Reagents for STAT LAB T Analyzer & Auto Chemistry Analyzer

HbA1c kit

REF: 401 001  50 Tests  REF: 401 002  250 Tests
R1: 1 x 7.8 ml  R1: 1 x 38 ml
R2: 1 x 2.7 ml  R2: 1 x 12.8 ml
Lysing  Lysing
Calibrator 4 level  Calibrator 4 level

Procedure:
Wavelength  700 nm
Method  fixed rate
Temperature  37 °C

<table>
<thead>
<tr>
<th>Calibrator (μL)</th>
<th>Sample (μL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 150</td>
<td>150</td>
</tr>
<tr>
<td>Calibrator(μL)</td>
<td>10</td>
</tr>
<tr>
<td>Sample (μL)</td>
<td>10</td>
</tr>
<tr>
<td>Mix and incubate for 5 min at 37°C.</td>
<td>50 50</td>
</tr>
</tbody>
</table>

Mix then read absorbance (A1) after 10 seconds, at 700 nm, After 5 minutes, read (A2) and calculate ΔAbs.

Calculation
Calculate the Abs of Calibrators.
ΔAbs = A2 – A1
Plot the ΔAbs of each calibrator versus assigned concentration. Then HbA1c concentration of the sample is calculated by interpolation of ΔAbs on the calibration curve.

Expected Values
(%): DCCT / NGSP
4.0 – 6.0 Non Diabetic
6.0 – 6.5 Mean
6.5 – 6.0 Good Control

Conversion from HbA1c % to mmol/mol

<table>
<thead>
<tr>
<th>HbA1c %</th>
<th>HbA1C mmol/mol</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>42</td>
</tr>
<tr>
<td>6.5</td>
<td>48</td>
</tr>
<tr>
<td>7.0</td>
<td>53</td>
</tr>
<tr>
<td>7.5</td>
<td>59</td>
</tr>
<tr>
<td>8.0</td>
<td>65</td>
</tr>
<tr>
<td>9.0</td>
<td>75</td>
</tr>
<tr>
<td>10</td>
<td>86</td>
</tr>
</tbody>
</table>

Note: Each laboratory should establish its own expected values. The given values can only be an average indication.

Limitations
1. Results may be inconsistent in patients e.g. with opiate addiction, lead-poisoning, alcoholism, ingestion of large doses of aspirin.
2. Elevated levels (> 10%) of HbF may lead to underestimation of HA1c.
3. Hemoglobin variants HbS, HbC and HbE do not interfere in this assay.
4. There is also no interference by labile intermediates, and uremia does not interfere too.
Performance Characteristics:

Dynamic Range:
The Hemoglobin A1c assay range is 3.0% to 16.0%. Results in this range can be reported and used directly.

Linearity: up to 15%

Correlation:
A study using 40 human specimens between this procedure and the reference method yielded a correlation coefficient of 0.9874 and a linear regression equation of \( y = 1.021x + 0.014 \)

Precision:
Within Run: The intra assay precision was established by assaying blood with two Hemoglobin A1c levels twenty times each.

<table>
<thead>
<tr>
<th>Level</th>
<th>Mean</th>
<th>% C.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium</td>
<td>5.7</td>
<td>1.0</td>
</tr>
<tr>
<td>High</td>
<td>10.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Interferences:
1. Bilirubin to 15mg/dL, ascorbic acid to 10mg/dL, triglycerides to 3000mg/dL, Glucose to 4000mg/dL, car bamylated Hb to 5mmol/L and acetylated Hb to 5.0mmol/L do not interfere in the assay.
2. It has been reported that results may be inconsistent in patients who have the conditions like opiate addiction, lead poisoning, alcoholism, ingestion of large doses of aspirin.

References
10. American Diabetes Association: Clinical Practice Recommendations, Diabetes Care 24 (Suppl. 1):