**INTENDED USE**

ichroma™ HbA1c is a fluorescence immunoassay (FIA) for the quantitative determination of HbA1c (Hemoglobin A1c) in test samples. It is used in vitro.

**INTERPRETATION OF TEST RESULT**

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

The test may yield false negative results. The non responsiveness of the antigen to the antibodies is most common where the sample is masked by some unspecific component in the test sample which cannot be detected or captured by the antibodies. The instability or degradation of the antigen with time and temperature changes may also 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 reagents, or interfering substances.

The test conditions for ichroma™ HbA1c are as follows:

- Temperature: 20-30 °C
- Humidity: 10-70 %

**REFERENCE**

1. Draw 100 µL of human hemoglobin and transfer it into detection buffer tube.
2. Draw 5 µL of fingertip blood or tube blood using 5 µL capillary tube and put the capillary tube into the detection buffer tube.
3. Close the lid of the detection buffer tube and mix the sample mixture on a rotating mixer.
4. Take out the cartridge half from ichroma™ reader.
5. Pipette out 57 µL of sample mixture and load it into a sample well in the test cartridge.
6. Wait till the sample mixture flows in the window. (about 10 seconds)
7. Insert the cartridge into ichroma™ reader.
8. Leave the cartridge in ichroma™ reader for 12 minutes before removing.
9. Remove the cartridge from ichroma™ reader and take out the cartridge holder of the instrument for ichroma™ tests. Ensure proper positioning of the cartridge holder before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge holder to ensure proper positioning of the cartridge.
10. Press ‘Select’ button on the instrument for ichroma™ tests to activate the printed menu.
11. Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
12. Read the test result on the display screen of the instrument for ichroma™ tests.

**STORAGE AND STABILITY**

- The cartridge is stable for 20 months (when sealed in an aluminum foil pouch) if stored at 2-8 °C.
- Detection buffer tube is stable for 20 months if stored at 2-8 °C.
- The hemolysis buffer dispensed in a vial is stable for 20 months if stored at 2-30 °C.
- After the cartridge open is opened, the test should be performed immediately.

**DIABETES**

HbA1c is a clinically useful index of mean glycemia during the preceding months.

**COMPONENTS**

ichroma™ HbA1c consists of Cartridge, Detection Buffer Tube, Hemolysis Buffer Vial and an 10 µL Pipette.

- The cartridge contains a test strip, the membrane which has anti-human HbA1c at the test line, and rabbit IgG fluorescence conjugate at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing desiccant.
- 25 sealed cartridges are packed in a box which also contains an ice pack.
- The detection buffer tube contains anti-human HbA1c fluorescence conjugate, anti rabbit IgG fluorescence conjugate, bovine serum albumin (BSA), as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer tube is pre-dispensed in a separate tube.
- The hemolysis buffer contains nontoxic detergent and sodium azide as a preservative in PBS.
- 25 detection buffer tubes and hemolysis buffer vial are packaged in a box and further packaged in a SYRTOX box with ice-pack for transportation.

**MATERIALS SUPPLIED**

- ichroma™ HbA1c Cartridge
- Detection Buffer Tube
- Hemolysis Buffer Vial

**QUALITY CONTROL**

- Control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- If testing will be delayed more than 8 weeks, please store the samples frozen at -70 °C or below. Samples should be stored frozen at -70 °C or below for more than 30 months to ensure performance.
- If the sample was frozen, it should be used one time only for test, because repeated thawing and freezing can result in the change of test values.

**REFERENCE**


