Pointe Scientific Brand HbA1c by MedTest Dx: We provide custom branded bulk volumes of HbA1c based on the diabetes market in YOUR region

Market: Diabetes Testing

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.

Product

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.

Regulatory and Certification

- 510(k) Cleared
- FDA Registered
- CE Marked
- ISO 13485
- cGMP Compliant
- NGSP Certified*
- References to IFFC Standard

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

- No offline sample pretreatment
- Broad range of instrument applications
- Private labeling/OEM partnerships
- Proprietor of 510(k)
- CE marked
- Manufactured in a highly regulated FDA environment

## Benefits

- Save your customer time and money on sample preparation due to our fully automated 2-part assay
- Offers a solution to any customer while providing validated or theoretical parameters
- Maintain your own brand identity while saving money on packaging and labeling tasks
- Streamline your customer’s technical questions by dealing directly with the company that owns the 510(k)
- Eliminates the restriction of being able to sell product into different countries
- Increase customer’s confidence with a high quality product that adheres to FDA standards

### OEM SOLUTIONS

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Analyzer Specific</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-H7546-40</td>
<td>Open Channel</td>
<td>Hemoglobin A1c (2 part) unlabeled ‘kit’</td>
</tr>
<tr>
<td>7-H7546-120</td>
<td>Open Channel</td>
<td>Hemoglobin A1c (2 part) unlabeled ‘kit’</td>
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<td>3-H7546-L</td>
<td>Open Channel</td>
<td>Hemoglobin A1c bulk</td>
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### REAGENTS

<table>
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<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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<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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<td>HBA480</td>
<td>BS-480</td>
<td>R1: 2 x 60 mL, R2: 2 x 20 mL</td>
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<tr>
<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>
</tr>
</tbody>
</table>

### CALIBRATORS

- H7541-CAL Lyophilized 1 vial each of 4 levels

### CONTROLS

- H7541-CTL Lyophilized 2 vials each of 2 levels

## 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

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**Figure 1:** Diabetes population per IDF diabetes Atlas Eighth Edition 2017