**ORDER INFORMATION**

| REF: A1C 20 | Cont. | 1x20 Tests |

**PRINCIPLE**

After preparing the hemolysate, where the labile fraction is eliminated, hemoglobins are retained by a cationic exchange resin. Hemoglobin A1C is specifically eluted after washing away the HbA1a+b fraction.

**REAGENT COMPOSITION**

| Reagent 1 | Detergent 0.33% Borate 0.8 M | 25 ml |
| Reagent 2 | Borate/Phosphate reagent pH 7.0 and preservative | 50 ml |
| Reagent 3 | Phosphate Buffer pH 6.7 and preservative | 250 ml |

**RESIN COLUMNS**

Disposable columns 20 no:s containing weakly acidic cation exchange resin in phosphate buffer.

**NECESSARY INSTRUMENTS**

Spectrophotometer or photometer with 415nm filter (405-425)

**SAMPLE COLLECTION AND PRESERVATION**

Whole blood collected with heparin or EDTA.

**REAGENT STABILITY**

10 Days at 2-8℃

**ASSAY PROCEDURE**

Hemolysate Preparation and Lable Fraction Elimination

1. Bring all the reagents and columns to room temperature (21-26℃) for some minutes, before use.
2. Pipette in a test tube.
3. Mix vigorously and let it stand at room temperature for 10 minutes.

**PREPARATION OF COLUMNS**

Uncap each column and snap off bottom tips. Then using rounded end of a pipette, push the upper filter disc down to the resin surface taking care not to compress it. Let the column drain completely to waste.

**CALCULATION**

\[
\frac{(AHbA1C)}{5xAHbTOTAL} \times 100 = \% \text{ HbA1C}
\]

**QUALITY CONTROL**

Accutestrol N - H

**REFERENCE INTERVAL**

Normal range: 3.8 - 6.3%

It is advisable that every laboratory determines its reference values.

**Suggested Interpretation of results**

<table>
<thead>
<tr>
<th>Hemoglobin A1C</th>
<th>Degree of Glucose Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 10%</td>
<td>Poor*</td>
</tr>
<tr>
<td>9-10%</td>
<td>Fair</td>
</tr>
<tr>
<td>8-9%</td>
<td>Good</td>
</tr>
<tr>
<td>7-8%</td>
<td>Excellent</td>
</tr>
<tr>
<td>6-7%</td>
<td>Near Normal glycemia**</td>
</tr>
<tr>
<td>&lt;6%</td>
<td>Non-Diabetic Level</td>
</tr>
</tbody>
</table>

Note:

- In case of urine, samples should be diluted 1:10 and the result multiplied by 10.
* Indicates high risk of developing long-term complications such as retinopathy, nephropathy, neuropathy, cardiopathy etc. ** Indicates some danger of hypoglycemic reaction in Type I diabetics may demonstrate HbA1c levels in this area. Estimation of Mean Blood Glucose (over the past 60 days) from the HbA1c result

MBG Estimate = 33.3 (HbA1c)-86
eg.: HbA1c -6.0% MBG - 115 mg/dl

PERFORMANCE CHARACTERISTICS

Working temperature 21-26°C (Note 1) Interferences: Erroneous value might be obtained from samples with abnormally elevated quantities of other hemoglobins as a result of either their simultaneous elution with HbA1c (HbF) or differences in their glycation from that of HbA (HbS).

NOTES

1. The obtained values are temperature independent when the best is performed at the recommended temperature (21-25°C). If working temperature is out of the range, multiply the obtained value by the corresponding factor showed in the following table:

<table>
<thead>
<tr>
<th>Working Temperature</th>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-20OC</td>
<td>1.15</td>
</tr>
<tr>
<td>21-26OC</td>
<td>1.0</td>
</tr>
<tr>
<td>27-30OC</td>
<td>0.90</td>
</tr>
</tbody>
</table>

2. The long term storage of the columns leads to an excessive packing of the resin diminishing the flow rate and lengthening the elution step. To regain the flow efficiency it is advisable that 10 minutes before starting the test to invest the columns to resuspend the contents, place them back to their upright position and let the resin settle for few minutes.

3. Some air bubbles may occasionally appear inside the resin bed. Their presence do not alter the test performance. It is recommended to run the test below 30°C. If the room temperature is more than 30°C then please perform the test in A/c room to get accurate results.

BIBLIOGRAPHY

Bisse E. Abraham EC. J Chromatog 1985:81-91