

EpineX Diagnostics, Inc.

CREATING A REVOLUTION IN DIABETES MONITORING AND DIAGNOSTICS



Safe Harbor Statement

EPINEX DIAGNOSTICS

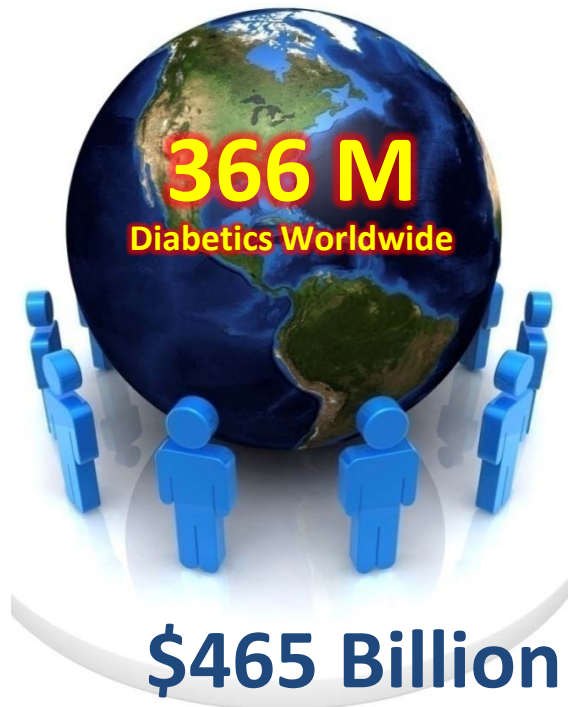
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Diabetes is a Global Epidemic



Total Annual Diabetes Care Spending in 2010
(International Diabetes Federation)



\$174 Billion

Total Estimated Diabetes Costs in US in 2007
(National Diabetes Information Clearing House,
NIDDK NIH)

*95% of
Diabetics
are Type 2*

Type 1

Type 2



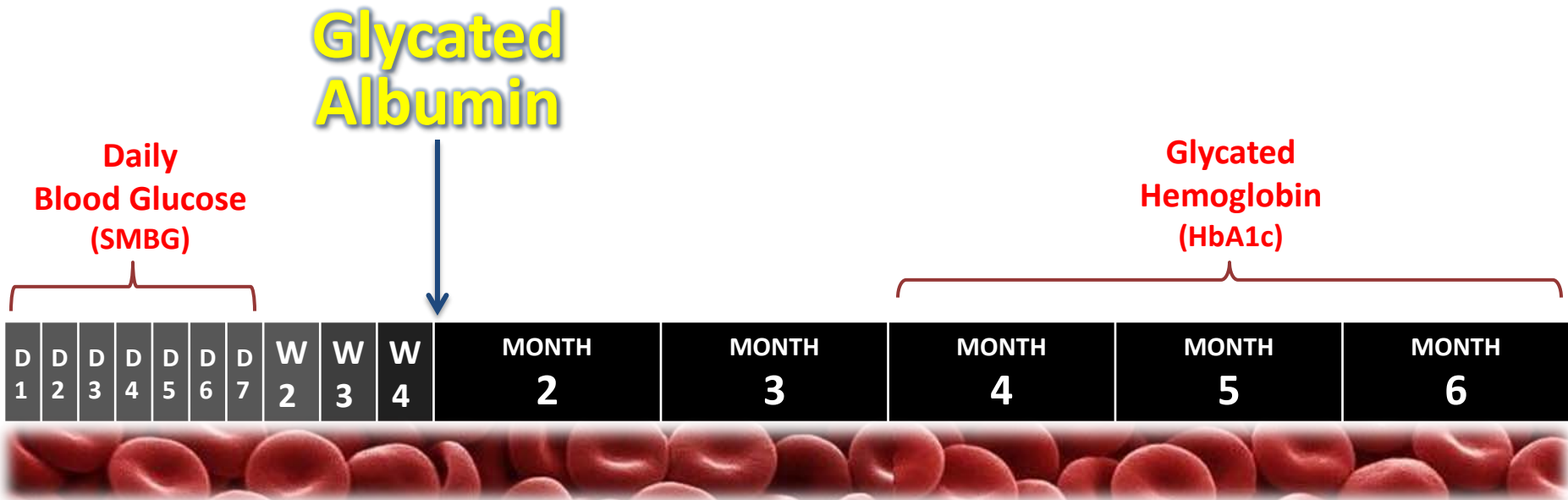
Epinex Mission



Provide **effective** diabetes screening, diagnosis, and management through a single biomarker at the point of care.



Diabetes Monitoring Practices



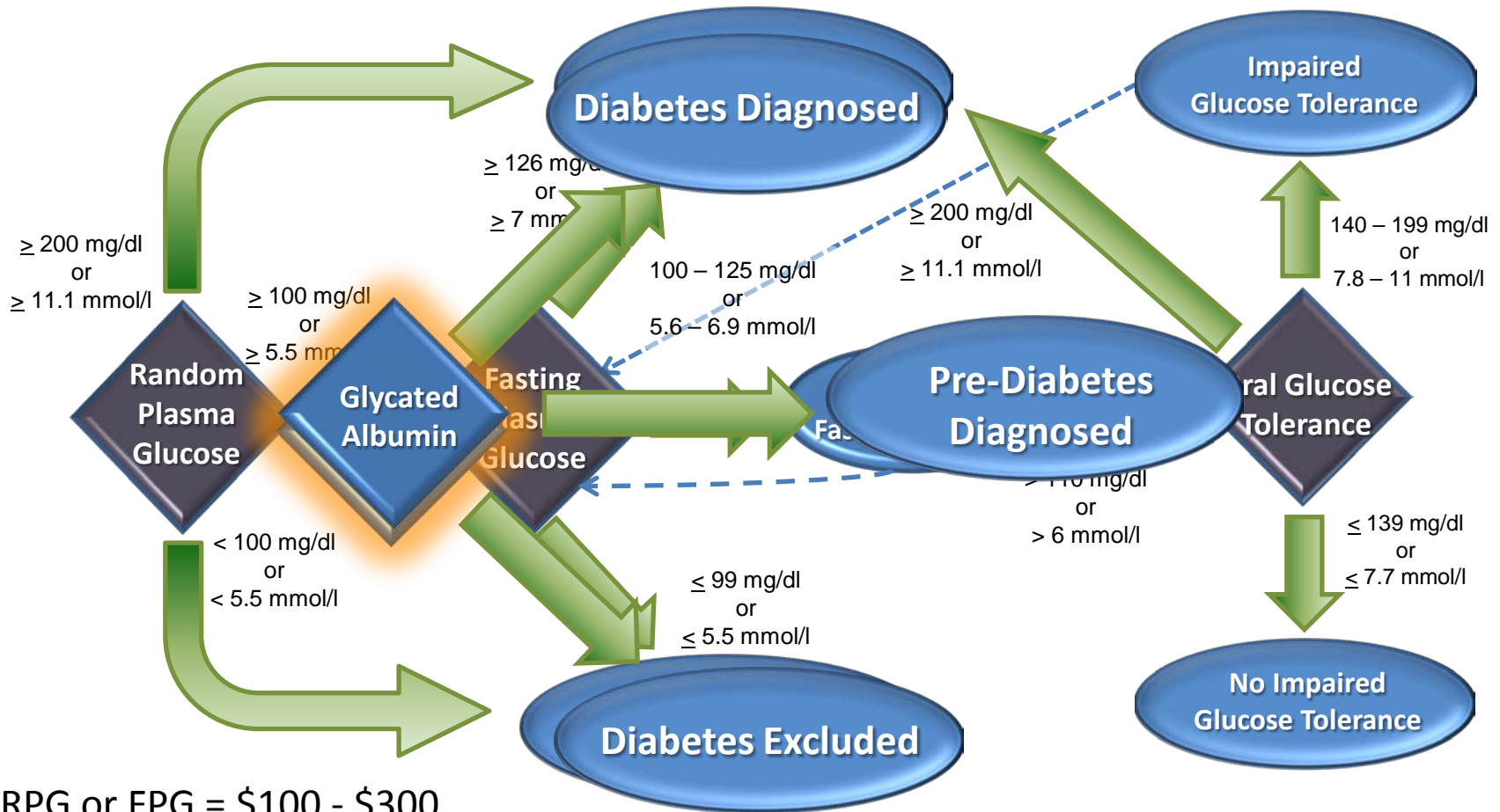
Painful
Expensive
Low Compliance
Ineffective

Accurate
Timely
Cost Reducing

Inaccurate
Unreliable
Delayed
Inadequate



Diabetes Diagnosis Algorithm



RPG or FPG = \$100 - \$300
(For each visit)

OGTT = \$149 - \$400
(sometimes not covered by insurance)



The G1A™ Test System

Screening



Diagnosis



Monitoring



**Point-of-Care (POC)
G1A™ Test System**

A Rapid Glycated Albumin Test

- Lateral flow immunoassay
- Disposable cassette
- Handheld reader and docking station

Monthly monitoring index

Enables early lifestyle/therapeutic intervention

Companion diagnostic

Healthcare savings

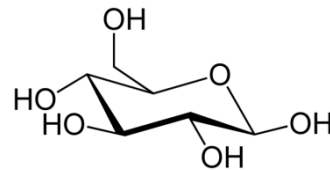
Why Albumin?



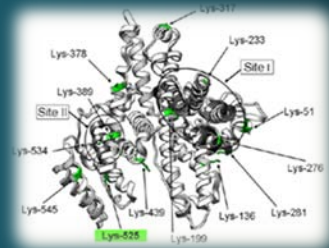
**Regulates
fluid distribution**

**Transports
small metabolites**

**Provides
antioxidant activity**



GLYCATION

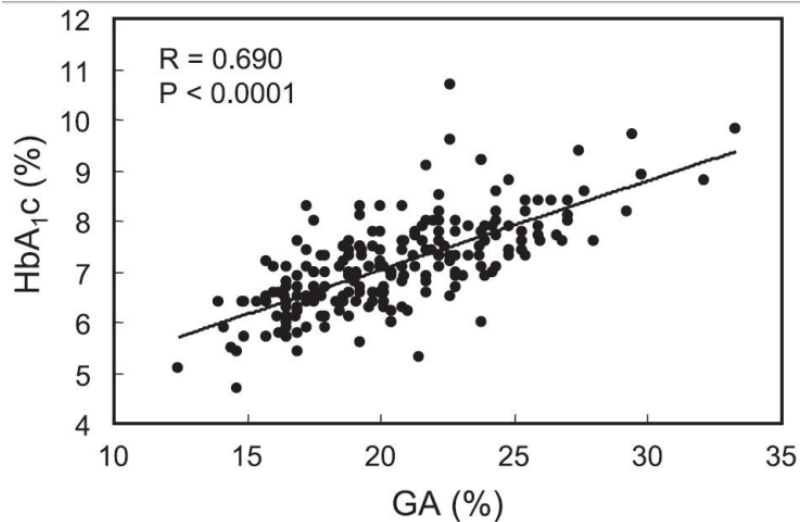


**Alters
glucose metabolism**

**Alters
binding properties**

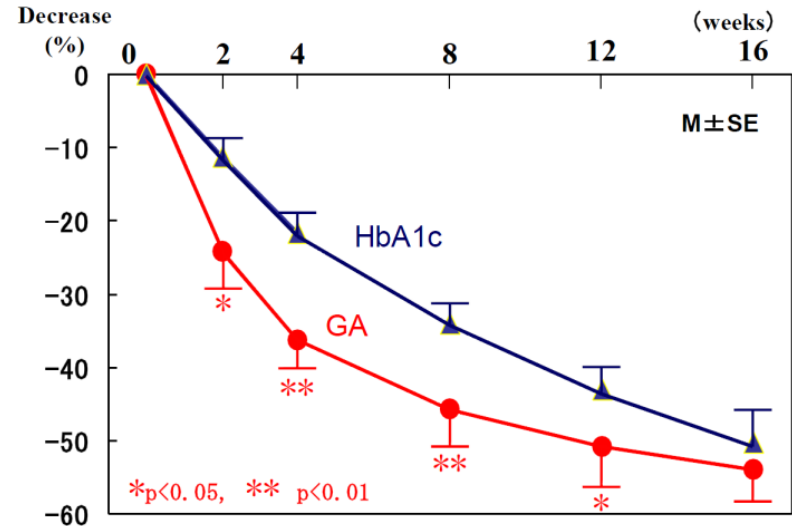
**Impairs
antioxidant capacity**

Glycated Albumin as a Glycation Marker



Correlation of HbA_{1c} levels with GA levels in 209 diabetic patients (Koga 2006)

Strong linear relationship
between GA and hemoglobin A1c

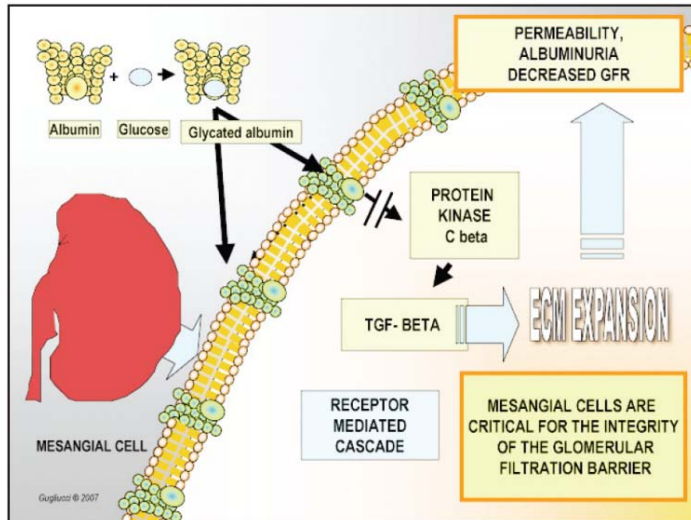


Time course of % decrease of GA & HbA_{1c} during intensive insulin treatment (Takahashi 2007)

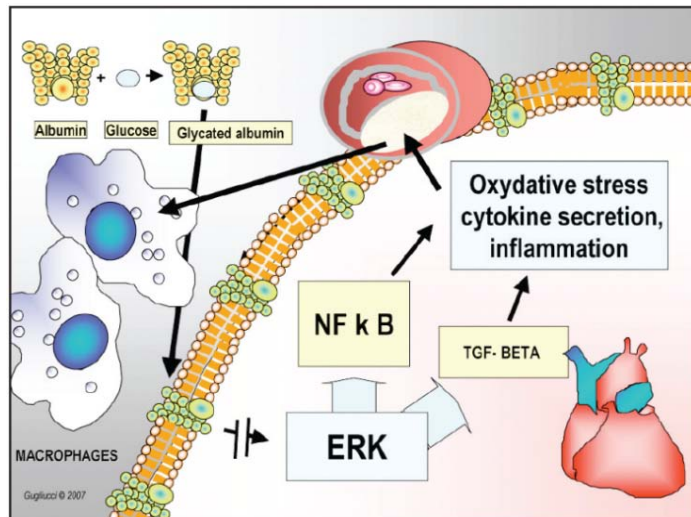
GA is more sensitive
to early changes in glycemia

GA is a “witness” to glycemic changes over the past 25-30 days

GA Causes Diabetes Complications



- Affects structure of mesangial cells
- Inhibits synthesis of nephrin
- Induces cell death
- Stimulates inflammatory pathways
- Promotes angiogenesis



GA is a “culprit” in the pathogenesis of diabetes complications

US Market Potential for G1A™



Screening/Dx
(33.6 million)

\$840 million
Annually



Pre-Diabetes
(79 million)

\$1.98 billion
Annually



Monitoring (DM)
(18.8 million)

\$5.64 billion
Annually

Total US Market Potential (\$25/test): \$8.46 Billion

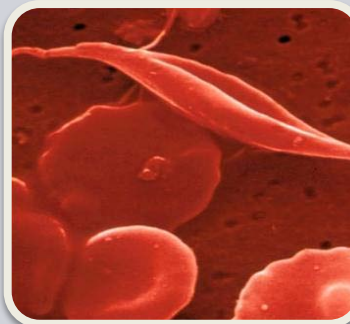
Meeting the Immediate Clinical Need



GESTATIONAL
180,000



HEMODIALYSIS
200,000



RBC DISORDERS
560,000



GERIATRIC
420,000

**Over 1.3 million diabetics
need G1A™ today**



**\$70 million potential revenue
with 15% adoption (\$25/test)**

Razor-Razorblade Business Model

Place Test Reader



- Initial Cost: \$600
- Place at no cost*

Sell Test Cassettes



- Unit Cost: \$3.00
- Sale Price: \$25.00
- Gross Margin: 88%

Generate Revenue

\$30,000

Annual cassette revenue per placement

- (low usage estimate)
- 100 tests / month
- 5 tests / day

*With guaranteed minimum cassette usage contract

Market Validation

GA test is a good tool for gestational diabetes

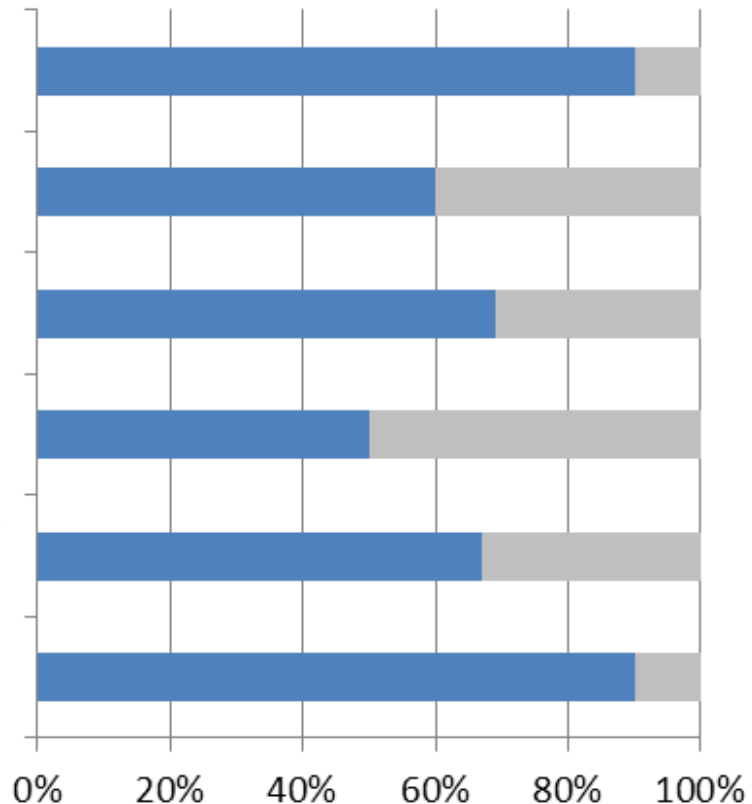
G1A™ can be used to screen patients with metabolic syndrome

SMBG could be reduced w/ reliable GA test

G1A™ should be done before FPG and OGTT tests

Wish to participate in further evaluation of G1A™ test

Interested in knowing more about G1A™ test



Survey of 3,500 Endocrinologists/Diabetes Specialists

(~10% response rate; margin of error +/- 6.5% @ 95% confidence level)

Reimbursement and IP



Reimbursement Codes

CPT Code #	Reimb. Amount	Testing Procedure
82985	\$21.06	Glycated Protein
83036	\$13.56	Glycosylated Hemoglobin (A1c)
83037	\$34.00	Glycosylated Hemoglobin (A1c) POC/home use



Private insurers: up to \$80
for glycated protein testing

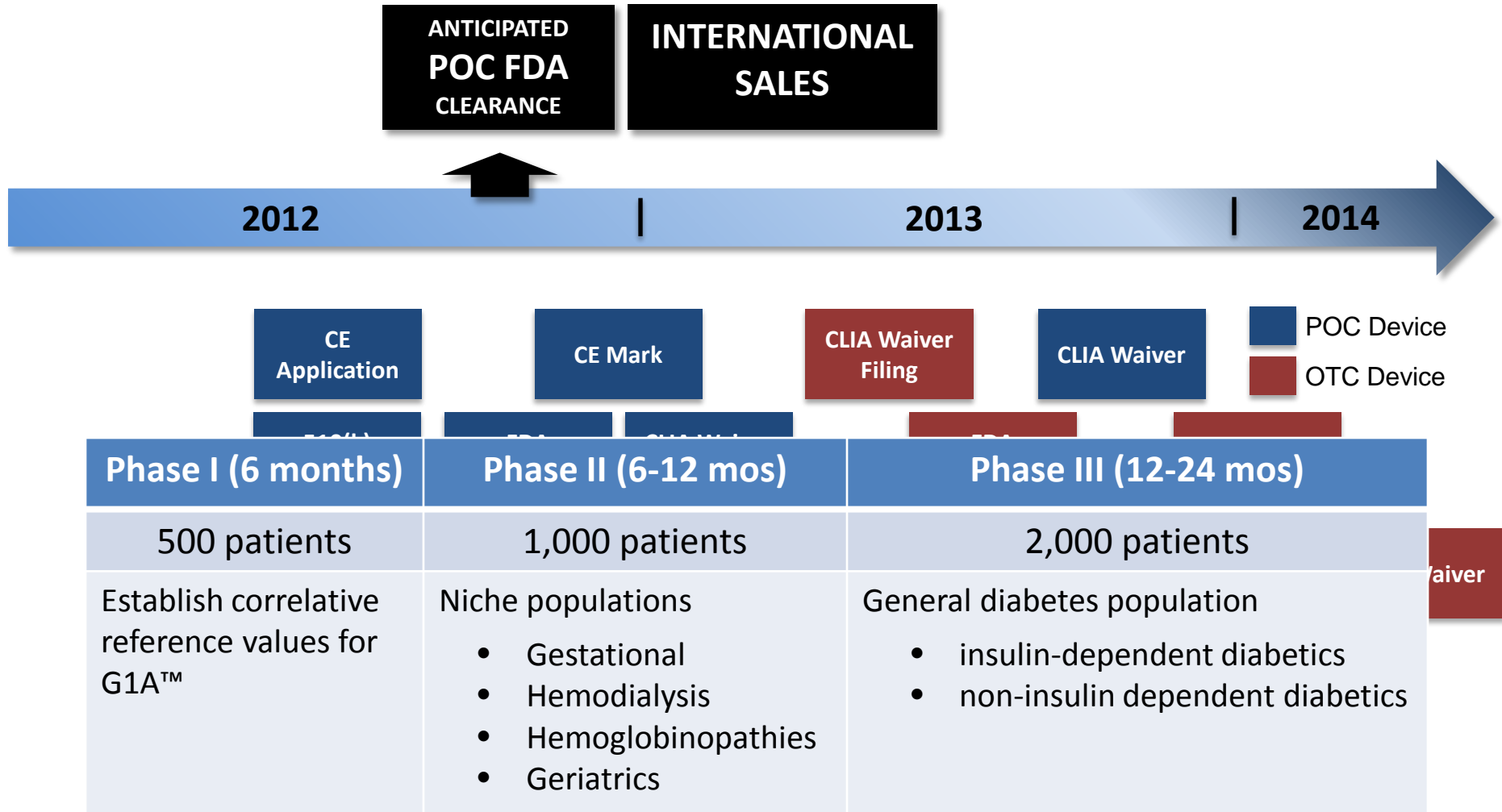
Select Patent Applications

Country/Agency (Application No.)	Patent Application Status
Canada (CA2510277)	Response to first Official Action has been filed
Japan (2006-527157)	Response and argument to first Official Action has been filed
US (12/221.429)	Pending: Aptamer-based POC GA test
US (12/344.416)	Pending: Rapid test for GA in saliva

US Patent granted in February 2010
European Patent granted in May 2011
Hong Kong patent registered 2011



Regulatory Pathway & Timing



Milestones Completed



Product Development

- Intellectual property secured
- Conceptual testing completed
- Design refinements in process
- Proprietary antibodies developed – optimization in process

Funding

- \$8 million – PPM and rights offerings
- \$1 million – preferred shares
- \$2 million – strategic investment (Korea)

Investment Opportunity and Use of Proceeds

\$15 million needed for full market launch

- POC and OTC device development
- Large-scale clinical trials
- Product Launches
 - International
 - Niche Markets
 - General Diabetes Market

Category	Cost (\$)
SG&A	5,309,000
Product Development	1,842,000
Regulatory and Clinical Validation Costs	2,250,000
Capital Equipment	613,500
Manufacturing	756,500
Sales and Marketing	2,139,000
Other expenses	1,440,000
Total	15,000,000

Experienced Management Team



Mr. Asad Zaidi

CO-FOUNDER, CEO, & PRESIDENT

- B.S. Biochemistry, B.S. Biomedical Engineering Sciences, University of California, Irvine
- Has been involved with the development of various in-vitro diagnostic and biomedical devices since 1973 in companies such as Shiley (Pfizer), C.R. Bard, Mitral Medical, Bicer Medical, and Medtronic



Henry Smith, Ph.D.

CO-FOUNDER & CTO

- PhD, Immunology – University of Leeds School of Medicine (England), B.Sc. – University of London, England
- Over 30 years of experience in developing medical diagnostic assays
- Several patents in the diagnostic field, including the methodology for the rapid glycosylated albumin assay



Jeff Byrd

VP, CORPORATE FINANCE

- B.A. Sociology, M.A. Communications, Stanford University
- 15 years of sales, marketing, promotions and management experience



Scientific Advisory Board



Dr. Alejandro Gugliucci, M.D., Ph.D.

Research Director and Biochemistry Professor at Touro University; world-renowned authority on protein glycation.



Pamela Comstock, R.Ph.; M.B.A.

Over 15 years of clinical and business pharmacy experience as Corporate Director of Pharmacy for Total Renal Care (Davita) and other healthcare companies.



Dr. Saul Ship, Ph.D.

25 years of marketing and management experience in the diagnostics industry, including 14 years with Bayer/Miles.



Dr. Salim Aziz, M.D., F.A.C.S.

A Clinical Professor of thoracic and cardiovascular surgery in the Department of Surgery at George Washington University Hospital, in Washington, D.C.



Dr. Alan W Carter, Pharm D.

Chair of the Kansas Diabetes Action Council. Provided disease management/formulary consulting for Argus Health Systems, Children's Mercy Family Health Partners, Johnson & Johnson Lifescan Division, LXN, Lockheed Martin Aerospace, and the US Army Research Institute of Environmental Medicine.



Dr. H. Vernon Roohk, Ph.D.

Over 30 years of experience as a biomedical and bioengineering researcher and consultant. Associate Clinical Professor in the Department of Surgery at University of California, Irvine Medical Center. Published widely in his research specialties and holds several patents.



Dr. Omar Ali, M.D.

Professor of Pediatric Endocrinology and Diabetes at the Medical College of Wisconsin in Milwaukee, Wisconsin. Former practice includes the Loma Linda University Medical Center, Loma Linda, California, and the UCLA-Mattel Children's Hospital, Los Angeles, California.

THANK YOU



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