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Diabetes

AFIAS HbA1c

INTENDED USE

AFIAS HbA1c is a fluorescence Immunoassay (FIA) for the quantitative determination of HbA1c (Hemoglobin A1c) in human whole blood. It is useful as an aid in management and monitoring of the long-term glycemic status in patients with diabetes mellitus.

For *in vitro* diagnostic use only.

INTRODUCTION

Glycated protein is formed post-translationally through the slow, nonenzymatic reaction between glucose and amino groups on proteins. HbA1c is a clinically useful index of mean glycemia 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 glycemia. HbA1c is considered as a more reliable parameter in monitoring glycemia over the glycemic reading with the conventional glucometer.

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 matrix to be captured by the other immobilized-antibody on test strip.

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is Instrument for the instrument for AFIAS tests displays the content of glycated hemoglobin in terms of percent of the total hemoglobin in blood.

COMPONENTS

AFIAS HbA1c consists of 'Cartridge', 'C- tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has three components, detection buffer part, hemolysis buffer part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human HbA1c at the test line, while rabbit IgG at the control line.
- Detection buffer part 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.
- Hemolysis buffer part contains non-ionic detergent and sodium azide in phosphate buffered saline (PBS) as a preservative.
- C-tip (Capillary tip) is a useful tool for point of care testing which requires a small volume of capillary blood from fingertip, heel site (in infants) or ear-lobe.

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 the test components (cartridge and ID chip) 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 result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- **AFIAS HbA1c** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used C-tips, and cartridges should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **AFIAS HbA1c** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS HbA1c** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **EDTA, sodium heparin, sodium citrate** should be avoided.
- **C-tip should be used when the following conditions are met.**
  - C-tip provided with the kit is recommended to obtain correct test result.
  - Capillary blood should be immediately tested after collection.
  - Do not leave C-tip after collection of blood, test immediately.
  - Do not perform a test with C-tip on General Mode. It might cause an erroneous result.
  - Excess capillary blood around the C-tip should be wiped off.
  - In order to avoid cross-contamination, please do not re-use C-tip for multiple samples.
  - AFIAS cartridge should be inserted and positioned in the cartridge holder prior to the blood sample collection.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies 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/reagents 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.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-28

Components of **AFIAS HbA1c**

- Cartridge Box Contains
  - Cartridge 24
  - C-tip (Zipper bag, 10 µL) 24
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS HbA1c**.
Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech HbA1c Control** REF CFPO-96
- **Boditech HbA1c Calibrator** REF CFPO-108

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS HbA1c** is human whole blood.

- It is recommended to test the sample within 12 hours after collection.
- Samples may be stored for up to a week at 2-8 °C prior to being tested.
- If testing will be delayed more than a week, samples should be frozen at -70 °C or below. Samples stored frozen at -70 °C or below for 3 months showed no performance difference.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.
- Collection of capillary blood sample using C-tip (Fingertip blood)
  (1) Clean the area with a pre-injection swab.
  (2) Pierce with a sterile lancet.
  (3) Wipe away first drop of blood.
  (4) Gently massage the surrounding area towards a C-tip for a second drop.
  (5) Hold a C-tip horizontally and touch the tip of C-tip to the blood drop.
  (6) Capillary action will automatically draw the blood sample to C-tip and stop
  (7) Wipe off any excess blood around the tip.
  (8) Double-check if capillary blood is fully filled in the C-tip and AFIAS reader is ready for a test on the 'C-tip mode'.

TEST SETUP

- Check the components of the **AFIAS HbA1c** as described below. : Cartridge, C-tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS tests 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

1) Select "Test Mode" in the instrument for AFIAS tests.
   - General Mode : Tube blood (with anticoagulant)
   - C-tip Mode : Fingertips blood (non-anticoagulant blood)
   - **You must use C-tip only to collect test samples in both test mode (General / C-tip mode). Do not use a general pipette tip to collect test samples.**
2) Insert the cartridge into the cartridge holder.
3) Take 10 µL of whole blood (tube blood or fingertip blood) with a C-tip. (Please refer to "SAMPLE COLLECTION AND PROCESSING")
4) Insert the whole blood-filled C-tip into the tip hole of the cartridge.
5) Tap the 'START' icon on the screen.
6) The test result will be displayed on the screen after 10 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays HbA1c concentration of the test sample in terms of percentage (%).
- The reference value
  - NGSP (%): 4.5-6.5 %
- The working range
  - NGSP (%): 4-15 %

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **AFIAS HbA1c**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**
  - Limit of Blank (LoB) 2.26%
  - Limit of Detection (LoD) 2.39%
  - Limit of Quantification (LoQ) 3.0 %
- **Analytical Specificity**
  - Cross-reactivity
    There was no significant cross-reactivity from these materials with the **AFIAS HbA1c** test measurements.

cross-reactivity material	Standard material conc. (%)		
	5.3	8.1	13.5
	Recovery (%)		
HbA0 (2 mg/mL)	98.9	102.0	101.0
HbA1a&A1b mixture (5 mg/mL)	100.9	101.9	100.1
Acetylated hemoglobin (100 mg/mL)	100.7	100.2	100.5
Carbamylated hemoglobin (100 mg/mL)	100.2	101.2	100.6
Glycated h-Albumin (2.2 mg/mL)	100.1	100.6	102.0
HbA1d (100 mg/mL)	101.6	101.3	100.5
Acetylaldehyde hemoglobin (100 mg/mL)	99.8	101.4	100.7

  - Cross-reactivity
    There was no significant interference from these materials with the **AFIAS HbA1c** test measurements.

Interference material	Standard material conc. (%)		
	5.3	8.1	13.5
	Recovery (%)		
Non-interference	100.0	99.8	99.5
Acetaminophen (1.5 mmol/L)	100.3	100.6	99.6
L-Ascorbic acid (5 mg/dL)	100.1	100.6	100.8
Bilirubin (20 mg/mL)	100.3	100.3	100.0
D-Glucose (500 mg/dL)	99.8	100.6	102.0
Intralipid (1 mg/mL)	101.0	99.7	100.5
Triglyceride (3000 mg/mL)	100.4	99.6	99.9
Urea (100 mmol/L)	100.3	100.0	100.8

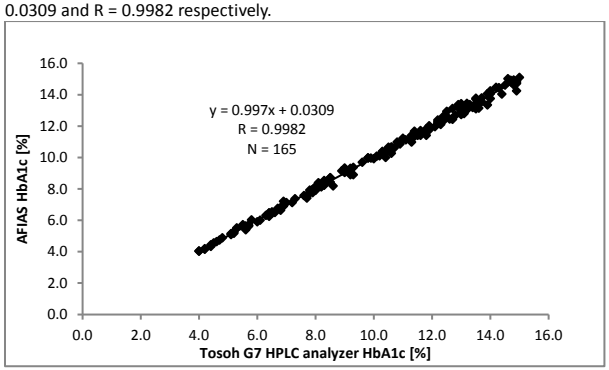
- **Precision**
  - Between lot
    One person tested three different lots of **AFIAS HbA1c**, five times at each concentration of the control standard.
  - Between reader
    Three different persons tested **AFIAS HbA1c** at three different reader; five times at each concentration of the control standard.
  - Between day
    One person tested **AFIAS HbA1c** during five days; five times at each concentration of the control standard.
  - Between site
    One person tested **AFIAS HbA1c** at three different sites; five times at each concentration of the control standard.

HbA1c (%)	Between lot		Between reader		Between day		Between site	
	Avg.	CV(%)	Avg.	CV(%)	Avg.	CV(%)	Avg.	CV(%)
5.3	5.21	2.7	5.25	3.6	5.31	2.5	5.27	2.3
8.1	8.15	3.1	8.12	2.7	8.20	2.9	8.23	3.0
13.5	13.48	2.8	13.38	3.3	13.60	2.8	13.57	2.8

- **Accuracy**
  The accuracy was confirmed each different concentrations.

HbA1c (%)	Between lot		Between reader		Between day		Between site	
	Avg.	Bias(%)	Avg.	Bias(%)	Avg.	Bias(%)	Avg.	Bias(%)
5.3	5.21	-0.02	5.25	-0.01	5.31	0.00	5.27	-0.01
8.1	8.15	0.01	8.12	0.00	8.20	0.01	8.23	0.02
13.5	13.48	0.00	13.38	-0.01	13.60	0.01	13.57	0.01

- **Comparability**
  HbA1c concentrations of 165 clinical samples were quantified independently with **AFIAS HbA1c** and Tosoh G7 HPLC (Tosoh Bioscience Inc. Japan) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 0.997X + 0.0309 and R = 0.9982 respectively.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance; please contact:
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