Pointe Scientific Hemoglobin A1c Assay:
Streamlining diabetes testing with a 2-part HbA1c assay

As shown in figure 1, diabetes on a global basis is increasing at an exponential rate. To monitor diabetes it is necessary to evaluate patient’s glucose and HbA1c levels. Glucose levels reflect an individual’s glycemia at a specific point in time, whereas HbA1c levels reflect the average glucose levels over the previous 2-3 months. Therefore, HbA1c has been recommended for the monitoring of diabetes.

Market: Diabetes Testing

The Pointe Scientific HbA1c assay is an innovative two-part reagent. This reagent includes additional stabilizers in the R2, allowing it to become a single component. There are many onboard lyse applications available, eliminating off-board pretreatment of samples.

Product

Features
- Patented antibody with high specificity for HbA1c
- Fully Automated
- Direct measurement of HbA1c
- Does not require a standalone system
- NGSP Certification & Traceable to IFCC Standard

Advantages
- Minimizes cross-reactivity from hemoglobin variant molecules
- No offline sample pretreatment
- Does not require additional channel for determination of total hemoglobin
- Eliminates the need for HbA1c specific analyzers
- Standardized test results to test methods used in clinical studies

Benefits
- More precise results » no interference from hemoglobin variants / adducts; Carbamylated Hb, Acetylated Hb, HbA2, HbS, HbC, HbE and HbD
- Streamline testing process with more accurate results and less hands-on activities
- Saves space on analyzer and cost of running additional test
- Save laboratory space and money by the consolidation of clinical laboratory equipment
- Increase patient confidence by a NGSP certified test

Regulatory and Certification
- 510(k) Cleared
- CE Mark
- NGSP Certified*
- Referenced to IFCC Standard
- Health Canada Medical Device Licensed

*NGSP certified on the BS-480, BA-800M, AU400 and BioLis 24i
Features, Advantages, and Benefits

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**REAGENTS**

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<thead>
<tr>
<th>Product Number</th>
<th>Analyzer Specific</th>
<th>Description</th>
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<tbody>
<tr>
<td>H7546-40</td>
<td>Open Channel</td>
<td>R1: 1 x 30 mL, R2: 1 x 10 mL Lyse: 1 x 125 mL</td>
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<tr>
<td>H7546-120</td>
<td>Open Channel</td>
<td>R1: 1 x 90 mL, R2: 1 x 30 mL</td>
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<tr>
<td>OH546-40</td>
<td>Beckman AU</td>
<td>R1: 2 x 15 mL, R2: 1 x 10 mL</td>
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<tr>
<td>HBA600</td>
<td>BS-200</td>
<td>R1: 1 x 30 mL, R2: 1 x 10 mL Lyse: 1 x 125 mL</td>
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<tr>
<td>HBA480</td>
<td>BS-480</td>
<td>R1: 2 x 60 mL, R2: 2 x 20 mL</td>
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<td>12-H7546-40</td>
<td>BS-200 (International)</td>
<td>R1: 1 x 30 mL, R2: 1 x 10 mL Lyse: 1 x 125 mL</td>
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**CALIBRATORS**

<table>
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<tr>
<th>Product Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>H7541-CAL</td>
<td>Lyophilized 1 vial each of 4 levels</td>
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**CONTROLS**

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<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>H7541-CTL</td>
<td>Lyophilized 2 vials each of 2 levels</td>
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**Instrument Applications**

- Beckman Coulter AU400
- Beckman DxC
- Beckman Synchron CX
- Biolis 24i
- Cobas Mira
- Envoy 500
- Hitachi 717
- Hitachi 911
- Hitachi 917
- Mindray BS-200
- Mindray BS-480
- Mindray BA-800M