The test described below will meet the specific requirements encountered in the following contexts:

**INTENDED USES OF THE TEST**

First priority: Monitoring of treatment in people with diagnosed diabetes

Second priority: Diagnosis of diabetes

**TARGET POPULATION/PATIENT**

Type 1 and Type 2 diabetes patients

**HEALTH FACILITY WHERE THE TEST WILL BE USED**

The tests will be performed in health care facilities that can provide diabetes care (e.g. GP, small clinics or district and regional hospitals).

**ADDITIONAL COMMENTS: features to take in account for the implementation of any new tests**

1. QA reference material to be used in addition to the kit: QA panels to be made available to all stakeholders for their quality control needs
2. Training material to be designed for end-users
<table>
<thead>
<tr>
<th>KEY FEATURES</th>
<th>DESIRED</th>
<th>ACCEPTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TARGET MOLECULE</strong></td>
<td>HbA1c</td>
<td>HbA1c</td>
</tr>
<tr>
<td><strong>ANALYTE TO BE DETECTED</strong></td>
<td>HbA1c</td>
<td>HbA1c</td>
</tr>
<tr>
<td><strong>MEASUREMENT RANGE</strong></td>
<td>4 to 15% ( \text{(DCCT)} ) 20 to 140 mmol/mol (SI) Harmonized HbA1c</td>
<td>4 to 15% ( \text{(DCCT)} ) 20 to 140 mmol/mol (SI) Harmonized HbA1c</td>
</tr>
<tr>
<td><strong>INTERFERENCE</strong></td>
<td>No interference from Hb variants and carbamylated Hb Testing according to CLSI guideline EP7-A2 shows no effect from potentially interfering substances</td>
<td>Variant Hb identified Testing according to CLSI guideline EP7-A2 shows no effect from potentially interfering substances</td>
</tr>
<tr>
<td><strong>WITHIN RUN IMPRECISION</strong></td>
<td>&lt; 3% CV</td>
<td>&lt; 5% CV</td>
</tr>
<tr>
<td><strong>BETWEEN RUN IMPRECISION</strong></td>
<td>&lt; 3% CV</td>
<td>&lt; 5% CV</td>
</tr>
<tr>
<td><strong>TYPE OF ANALYSIS</strong></td>
<td>Quantitative. Dual reporting in mmol/mol (SI) and % ( \text{(NGSP/DCCT)} )*</td>
<td>Quantitative. Reporting in mmol/mol (SI)*</td>
</tr>
<tr>
<td><strong>CERTIFICATION</strong></td>
<td>IFCC Standardised</td>
<td>IFCC Standardised</td>
</tr>
<tr>
<td><strong>READING SYSTEM</strong></td>
<td>Instrument reading</td>
<td>Instrument reading</td>
</tr>
<tr>
<td><strong>SAMPLE TYPE</strong></td>
<td>Capillary + venous whole blood</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td><strong>TEST PROCEDURE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NUMBER OF TIMED STEPS</strong></td>
<td>0</td>
<td>2*</td>
</tr>
<tr>
<td><strong>NEED TO TRANSFER A PRECISE VOLUME OF BLOOD</strong></td>
<td>No</td>
<td>Acceptable if adequate blood transfer device is provided</td>
</tr>
<tr>
<td><strong>TIME TO RESULT</strong></td>
<td>Up to 5 minutes</td>
<td>&lt; 10 minutes</td>
</tr>
<tr>
<td><strong>VOLUME OF SAMPLE REQUIRED</strong></td>
<td>&lt; 50 micro liters</td>
<td>&lt; 100 micro liters</td>
</tr>
<tr>
<td><strong>SAMPLING PREPARATION</strong></td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

*readout automated and independent of time at which operator reads the result
### ADDITIONAL CHARACTERISTICS

| Operating conditions | 15 – 35°C  
|                      | 25-90% RH  
|                      | 15 – 30°C  
|                      | 25-80% RH  
| Reagent storage (stability) | 18 months at 40°C  
|                          | and 3 days at 45°C  
|                          | 18 months at 25°C  
|                          | and 1 day at 45°C  
| Storage conditions | No cold chain needed  
| Specific conditions for the test to be transported and stored prior utilization | No cold chain needed  
| In use stability (under tropical conditions) | ½ hour for single use test after opening the pouch  
| Reagents reconstitution | All reagents ready to use  
| Need to prepare the reagents prior utilization | Reconstitution acceptable if very simple to do.  
| All liquids, including water, already in kit  
| End user profile | Trained staff in health care centres  
| Level of education of the person in charge of the test | Trained staff in health care centres  
| Biosafety requirement | None apart waste management and use of non-sterile gloves  
| Level of protection to be made available for the staff and the samples | None apart waste management and use of non-sterile gloves  
| Training needs | Half a day  
| Time dedicated to training session for end users | One day  
| Need for additional equipment in addition to the reader | None  
| Simple equipment acceptable  
| Need for maintenance/spare parts | None  
| None  
| Self-test | Yes  
| PRICING  
| Cost per consumables (e.g. cartridges, strips,..) (for procurement) | < 1 US$  
| < 5 US$  
| Cost per equipment (for procurement) | < 250 US$  
| < 1000 US$  