Glycosylated Hemoglobin Test Kit (FIA) Package Insert

REF VID16-04-011	English

INTENDED USE

VivaDiag Glycosylated Hemoglobin Test Kit (FIA) is a fluorescence immunoassay (FIA) for the quantitative determination of Glycosylated Hemoglobin (HbA1c) in human whole blood. The measurement of Glycosylated Hemoglobin (HbA1c) is considered as a more reliable parameter in monitoring glycaemia. [1]

For *in vitro* diagnostic use only.

For professional use only.

INTRODUCTION

Glycosylated Hemoglobin (HbA1c) is formed by the reaction of glucose with the N-terminal amino group of the hemoglobin beta chain. In the erythrocytes, the relative amount of HbA converted to HbA1c increases with the average concentration of glucose in the blood. The conversion to HbA1c is limited by the erythrocyte's life span of approximately 100 to 120 days. As a result, HbA1c reflects the average blood glucose level during the preceding 2 to 3 months rather than daily variations in blood glucose levels. HbA1c is thus suitable to monitor long-term blood glucose control in individuals with diabetes mellitus. [2, 3]

The main functions of HbA1c are: (1) As an indicator of the overall control of blood glucose in diabetic patients; (2) If the value is over 9%, it indicates that diabetic nephropathy, arteriosclerosis, cataract and other complications will occur in patients with persistent hyperglycemia; (3) It can be used to guide the adjustment of treatment programs; (4) It is important for gestational diabetes mellitus to avoid fetal macrosomia, stillbirth, teratosis and preeclampsia. [4]

PRINCIPLE

VivaDiag Glycosylated Hemoglobin Test Kit (FIA) is based on fluorescence immunoassay technology. VivaDiag Glycosylated Hemoglobin Test Kit (FIA) uses a sandwich immunodetection principle, such that the fluorescence-labeled detector antibody binds to the target protein (Glycosylated Hemoglobin) in blood specimen. In the sample well of the device there is a membrane coated with HbA1c-specific monoclonal antibodies. A diluted sample is applied to the test device. The HbA1c will be bound by the HbA1c antibody which conjugated by the fluorescence to form fluorescence complex. When the fluorescence complex flows through the membrane, it will be captured by the HbA1c antibody. Signal intensity of fluorescence reflects amount of the HbA1c captured and is detected by VivaDiag POCT Analyzer to show the HbA1c concentration in specimen.

TRACEABILITY

Each VivaDiag Glycosylated Hemoglobin Test Kit (FIA) has the ID Card containing information about calibration curve of the particular reagent lot. The predefined calibration curve is adapted to VivaDiag POCT Analyzer.

The metrological traceability of values assigned to trueness-control materials can be traced to Certified Reference Material (IRMM/IFCC-466 HbA1c and IRMM/ IFCC-467 HbA1c).

COMPONENT

VivaDiag Glycosylated Hemoglobin Test Kit (FIA) contains the 'Test Device (packaged in pouch with desiccant)', 'ID Card', 'Buffer Tube (prefilled with buffer)', 'Sample Collector', 'Safety Lancet', 'Alcohol Pad' and 'Package Insert'.

- Test Device: It is composed of glass fiber, nitrocellulose membrane, plastic backer, absorbent paper and plastic cassette.
- ID Card: Calibration information.
- Buffer Tube: Sample diluent.
- Sample Collector: Collect sample.
- Safety Lancet: Puncture.
- Alcohol Pad: Disinfection.
- Package Insert: Instruction for use.

MATERIALS SUPPLIED

Each VivaDiag Glycosylated Hemoglobin Test Kit (FIA) contains:

- 25 Test Devices
- ID Card
- 25 Buffer Tubes
- 25 Sample Collectors
- 25 Safety Lancets
- 25 Alcohol Pads
- 1 Package Insert

MATERIALS REQUIRED BUT NOT SUPPLIED

- VivaDiag POCT Analyzer
- VivaDiag Glycosylated Hemoglobin Control Solution (FIA)
- Timer

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2 ~ 30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze.
- Do not open the pouch until ready to perform the assay.
- Once the pouch is opened, the test device should be used in 1 hour.
- All expiration dates are printed in Year-Month-Day format. Example: 2026-06-18 indicates June 18, 2026.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only. Testing should be applied by well-trained healthcare professionals, and conducted in central laboratories, GP offices, clinics, pharmacy and medical examination centers etc.
- Please follow the Package Insert when testing.
- The Test Device should remain sealed in its original pouch until just before use. Do not use the Test Device, if pouch is damaged or has already been opened.
- Do not reuse the Test Device and do not use your test kits beyond the expiration date. Biological materials used beyond their expiry date can become unstable and fail.
- It is recommended to use an anticoagulant blood collection tube (EDTA, heparin, or citrate). Other anticoagulants have not been evaluated in VivaDiag Glycosylated Hemoglobin Test Kit (FIA) and thus should not be used.
- Use the test kits at temperatures between 18 ~ 25°C.
- Use the test kits between 10 ~ 90% humidity.
- Do not use the Test Device in extremely temperature. If the Test Device has been stored refrigerated, bring to the ambient temperature (18 ~ 25°C) prior to testing and avoid moisture absorption.
- Keep the test kit away from direct sunlight.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits and other accessories.
- Do not interchange the test components between different lots

or use the test components after the expiration date, either of which might yield incorrect test result(s).

- Please contact your local distributor to solve problems timely if you have any questions or need help.
- VivaDiag Glycosylated Hemoglobin Test Kit (FIA) will provide accurate and reliable results subject to the below conditions.
  a) VivaDiag Glycosylated Hemoglobin Test Kit (FIA) should be used combined with VivaDiag POCT Analyzer.
  b) Whole blood samples should be collected with a suitable anticoagulant blood collection tube (EDTA, heparin, or citrate is recommended).

SAMPLE COLLECTION AND PROCESSING

The sample type for VivaDiag Glycosylated Hemoglobin Test Kit (FIA) is human whole blood.

Sample Collection

- Collect **fingerstick whole blood** sample

1. Wash the patient's hands with soap and warm water or clean with an Alcohol Pad. Allow to dry.
2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
3. Puncture the skin with a Safety Lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

- Collect **whole blood** sample

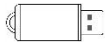
Collect the blood with a suitable anticoagulant blood collection tube (EDTA, heparin, or citrate is recommended).

Processing

- The fingerstick whole blood should be used immediately.
- If testing cannot be conducted within an hour after preparation of specimen, the whole blood should be stored at 2 ~ 8°C for 2 days, and avoid frozen.

PREPARE FOR TEST

- Turn on the Analyzer for at least 5 minutes before testing.
- If the test kit has been stored in a refrigerator, place it on a clean and flat surface at 18 ~ 25°C for at least 30 minutes before testing.
- Check the contents of VivaDiag Glycosylated Hemoglobin Test Kit (FIA): 'Test Device (packaged in pouch with desiccant)', 'ID Card', 'Buffer Tube (prefilled with buffer)', 'Sample Collector', 'Safety Lancet', 'Alcohol Pad' and 'Package Insert'.
- Check the label information of the ID Card to make sure that the ID Card matches the Test Device.
- Select the ID card that matches the current Analyzer being tested, according to the User's Manual of VivaDiag POCT Analyzer.

ID Card Type	
Code Chip 	USB Flash Drive 

TEST PROCEDURE

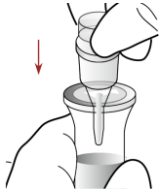
Input Information

1. Insert the ID Card into the port on the Analyzer.
2. When the information is read successfully, the test item will change to "**HbA1c**".
3. Select the correct sample type.

Note: *Please refer to the User's Manual of VivaDiag POCT Analyzer for complete information and operating instructions.*

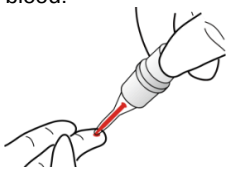
Run Test (Standard Test Model)

1. Take the Test Device out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Make a puncture on the top of the Buffer Tube by the Sample Collector. Do not touch the Buffer.

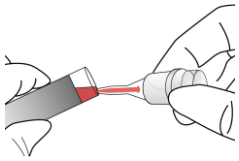


3. Collecting specimen refers to Sample Collection.
4. Draw **5 µL** human whole blood by using the Sample Collector.

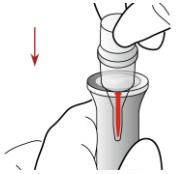
For fingerstick whole blood:



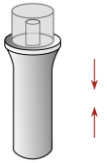
For whole blood (The whole blood sample should be well mixed at first):



5. Assemble the Sample Collector and Buffer Tube.



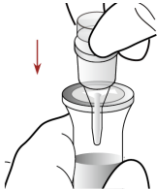
6. Start a **1 minute countdown**. Gently invert and mix the solution 10 times to mix it well. Use the mixed solution immediately after the countdown. Avoid bubbles.



7. Remove the cap from the assembled Buffer Tube. Discard the first drop of mixed solution onto the biological trash can.
8. Apply **3 drops** of the mixed solution vertically to the sample well of the Test Device. Avoid bubbles.
9. Insert the Test Device into the holder of VivaDiag POCT Analyzer. Ensure proper orientation of the Test Device before pushing it into the holder. An arrow has been marked on the Test Device especially for this purpose.
10. Click the button to start the test. The Analyzer will scan the sample-loaded Test Device after **5 minutes**.
11. Read the test result on the display screen of VivaDiag POCT Analyzer, or print it by clicking the "**Print**" button on the display screen.

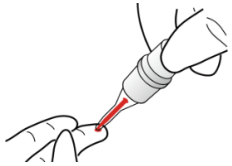
Run Test (Quick Test Model)

1. Take the Test Device out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Make a puncture on the top of the buffer tube by the Sample Collector. Do not touch the Buffer.

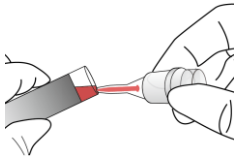


3. Collecting specimen refers to Sample Collection.
4. Draw **5 µL** human whole blood by using the Sample Collector.

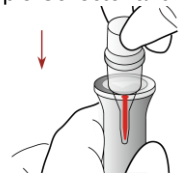
For fingerstick whole blood:



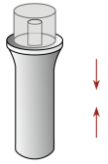
For whole blood (The whole blood sample should be well mixed at first):



5. Assemble the Sample Collector and Buffer Tube.



6. Start a **1 minute countdown**. Gently invert and mix the solution 10 times to mix it well. Use the mixed solution immediately after the countdown. Avoid bubbles.



7. Remove the cap from the assembled Buffer Tube. Discard the first drop of mixed solution onto the biological trash can.
8. Apply **3 drops** of the mixed solution vertically to the sample well of the Test Device. Avoid bubbles.
9. Place the sample-loaded Test Device on a clean, dust-free and flat surface and reaction for **5 minutes**.
10. Insert the Test Device into the holder of VivaDiag POCT Analyzer. Ensure proper orientation of the Test Device before pushing it into the holder. An arrow has been marked on the Test Device especially for this purpose.
11. Click the button to start the test. The Analyzer will scan the sample-loaded Test Device in seconds.
12. Read the test result on the display screen of VivaDiag POCT Analyzer, or print it by clicking the "**Print**" button on the display screen.

INTERPRETATION OF TEST RESULT

The Analyzer calculates the HbA1c test result automatically and displays "HbA1c" concentration on the screen.

Reference Interval:

NGSP (%): 4 ~ 6%

IFCC (mmol/mol): 20.22 ~ 42.08 mmol/mol

eAG (mg/dL): 68.1 ~ 125.5 mg/dL

Unit Conversion:

IFCC-HbA1c (mmol/mol) = [NGSP-HbA1c (%) - 2.15] * 10.929

eAG (mg/dL) = 28.7 * NGSP-HbA1c (%) - 46.7

Note: *Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings*

QUALITY CONTROL

- Users should follow government guidelines and/or accreditation requirements for 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.
- Quality 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 if the result and the symptoms are not consistent or if there are doubts about their accuracy.
- Control materials are not provided with VivaDiag Glycosylated Hemoglobin Test Kit (FIA). For more information regarding obtaining the control materials, contact with your local distributor for assistance.

Note: *Please refer to the Package Insert of VivaDiag Glycosylated Hemoglobin Control Solution (FIA) for detailed information.*

LIMITATIONS OF THE PROCEDURE

- The performance of this product has been established for human whole blood only. Other specimen types have not been evaluated.
- 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.
- There is a possibility that substances and/or factors may interfere with the test and cause false results. Technical or procedural errors can also contribute to erroneous results.
- The false positive results may be caused by the cross-reactions and/or other non-specific adhesion of certain sample components to the capture/detector antibodies.
- Test results must always be evaluated with other data available to the physician. 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 result cannot be used for diagnosis. If the result is not matched the clinical evaluation, please do more testing.

PERFORMANCE CHARACTERISTICS

- **Measuring Range and Detection Capability**

Measuring Range:

NGSP (%): 4 ~ 16%

IFCC (mmol/mol): 20.22 ~ 151.37 mmol/mol

eAG (mg/dL): 68.1 ~ 412.5 mg/dL

Limit of Blank (LoB): 2%

Limit of Detection (LoD): 3%

- **Precision**

Repeatability: On the one analyzer, the specified 3 levels of samples were tested for one day, measured 20 times a day.

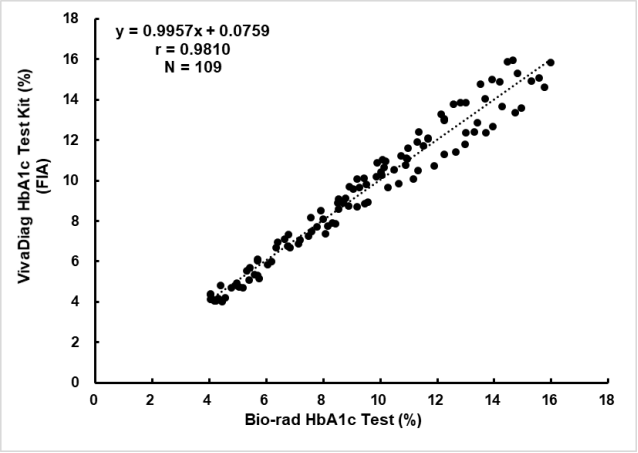
Reproducibility: In three laboratories, on the 3 analyzers, the specified 3 levels of samples were tested for 5 days by 3 operators, measured 5 times a day.

Sample	HbA1c (%)	Repeatability		Reproducibility	
		SD	CV (%)	SD	CV (%)
1	5	0.23	4.56	0.32	6.38
2	8	0.22	2.74	0.46	5.65
3	13	0.67	5.23	0.39	3.02

- **Accuracy**

A comparison study using 109 human fingerstick whole blood samples, demonstrated good correlation with a commercially available kit. Comparison between VivaDiag Glycosylated Hemoglobin Test Kit (FIA) and Bio-rad HbA1c Test is summarized in the following table and figure:

Method	Number	Intercept	Slope	Correlation Coefficient
Ordinary Linear Regression	109	0.0759	0.9957	0.9810



· **Specificity**

The following substances do not interfere with the test results at the indicated concentrations:

Interfering Substance	Concentration
Bilirubin	0.2 g/L
Triglycerides	10 g/L
Rheumatoid Factors	200 IU/mL

LITERATURE REFERENCES

[1] Goldstein DE,Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM. Tests of glycemia in diabetes. Diabetes Care 1995; 18:896-909.

[2] Goldstein DE, Little RR, Wiedmeyer HM, et al. Glycated hemoglobin: methodologies and clinical applications. Clin Chem 1986;32:B64-B70.

[3] Flückiger R, Mortensen HB. Review: glycated haemoglobins. J Chromatogr 1988;429:279-292.

[4] Goldstein DE, Little RR. More than you ever wanted to know (but need to know) about glycohemoglobin testing. Diabetes Care 1994; 17:938-939

INDEX OF SYMBOLS

	Consult instructions for use or consult electronic instructions for use
	Use-by date
	Contains sufficient for <n> tests
IVD	In vitro diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Manufacturer
	Date of manufacture
	Temperature limit
	Do not re-use
EC REP	Authorized representative in the European Community/European Union

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CE
IVD

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