



**EPINEX DIAGNOSTICS INC.**  
CREATING A REVOLUTION IN BIOTECH-BASED DIAGNOSTICS

## 2014 Global Diabetes Point of Care Diagnostics New Product Innovation Award



F R O S T &



50 Years of Growth

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## Background and Company Performance

### *Industry Challenges*

With each passing year, the scope of the worldwide diabetes epidemic becomes more evident. According to the International Diabetes Federation (“IDF”) there are currently more than 246 million people with diabetes worldwide and that this population will grow to 380 million by 2025. It is estimated that at least 50% of all people with diabetes are unaware of their condition. Diabetes accounts for approximately 5%-10% of a nation’s health budget. Diabetes is the fourth-leading cause of death in the United States and seventh globally. Its complications include heart attack, stroke, blindness, kidney failure, and amputation. The enormous potential human and economic costs of the diabetes epidemic are staggering, but the opportunity to reverse the health and financial toll by bringing the epidemic under control also offers great rewards. There is a pressing need for better diabetes management solutions in order to track and diagnose this disease and avoid the human and economic costs of its complications at an early stage.

Diabetics currently monitor their disease through daily self-monitored blood glucose (SMBG) testing and quarterly glycated hemoglobin (HbA1c) testing. While SMBG testing is necessary for type 1 diabetics, SMBG is painful, repetitive, and provides information that is of limited benefit to most type 2 diabetics (90-95% of diabetics). In addition, approximately 75% of type 2 diabetics are non-compliant with prescribed SMBG testing due to the pain and inconvenience of frequent blood glucose testing. Several publications have indicated that the economic benefit related to the use of SMBGs among type 2 diabetics is unclear and its effectiveness as a tool for diabetes management has been widely challenged.

The conventional SMBG meter and test strip market is experiencing heavy price pressure, with over 80 branded meters in the US market. Given that there are heavy reimbursement constraints for mail order pharmacies, the SMBG market reached market saturation in 2013. In addition, digital health technology is now invading this space. Smart phone connectivity and other features, such as cloud and mobile apps, are luring customers to move to innovative meter technologies.

HbA1c, which measure glycated hemoglobin, can only be measured every 3 to 6 months, which allows diabetes to progress unchecked for long periods of time and hinders healthcare providers’ ability to rapidly evaluate therapy effectiveness. Studies indicate that point-of-care testing or self-monitoring of HbA1c levels should always be verified with laboratory test results, and that decisions should not be taken in response to results from CLIA-waived point-of-care HbA1c meters.

There is an unmet need to control diabetes in a more effective manner. The frequency of available technologies for diabetes monitoring is currently too short (every day) or too long (3–6 months). Studies have also demonstrated that, for type 2 diabetics, both glucose testing and the HbA1c testing have low compliance rates. Given challenges such

as the timeframe of testing, the frequency of testing, and accuracy, alternative biomarkers have been studied that can bridge the gap between the SMBG and A1C tests to manage diabetes.

Glycated albumin (GA), a monthly measurement for glycation, is widely endorsed as the best potential marker for assessing diabetes, and is being used with success in a laboratory setting. Glycated albumin is the ideal analyte to measure short-term glycation, showing protein damage (glycation) that has occurred over the previous 2-3 weeks. Recent research has also pinpointed glycated albumin as one of the principal causes of diabetes complications. What is needed in order to make GA testing available on the scale required to work synergistically with an effective monthly care paradigm is a rapid test for GA that can be easily and cost-effectively used within the healthcare setting and by diabetics at home. Epinex Diagnostics has developed the Epinex G1A™ Rapid Diabetes Monitoring Index Test to fulfill that need.

## *New Product Attributes and Customer Impact of Epinex Diagnostics*

### **Match to Needs**

According to endocrinologists, glycation is best measured in short intervals, such as within a month's time, rather than having to wait for 3-6 months. Measuring the levels in a shorter time span helps the physician to modify the treatment for the patient, reducing the risk of long-term complications. The G1A™ test fills the gap between daily SMBG and quarterly HbA1c. It provides patients with a better management tool that directly measures damage (glycation) on a monthly basis. Therapeutic feedback can be obtained faster and more consistently compared to HbA1c, but without the inconvenience, cost, and stress associated with SMBG. Monthly glycation monitoring using the G1A™ test may improve diabetics' quality of life and is a superior alternative to the existing diabetes management paradigm. With potential applications in diabetes screening, diagnosis and monitoring, G1A™ test could change the standard of care for up to 95% of the global diabetic population – shifting medical practice away from conventional disease management and focusing it onto preventive care. The G1A™ test has the potential to reduce healthcare costs and improve patient outcomes for diabetics worldwide.

The Epinex G1A™ test measures serum albumin and its glycation at the same time. Albumin is the most abundant plasma protein produced by the liver. Endocrinologists have endorsed glycated albumin as an important, robust marker that can more accurately track the damage caused by excess sugar to the albumin. The timespan associated with the replacement of albumin is 2–3 weeks, which provides an ideal time to measure the glycated albumin and total albumin. Monthly monitoring of glycated albumin may help prevent the onset or severity of diabetes complications, such as kidney failure, heart disease, and blindness, thus improving the quality of life for diabetic patients. Epinex Diagnostics is the only company with a patented rapid test for glycated albumin, which

makes the company an interesting competitor to watch in this area. The technology has been granted patents worldwide, including the United States, Europe, Canada, Japan and Hong Kong.

### **Reliability**

The Epinex G1A™ test uses immunoassay technology in lateral flow format, resulting in a novel, rapid, quantitative test within a proven, reliable configuration. Immunoassays rely on the unique binding between an antigen and a chemically labeled antibody to indicate the presence or concentration of a particular analyte. The test will use a simple dual-channel cassette inserted into a proprietary reader device. It will be easy to use, with no training required, and will have the same sensitivity and specificity of a standard laboratory test. Epinex founder, Asad Zaidi, and his R&D group have used the latest technologies to develop synthetic peptides and monoclonal antibodies against glycated albumin for immunoassay development.

The test will be introduced in two models: a POC (Point-of-Care) test for Physician Office Laboratories, physicians, and health clinics; and an OTC (Over-the-Counter) model for direct sales to consumers through pharmacies, for in-home testing. The company also intends to investigate the potential for the G1A™ test to be used for diabetes screening and diagnosis.

### **Positioning**

The POC segment of the diabetes monitoring market is poised for growth. While a monthly paradigm for diabetes monitoring is gaining widespread acceptance among diabetes specialists, there is no rapid test currently available to measure glycation on a monthly basis. The G1A™ test has the opportunity to become the accepted standard of care in the diabetes market. The G1A™ test for could change the standard of care for up to 95% of the global diabetic population – shifting medical practice away from conventional disease management and focusing it onto preventive care. Epinex believes that the G1A™ test will be covered by one of several existing CPT codes for glycated protein as a point-of-care diabetes monitoring test.

### **Price/Performance Value**

Endocrinologists have stated that daily blood glucose testing could be reduced if a glycated albumin test becomes available in the market. From a cost perspective, the G1A™ test, if administered at \$25 to \$30 per month, could save \$75–\$100 per patient per month in the cost of SMBG test strips (assuming the cost per strip is \$1.00). The G1A™ test from Epinex Diagnostics could cause a paradigm shift in the way diabetes is tested and diagnosed and potentially save billions of dollars in healthcare expenditures. With specific reimbursement codes already in place, insurance providers are likely to offer coverage for the test. The cost–benefit ratio of conventional blood glucose testing for type 2 diabetics has instigated a move away from offering coverage for test strips. Frost &

Sullivan research states that in 2012, almost \$1.3 billion was paid by the U.S Center for Medicare and Medicaid Services (CMS) as reimbursement for blood glucose reagent test strips. Given this vast expenditure, the public health system in the United States is certainly questioning the rationale of advocating blood glucose testing for type 2 diabetics. Based on a recent report from Frost & Sullivan on the SMBG market, the G1A™ test from Epinex has the potential to displace approximately \$3.0 billion of the type 2 diabetes glucose test strip market (assuming a \$0.50 cost per strip). Although the company has not yet submitted the test for regulatory approval, the test has already raised very strong interest in the diabetes society.

## *Conclusion*

Given the potential value of the test, in terms of economic cost benefits and health benefits, the G1A™ test could truly change the way diabetes is monitored, with Epinex poised to become a major player in the diabetes market. The novelty of this approach using monthly glycation testing at a point of care site leads us to believe that this test has enormous potential. It can displace a significant SMBG market for type II diabetics, and replace HbA1C testing where HbA1C is not effective, such as for diabetics on dialysis, diabetics with hemoglobinopathies and for gestational diabetics. It may help reduce SMBG testing for Type II diabetics and become a new standard in diabetes screening, diagnosis and monitoring.

With its strong overall performance, Epinex Diagnostics has earned Frost & Sullivan's New Product Innovation Award.

## Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market, and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, differentiating from the competition. This three-fold approach to delivering New Product Innovation is explored further below.



## Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for translating ideas into high quality products that are of a consistently high quality and have a deep impact on the customer.

## Key Benchmarking Criteria

For the New Product Innovation Award, we evaluated two key factors— New Product Attributes and Customer Impact—according to the criteria identified below.

### New Product Attributes

- Criterion 1: Match to Needs
- Criterion 2: Reliability
- Criterion 3: Quality
- Criterion 4: Positioning
- Criterion 5: Design

### Customer Impact

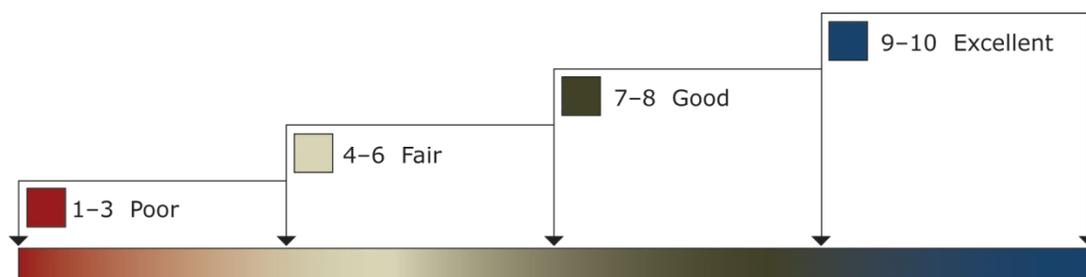
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

## Best Practice Award Analysis for Epinex Diagnostics

### Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are illustrated below.

#### RATINGS GUIDELINES



The Decision Support Scorecard is organized by New Product Attributes and Customer Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key players in as Company 2 and Company 3.

**DECISION SUPPORT SCORECARD FOR NEW PRODUCT INNOVATION AWARD (ILLUSTRATIVE)**

<i>Measurement of 1-10 (1 = poor; 10 = excellent)</i>			
	New Product Attributes	Customer Impact	Average Rating
EpineX Diagnostics	9	9	9.0
Competitor 2	7	8	7.5
Competitor 3	6	7	6.5

*New Product Attributes*

**Criterion 1: Match to Needs**

Requirement: Customer needs directly influence and inspire the product’s design and positioning

**Criterion 2: Reliability**

Requirement: The product has the potential to consistently meet or exceed customer expectations for consistent performance during its entire life cycle

**Criterion 3: Quality**

Requirement: Product will offer best-in-class quality, with a full complement of features and functionality

**Criterion 4: Positioning**

Requirement: The product will serve a unique, unmet need that competitors cannot easily replicate

**Criterion 5: Design**

Requirement: The product will feature an innovative design, enhancing both visual appeal and ease of use

*Customer Impact*

**Criterion 1: Price/Performance Value**

Requirement: Products or services will offer the best value for the price, compared to similar offerings in the market

**Criterion 2: Customer Purchase Experience**

Requirement: Customers will feel that they are buying the most optimal solution that addresses both their unique needs and their unique constraints

**Criterion 3: Customer Ownership Experience**

Requirement: Customers will be proud to own the company’s product or service, and have a positive experience throughout the life of the product or service

**Criterion 4: Customer Service Experience**

Requirement: Customer service will be accessible, fast, stress-free, and of high quality

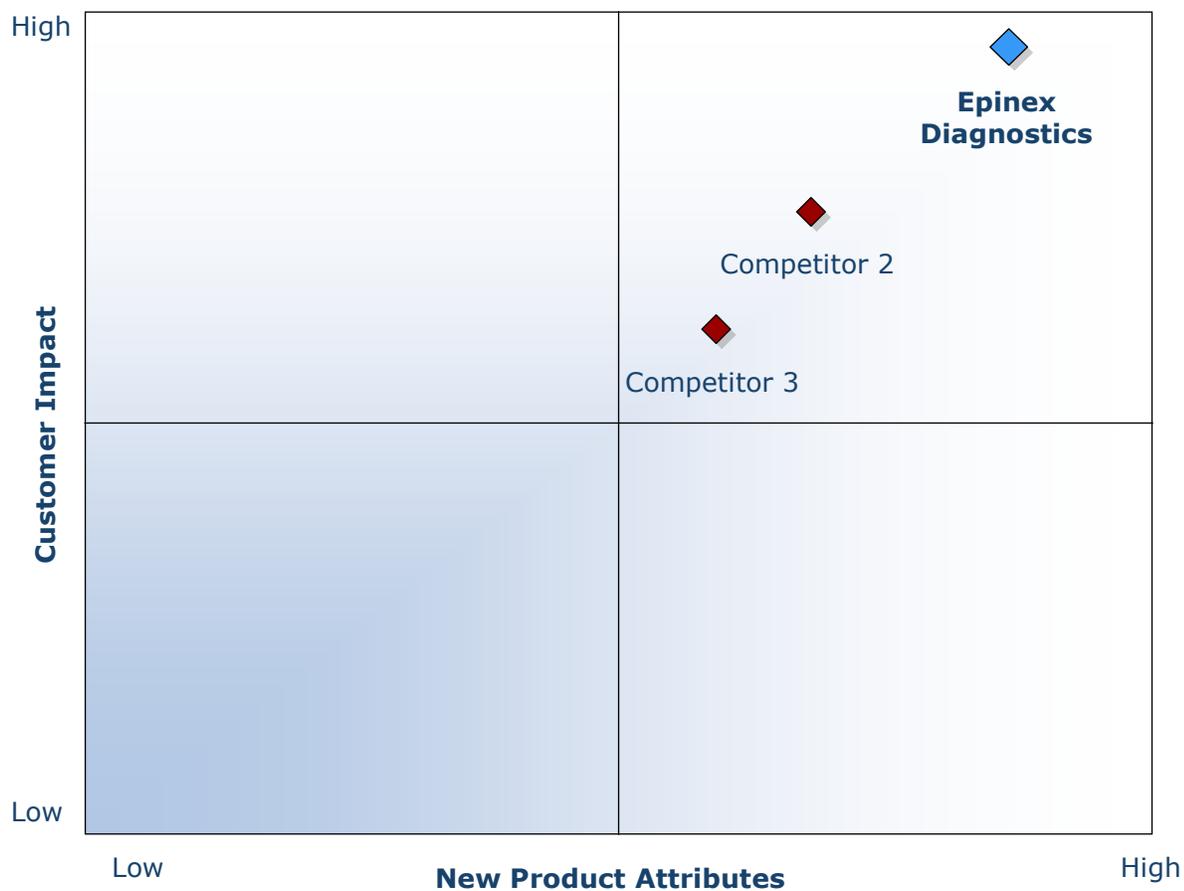
**Criterion 5: Brand Equity**

Requirement: Customers will have a positive view of the brand and exhibit high brand loyalty

*Decision Support Matrix*

Once all companies have been evaluated according to the Decision Support Scorecard, analysts can then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.

DECISION SUPPORT MATRIX FOR NEW PRODUCT INNOVATION AWARD (ILLUSTRATIVE)



## The Intersection between 360-Degree Research and Best Practices Awards

### *Research Methodology*

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.

### 360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



## Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Our awards team follows a 10-step process (illustrated below) to evaluate award candidates and assess their fit with our best practice criteria. The reputation and integrity of our awards process are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 <b>Monitor, target, and screen</b>	Identify award recipient candidates from around the globe	<ul style="list-style-type: none"> <li>• Conduct in-depth industry research</li> <li>• Identify emerging sectors</li> <li>• Scan multiple geographies</li> </ul>	Pipeline of candidates who potentially meet all best-practice criteria
2 <b>Perform 360-degree research</b>	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> <li>• Interview thought leaders and industry practitioners</li> <li>• Assess candidates' fit with best-practice criteria</li> <li>• Rank all candidates</li> </ul>	Matrix positioning all candidates' performance relative to one another
3 <b>Invite thought leadership in best practices</b>	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> <li>• Confirm best-practice criteria</li> <li>• Examine eligibility of all candidates</li> <li>• Identify any information gaps</li> </ul>	Detailed profiles of all ranked candidates
4 <b>Initiate research director review</b>	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> <li>• Brainstorm ranking options</li> <li>• Invite multiple perspectives on candidates' performance</li> <li>• Update candidate profiles</li> </ul>	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 <b>Assemble panel of industry experts</b>	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> <li>• Share findings</li> <li>• Strengthen cases for candidate eligibility</li> <li>• Prioritize candidates</li> </ul>	Refined list of prioritized award candidates
6 <b>Conduct global industry review</b>	Build consensus on award candidates' eligibility	<ul style="list-style-type: none"> <li>• Hold global team meeting to review all candidates</li> <li>• Pressure-test fit with criteria</li> <li>• Confirm inclusion of all eligible candidates</li> </ul>	Final list of eligible award candidates, representing success stories worldwide
7 <b>Perform quality check</b>	Develop official award consideration materials	<ul style="list-style-type: none"> <li>• Perform final performance benchmarking activities</li> <li>• Write nominations</li> <li>• Perform quality review</li> </ul>	High-quality, accurate, and creative presentation of nominees' successes
8 <b>Reconnect with panel of industry experts</b>	Finalize the selection of the best-practice award recipient	<ul style="list-style-type: none"> <li>• Review analysis with panel</li> <li>• Build consensus</li> <li>• Select winner</li> </ul>	Decision on which company performs best against all best-practice criteria
9 <b>Communicate recognition</b>	Inform award recipient of award recognition	<ul style="list-style-type: none"> <li>• Present award to the CEO</li> <li>• Inspire the organization for continued success</li> <li>• Celebrate the recipient's performance</li> </ul>	Announcement of award and plan for how recipient can use the award to enhance the brand
10 <b>Take strategic action</b>	Once licensed, share award news with stakeholders and customers	<ul style="list-style-type: none"> <li>• Coordinate media outreach</li> <li>• Design a marketing plan</li> <li>• Assess award's role in future strategic planning</li> </ul>	Widespread awareness of recipient's award status among investors, media personnel, and employees

## About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best in class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages almost 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 31 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.