single line

**Efficient** Reduces variable manufacturing costs

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# Management Team

## *150+ Years of Industry Leadership Experience*

| | | |
|---|---|---|
| Richard Eberly | *President & CEO* | meridian BIOSCIENCE, Abbott |
| Javan Esfandiari | *EVP, Chief Science and Technology Officer* | CHEMBIO DIAGNOSTICS, INC. |
| Neil Goldman | *EVP, Chief Financial Officer* | EY |
| Tom Ippolito | *VP, Quality & Regulatory Affairs* | CHEMBIO DIAGNOSTICS, INC. |
| Charles Caso | *VP, Sales & Marketing* | meridian BIOSCIENCE, Beckman Coulter, Quest Diagnostics, Abbott |
| Robert Passas, Ph.D | *VP, International Sales & Business Development* | Trinity Biotech, QUIDEL, Abbott |
| Paul Angelico | *VP, Global Operations* | P&G |



 

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