**Diabetes**

**ICHROMA™ HbA1c**

**INTENDED USE**

ICHROMA™ HbA1c is a fluorescence immunoassay (FIA) for the quantitative determination of HbA1c (hemoglobin A1c) in human whole blood. It may be used in aid in management and monitoring of the long-term glycaemic status in patients with diabetes mellitus.

For in vitro diagnostic use only.

**INTRODUCTION**

Glycoprotein is formed post-translationally through the sialo, nonenymatic reaction between glucose and amino groups on proteins. HbA1c is a clinically useful index of mean glucose during the preceding 120 days, the average life span of erythrocytes. Carefully controlled studies have documented a close relationship between the concentrations of HbA1c and mean glucose. HbA1c is considered as a more reliable parameter in monitoring glycaemia over the glycaemic reading with the conventional glycosylated haemoglobin.

**PRINCIPLE**

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose. 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buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose

**COMPONENTS**

ICHROMA™ HbA1c consists of ‘Cartridge’, ‘Detection Buffer Tubes’, ‘Hemolysis Buffer Vial’ and an ‘ID chip’.

- The cartridge contains a test strip, the membrane which has an anti human HbA1c at the test line, while rabbit IgG at the control line.

- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains anti human HbA1c-conjugate, anti rabbit IgG (fluorescein conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.

- The detection buffer is pre-dispersed in a tube. 25 detection buffer tubes are packed in a box and further packed in a styrofoam box with ice-pack for the shipment.

- The hemolysis buffer contains nonionic detergent and sodium azide as preservative in PBS.

**WARNINGS AND PRECAUTIONS**

For in vitro diagnostic use only.

- Carefully follow the instructions and procedures described in this ‘Instruction for use’.

- Use only fresh samples and avoid direct sunlight.

- Lot numbers of all test components (cartridge, ID-chip and detection buffer) must match each other.

- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test results.

- Do not aseptically cut the detector buffer tube should be used for processing one sample only. So should the cartridge. The cartridge should be removed sealed in its original pack before use. Do not use the cartridge, if it is damaged or already opened.

- Fresh sample should be thoroly opened. For shipping, samples must be packed in accordance with the respective declarations. HbA1c sample with high glucose, hyperlipidemia cannot be used and should be recollected. Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.

- HbA1c in human whole blood.

**STORAGE AND STABILITY**

- The cartridge is stable for 20 months (white sealed in an aluminum foil pouch) if stored at -4 °C.

- The detection buffer pre-dispersed in a tube is stable for 2 months if stored at 2-8 °C.

- The hemolysis buffer dispensed in a vial is stable for 20 months if stored at 4-30 °C.

- After the cartridge is opened, the test should be performed immediately.

**LIMITATIONS OF THE TEST SYSTEM**

- The test may yield false positive results due to the cross-reactions and/or non-specific identification of certain sample components to the capture or detector antibodies.

- The test may yield false negative results. The non-specificity of the antibodies to the antigens is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.

- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/seagents or presence of interfering substances in the test samples.

- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

- The test conditions for ICHROMA™ HbA1c are as follow:
  - Temperature: 20-30 °C
  - Humidity: 40-70%