

### RAPID Tests for EARLIER Treatment





**Investor Presentation** 

August 2011

#### **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 obtain additional financing 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. 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



#### **Chembio Overview**

- Develops, Manufactures and Markets
   Rapid Point-of-Care Test (POCT) Products
  - Current POCTs for HIV, Syphilis & Other Infectious Diseases, applicable to many other markets
- Branded & Private Label (OEM) Strategy
  - Enabled by Patented Dual Path Platform (DPP®)
  - Four products approved in Brazil 2010-11 now being launched by Brazilian OEM partner
- FDA & USDA Approved Leased Manufacturing Facility in Medford, NY
  - 130 Employees



#### **Financial Overview**

- Five Year Compounded Annual Revenue Growth of 33%
- Gross Margin Expansion Actual and %/Sales

- 2006: \$1.60MM - 25%

- 2010: \$8.10MM - 48%

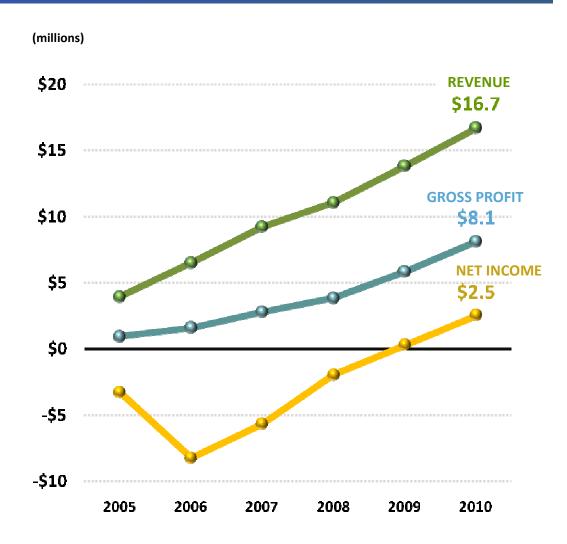
- 2010 6 Mos. YTD

\$3.40MM - 52%

- 2011 6 Mos. YTD

\$3.98MM - 55%

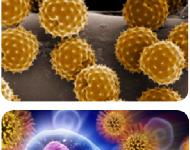
 Profitable 2009, 2010 and 2011YTD





#### **POCTs - A Growing Global Market**

- \$7B Global Point-of-Care Test (POCT)
   Market
- Fastest Growing Segment of \$39.5B
   In-Vitro Diagnostics Market
- POCTs for HIV, Syphilis Serve Crucial Public Health Objectives
  - Chembio Pursuing FDA Approval of Sure Check® HIV Test for Self Testing by Consumers
- Other Important POCT Markets
  - Infectious Diseases, Cardiac Markers, Companion Animal, OTC, Allergy





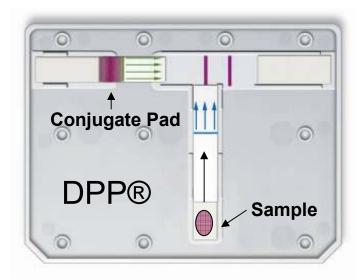


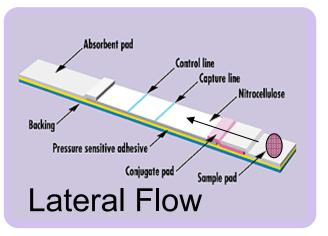




# **DUAL PATH PLATFORM (DPP®) Chembio's Proprietary POCT Technology**

- Independent Sample Flow Path Enables Improved Sensitivity & Use of More Challenging Sample Types
- Improved Multiplexing Facilitated by Direct Binding, Uniform Delivery of Samples
- Visual and/or Instrument Read-Out
- Patents issued in several global markets including U.S., UK, Australia, Eurasia and China
  - Additional DPP® Patents Pending in the U.S. and many foreign countries







### Pipeline of Chembio-Branded Products Complemented by Current & Future OEM Programs

Current OEM Customers and Licensees

FIOCRUZ (BRAZIL)

**BIORAD, ALERE** 

Chembio Branded Products in Clinical Trials



Potential Future **OEM/License Areas** 

INFECTIOUS DISEASES

VETERINARY WELLNESS

Future Branded Products in Development

DPP® HIV SCREENING TEST

DPP® SYPHILIS SCREEN & CONFIRM

SURE CHECK® HIV OTC OTHER
INFECTIOUS
DISEASE
PRODUCTS



#### **Lateral Flow Rapid HIV Tests**

- >20% of 1.1MM HIV+ individuals in U.S. not aware of their status
- Products sold in US professional market by Alere Inc. (NYSE:ALR) as Clearview<sup>®</sup> brand
  - 10-Year exclusive agreement through Sept. 2016
  - 42% increase YTD v. 2010
- Ex-US under Chembio Brands (STAT-PAK® & SURE CHECK®)





### **U.S. Rapid HIV Test Market**

	Clearview Complete	Clearview STAT PAK®	DPP® HIV Screen	OraQuick	Uni-Gold
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Manufacturer	Chembio	Chembio	Chembio	Orasure Technologies, Bethlehem PA	Trinity Biotech, Dublin Ireland
Current or Planned Distribution	Private Label for Alere Direct & Distribution	Private Label for Alere Direct & Distribution	Direct & Distributors	Direct sales force	Direct sales force & distributors
FDA Approval Date	2006	2006	Clinical trials	2003	2003
Technology	Lateral Flow	Lateral Flow	Dual Path Platform (DPP®)	Lateral Flow	Lateral Flow
Est. US Market Shr.	8%	12%	N/A	65%	15%
FDA Sensitivity	99.7%	99.7%	TBD	99.3%OF/99.6% WB	100%
FDA Specificity	99.9%	99.9%	TBD	99.8%OF/100% WB	99.7%
Features					
Sample Types	All Blood Matrices	All Blood Matrices	Blood & Oral Fluid Claims being pursued	Oral Fluid and all blood matrices except serum	All Blood Matrices
True IgG Control	Υ	Υ	Υ	Υ	N
Sample Size (in microliters)	<5	<5	<5	<5	40
HIV-2	Υ	Υ	Υ	Υ	N



### Pipeline: Chembio-Branded Products Anticipated Timelines – US Market

**CLINICAL TRIALS** 

APPROVALS/CLEARANCE

Product	2011	2012	Est. Current/Potential U.S. Market Size
DPP® HIV Screen	Clinical Trials Commenced 2010, Completing in Q4'11; Modular PMA Submissions in Q1'11, Q3'11 and Q4'11	FDA Approval, CLIA waiver, US Market Launch	\$70MM/\$150MM US POCT Market Developed into 7MM Unit Market since 2003
DPP® Syphilis Screen & Confirm	Clinical Trials Q3-4'11; 510(K) Submission	FDA Clearance & US Market Launch – Q3'11	NA/\$50MM 69MM Syphilis tests performed in US; 50MM Clinical; Assumes 20% convert to POCT
Sure Check® HIV OTC	Product Already Approved for Professional Use which is pre- requisite; Submitting IDE for Self Testing Protocol	Phase II Clinical Trials in 2012-2013	NA/\$150MM Assumes \$30 OTC Test

**Significant International Market Opportunities As Well** 



## Pipeline: OEM Contracts with FIOCRUZ Brazil Anticipate Minimum of \$3MM in 2011 Revenues v. \$.6MM in 2010

Contract	2010	2011	2012
DPP® HIV Screening	Approved, Commercial Sales	Commercial Sales	Commercial Sales
DPP® HIV Confirmatory	Approved	Commercial Sales	Commercial Sales
DPP® Syphilis Treponemal	Agreement Signed	Approved Q1 '11, Commercial Sales	Commercial Sales
DPP® Syphilis Treponemal/ Non-Treponemal	December 2010	Submission, Approval	Commercial Sales
DPP® Canine Leishmaniasis	Submitted	Approved Q1'11, Commercial Sales	Commercial Sales
DPP® Leptospirosis		Submitted, Approval, Commercial Sales	Commercial Sales



### **Pipeline: Other Projects**

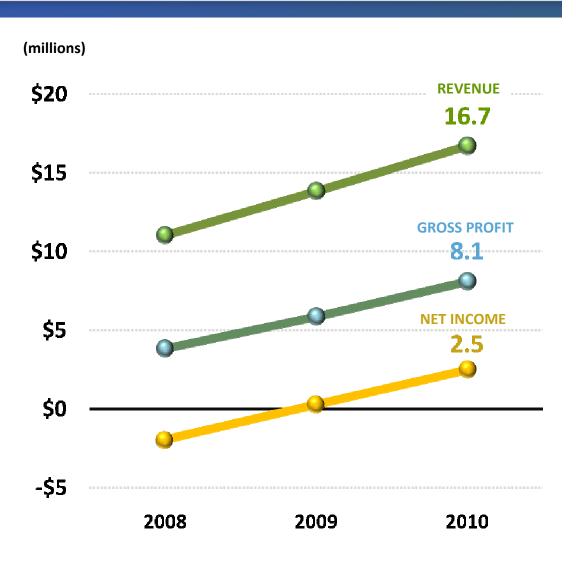
Project	Activity
Multiplex DPP® Product Developed for & Licensed to Bio-Rad Laboratories, Inc.	Development completed. Anticipate CE Mark EOY 2011 – Launch EU early 2012. Manufacturing by Bio-Rad. Royalties Upon Commercial Sales
Multiplex Influenza Immune Status Product Developed for Battelle/CDC	Prototype Development Completed; Prototype products being evaluated at CDC. Additional development work under consideration.
New OEM Applications	Veterinary, Wellness
Platform Enhancements	Buffer Integration and "Dual DPP®" projects in progress
NIH Phase II Grant – Leptospirosis	\$2.9MM 3 Year Grant awarded 6/2009. Prototype developed. Further reagent discovery underway. Approximately \$1.7MM funding remaining in 2011 and 2012 if renewed as anticipated. Chembio is principal grantee.
NIH Phase II Grant – Tuberculosis	\$2.4MM, 3 Year Grant Awarded Effective 3/1/2011. Prototype Developed. Planning Multi-site Evaluations and Optimization, Validation and Commercialization. Chembio is principal grantee.



### **Financial Summary**

#### **FY2008-2010** Results

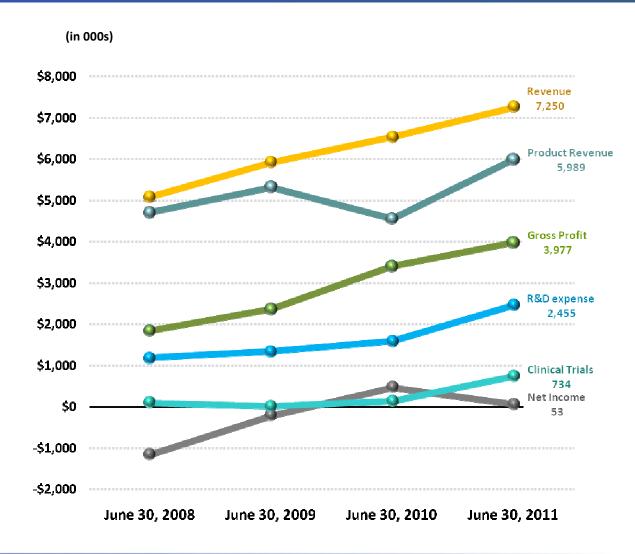
- Record Revenues and Earnings
- Improving Gross Margins
- Controlled Operating Expenses
- Operating Cash Flow Strengthened Balance Sheet





### Financial Summary - Second Quarter 2008 - 2011

- Steady increases in Revenue and Gross Profit
- Increased R&D expense in 2011YTD driven primarily by increased Clinical Trials expense
- Profitable Q2-2011 and YTD



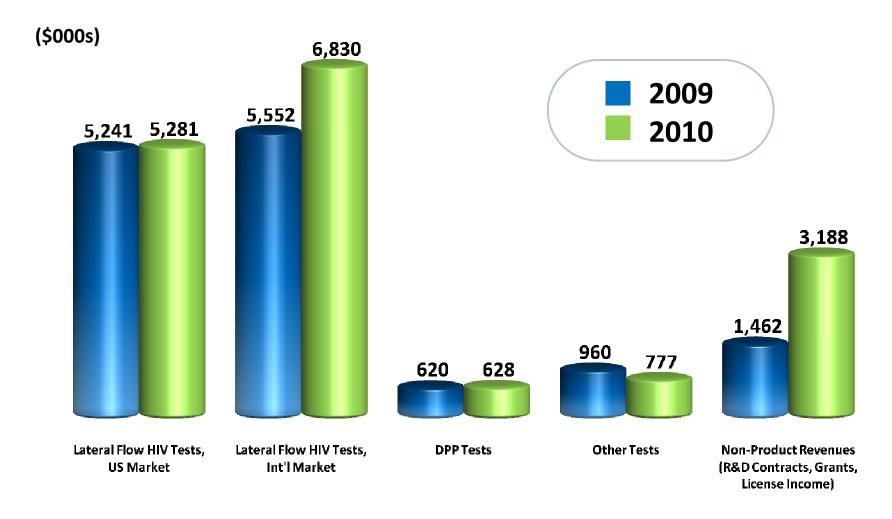


# Selected Comparative Operating Statement Items - 2010 vs. 2011

	3mos. June 30, 2011	3mos. June 30, 2010	June 30, 2011-YTD	June 30, 2010-YTD	December 31, 2010
Net Product Revenues	\$ 2,974,379	\$ 2,335,665	\$ 5,989,442	\$ 4,550,562	\$ 13,516,359
Non-Product Revenues	639,772	1,413,777	1,260,390	1,982,296	3,188,344
TOTAL REVENUES	\$ 3,614,151	\$ 3,419,442	\$ 7,249,832	\$ 6,532,858	\$ 16,704,703
GROSS MARGIN	2,050,278	57% <b>2,094,966</b> 6	<b>3,976,620</b>	55% <b>3,401,340</b>	<b>8,100,699</b> 48%
OPERATING COSTS:					
Research and development expenses	1,164,872	32% 791,596 2	2,455,014	34% 1,592,354	24% 2,586,308 15%
Selling, general and administrative expense	688,259	19% 680,014	20% 1,463,630	20% 1,341,862	21% 2,940,721 18%
	1,853,131	1,471,610	3,918,644	2,934,216	5,527,029
INCOME FROM OPERATIONS	197,147	623,356	57,976	467,124	2,573,670
OTHER INCOME (EXPENSES):	(2,308)	(1,439)	(5,434)	(2,533)	(60,326)
NET INCOME	194,839	5% <b>621,917</b>	<b>52,542</b>	1% 464,591	7% <b>2,513,344</b> 15%

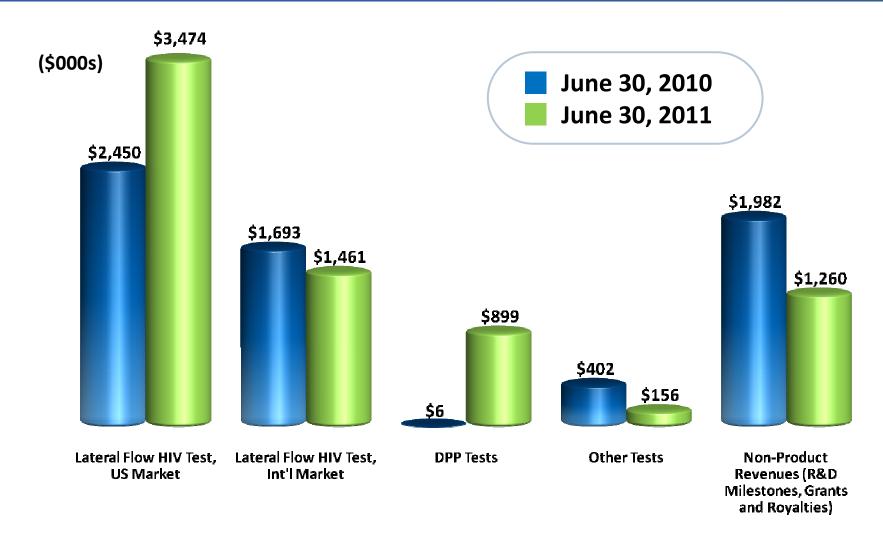


#### Revenue Growth by Category: 2009 vs. 2010





# Revenue Growth by Category: Q2'10 YTD vs. Q2'11 YTD





#### **Selected Balance Sheet Data**

(\$ in millions)	Ju	ıne'11	D	ec. '10	D	ec. '09	D	ec. <b>'08</b>
Cash	\$	2,139	\$	2,136	\$	1,068	\$	1,212
Accounts Receivable		1,643		3,946		1,776		809
Inventories		2,917		1,349		1,556		1,819
Total Current Assets		6,914		7,637		4,667		4,068
Net Fixed Assets		778		813		580		881
Other Assets		743		636		1,068		968
Total Assets	\$	8,435	\$	9,086	\$	6,315	\$	5,915
Total Current Liabilities		2,079		3,076		3,173		2,402
Total Liabilities		2,238		3,277		3,227		3,338
Total Equity		6,197		5,809		3,088		2,577
Total Liabilities & Stockholders Equity	\$	8,435	\$	9,086	\$	6,315	\$	5,915



#### **Anticipated Milestones 2011**

- Clinical & Regulatory Programs for Branded Products
  - HIV PMA Modular Submissions
  - Syphilis Clinical Trials
  - Sure Check HIV OTC IDE
- Commercialization of OEM Products
  - 2011 FIOCRUZ
  - 2012 BIO RAD

- New Branded Product Development
- New R&D & OEM Product Agreements
- Continued US Lateral Flow HIV Test Market Share Gains & Potential New International Market Opportunities

## Leadership

Executive		Joined Company
Lawrence Siebert	Chairman & CEO	2002
Richard Larkin	CFO	2003
Javan Esfandiari	SVP R&D	2000
Tom Ippolito	VP Regulatory, Clinical, QA/QC	2005
Rick Bruce	VP Operations	2000

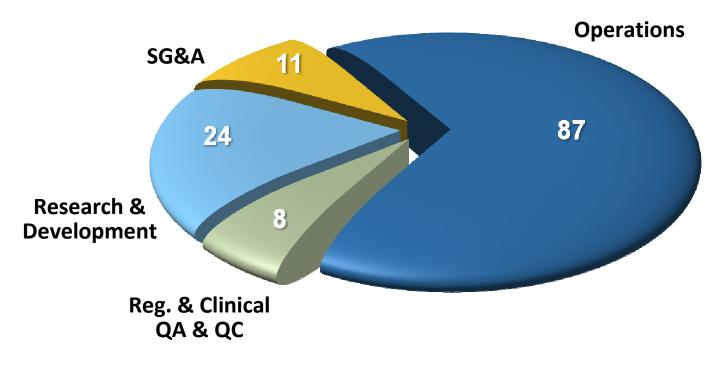
Independent Directors	Joined Board
Gary Meller, MD, MBA	2005
Kathy Davis, MBA	2007
Barbara DeBuono, MD MPH	2011
Peter Kissinger, Ph.D	2011



### **Organization & Facility**



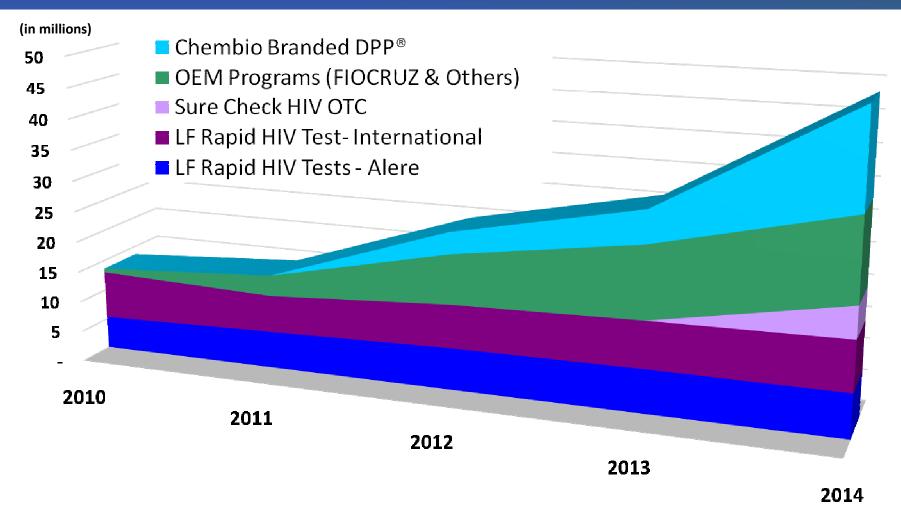
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Fully Integrated FDA & USDA Approved Development & Manufacturing in 24,000 S/F Leased Facility in Medford, NY



# Potential Impact of OEM & Branded Products on Revenue\*



<sup>\*</sup>This portrays one scenario of the potential impact of new products. It is based on a number of assumptions, including but not limited to regulatory approvals, market demand, market share, sales and marketing, and pricing, of which there can be no assurance



#### **CEMI Selected Share Data**

#### (in millions except per share data)

Ticker Symbol (OTC-QB)	CEMI.QB
Price 7/29/2011	\$0.420
52-Week High	\$0.580
52-Week Low	\$0.210
<b>Outstanding Shares</b>	63.3
<b>Market Capitalization</b>	\$26.6
Fully Diluted Shares	69.8
Management Holding	11.6
Average Daily Volume (3 months)	60,000

Options and Warrants	Amt.	Avg. Ex. Price
Options (3.89 MM held by mgmt. & board)	5.42	\$0.192
Warrants (MM) - Exp. Dates		
10/6/2011	1.17	\$0.454
2/5/2012	0.07	\$0.810
<b>Total Options &amp; Warrants</b>	2.41	\$0.254

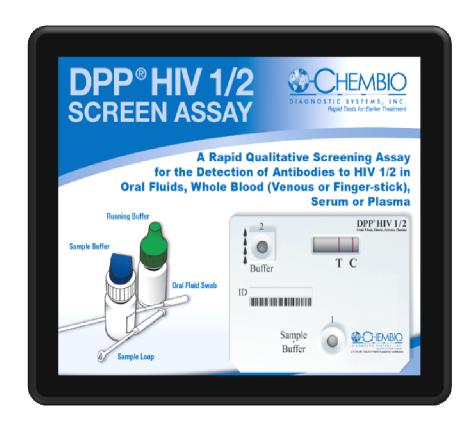
#### **CEMI** price performance





# DPP® HIV Screening Assay For Use with Oral Fluid or Blood Samples

- Improved Performance Based on Multiple Studies
- US Clinical Trials Being Completed 2011
  - Modular PMA Submission in 2011
  - Anticipated Approval 2012
- OTC Opportunity





#### **DPP® Syphilis Screen & Confirm**

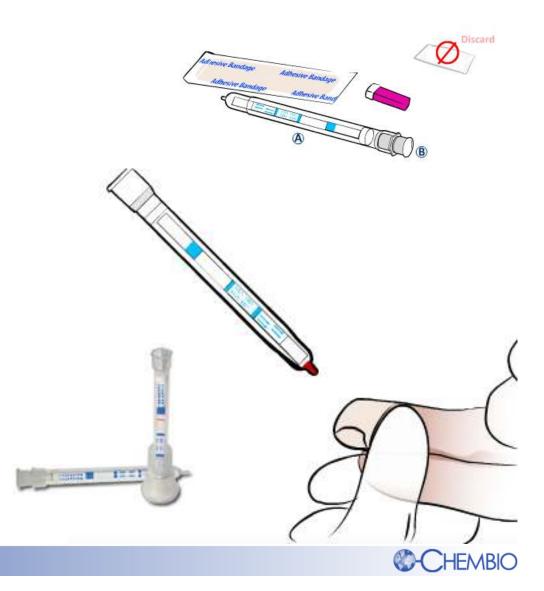
- First POCT in US for Syphilis
- All Pregnant Women Tested for Syphilis
- Current Laboratory Tests Inadequate
- Enables Confirmation & Treatment At POC
- International Evaluation in China Completed Q2 2011
- Anticipate FDA Clearance in 2012





## SURE CHECK® HIV OTC IDE Submission 2011

- Patented All-In-One Barrel Device
- Increasing Market
   Acceptance in Professional
   Market (Clearview by Alere)
- Alternative to Less Sensitive Oral Fluid Product from Only Competitor
- Potential Clinical Trials, Submission to FDA, and Approval in 2012-14





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