EN REF F-A1C

STANDARD F

HbA1c

STANDARD™ F HbA1c

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Test device
(individually in a foil pouch with desiccant and Spoit™)

Extraction buffer

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

• STANDARD F Analyzer

SPECIMEN COLLECTION AND PREPARATION

■ Whole blood

[Capillary whole blood]

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the accurate volume of capillary whole blood using the Spoit in kit for the testing.
5. The capillary whole blood must be tested immediately after collection.

[Venous whole blood]

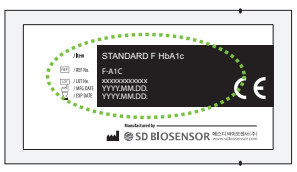
1. Collect the venous whole blood into the commercially available anticoagulant tube such as K2 EDTA, Sodium heparin, Sodium fluoride by venipuncture.
2. The venous blood treated by anticoagulant is able to test within 4 hours at room temperature.
3. If venous whole blood in an anticoagulant tube is stored in a refrigerator at 2-8°C / 36-46°F, the specimen can be used for testing within 24 hours after collection.
4. Do not use hemolyzed blood specimen.

- Anticoagulants such as K2 EDTA, Sodium heparin, Sodium fluoride do not affect the test result.
- As known relevant interference, haemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.
- Do not use the frozen blood or the artificial materials.

TEST PROCEDURE

■ Preparation

1. Allow kit components and collected specimen to room temperature (15-30°C/ 59-86°F) at least 30 minutes before starting the test.
2. Carefully read instructions for the STANDARD F HbA1c.
3. Check the expiry date at the back of the foil pouch. Use another lot if expiry date has passed.
4. Open the foil pouch, and check a test device, desiccant, and a Spoit containing a HbA1c latex tablet.



Foil pouch

Spoit™ (Blue)

Test device

Desiccant

If there is no violet colored Check Band on the membrane of the test device, do not use it.

Before Use **After Use**

Do not write on the barcode or damage the barcode of the test device.
If the color of the desiccant is changed from yellow to green, please do not use the test device.

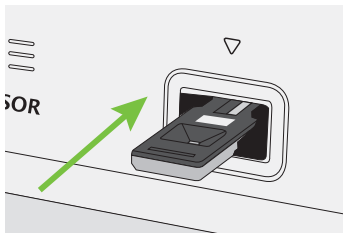
■ Analysis of specimen

'STANDARD TEST' mode | **STANDARD F200 and F2400 analyzer**

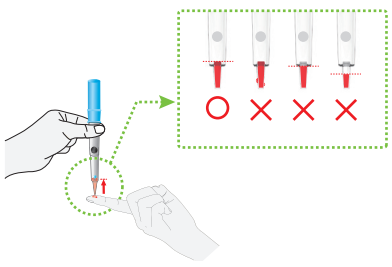
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device.

STANDARD F2400 analyzer	'Workplace' → 'Run Test' → Insert patient ID and / or operator ID on the analyzer
STANDARD F200 analyzer	'STANDARD TEST' mode → Insert patient ID and/or operator ID

2. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

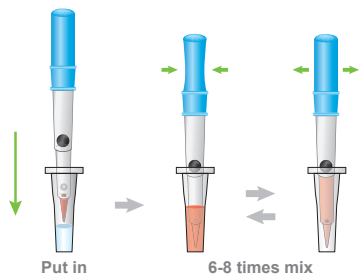


3. Collect the 5μl of blood specimen with the Spoit. The specimen will be collected automatically by the capillary action when the end of Spoit is put on the specimen.

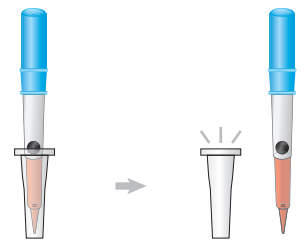


If you use the venous whole blood, check the collection date and the anticoagulant.

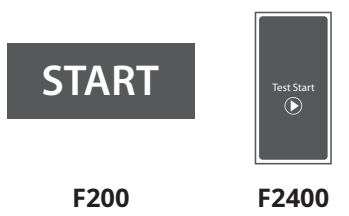
4. Insert the edge of the Spoit into an extraction buffer tube.
5. Mix the specimen, latex tablet, and extraction buffer by carefully pressing and releasing the rubber at the top of the Spoit for 6-8 times. Mix well to avoid bubble forming.



6. Collect all the specimen mixture with the Spoit from the tube.



7. After applying the specimen, immediately press the **'TEST START'** button.



F200 **F2400**

8. The analyzer will automatically display the test result after 3 minutes.

Read
After 3 mins

- Do not put bubbles in the specimen well of the test device.
- Discard the used test kit in proper container, according to your healthcare professional's recommendation.
- If you feel the test result is inaccurate or do not agree your test result, do not change the treatment and contact your healthcare professional.

The mark on the label between specimen well and result window is scanned by the STANDARD Analyzer and displayed on the screen.

INTERPRETATION OF TEST RESULTS

The STANDARD F HbA1c test range is reported 4.0% to 15.0%. If the result is below 4%, it will be reported as "↓4.0%". If the result is above 15%, it will be reported as "↑15%".

- Results should be considered in conjunction with the clinical history and other data available to the physician.
- If an error message appears on the analyzer's screen, refer to the analyzer's manual.

■ Calibration

STANDARD F HbA1c is calibrated to %HbA1c result of the Diabetes Control and Complication Trial (DCCT) through the National Glycohemoglobin Standardization Program (NGSP). All values in this insert manual are in NGSP calibration.

■ Expected values

%HbA1c	Interpretation of results
≤ 5.6%	Normal
5.7~6.4%	Pre-diabetes
≥ 6.5%	Diabetes

*ADA (American Diabetes Association) target for diabetes patients: 7%

EXPLANATION AND SUMMARY

■ Introduction

High levels of blood glucose result in over-glycation of proteins throughout the body including hemoglobin.[1] Glycation of hemoglobin can occur at the amino termini of the alpha and beta chains, as well as other sites with free amino groups.[1] Hemoglobin A undergoes a slow glycation with glucose that is dependent on the time-average concentration of glucose over the 3 months life span of red blood cells. The correlation of glycated hemoglobin (HbA1c) and blood glucose levels makes it a useful method of monitoring long-term blood glucose levels in people with diabetes.[2] Previous studies, such as the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), used glycated hemoglobin as a way to measure overall glycemic control during the studies. These studies and others have shown that tight glycemic control is associated with fewer diabetes-related complications (e.g., vision problems, cardiovascular problems, and kidney problems).[3] Studies show a direct relationship between %HbA1c and mean blood glucose (MBG) levels. For every 1% change in HbA1c, there is a change of about 30 mg/dL in MBG.[4-8]

■ Intended use

STANDARD F HbA1c is an *in vitro* diagnostic system for quantitative measurement of HbA1c in human capillary or venous whole blood. This test is for professional use to monitor glycemic control in people with diabetes. STANDARD F HbA1c should be used with the appropriate analyzer, STANDARD F Analyzers, manufactured by SD BIOSENSOR.

■ Test principle

STANDARD F HbA1c is based on a reflectometry and immunoassay technology. STANDARD F HbA1c uses an anti-HbA1c(%) antibody which is specific for the first few amino acid residues of the glycated N-terminus of the β-chain of hemoglobin A0. STANDARD F HbA1c contains a test device, latex-tablet and extraction buffer. The extraction buffer is instantly lysed to release the glycated hemoglobin (hereafter, HbA1c) and the latex-tablet included the blue dyed latex-microparticles conjugated to specific antibodies. When whole blood is added to the buffer solution and is mixed with the latex-tablet, the erythrocytes are instantly lysed to release the HbA1c. When the specimen mixture is loaded onto the specimen port of the test device, the mixture fluid migrates along the membrane of test device by capillary action and then HbA1c has been immobilized onto the anti-HbA1c antibody coated line. The amount of the blue conjugates on the anti-HbA1c line reflects the amount of HbA1c in the specimen. For measuring of total hemoglobin in the specimen, STANDARD F Analyzer measured the intensity of the total Hb assay zone color at the test device. Chemical and immuno reaction that occurs on the test panel are measured by optical system in STANDARD F Analyzer. This analyzer measures both fractions and an algorithm converts the result into the percentage HbA1c in the specimen.

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

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WARNINGS AND PRECAUTIONS

1. STANDARD F HbA1c is only use for *in vitro* diagnostic.
2. Carefully follow instructions and procedures described in this instruction before testing.
3. STANDARD F HbA1c should be used with STANDARD F Analyzers.
4. STANDARD F HbA1c should remain in its original sealed pouch until ready to use. Do not use the test kit if the pouch is damaged or the seal is broken.
5. STANDARD F HbA1c is only single use. Do not re-use it.
6. A blood specimen of person with hemolytic anemia or microorganism infection can produce the inaccurate results.
7. Extreme Hematocrit (below 25% or over 65%) may affect the test result.
8. Do not use frozen blood or any artificial materials.
9. If the total hemoglobin result is out of 7-23g/dL, the test result the test result could be inaccurate.
10. Do not use other anticoagulant. (K2 EDTA, Sodium heparin, Sodium fluoride is available.)
11. Before testing, check the latex tablet if it is not contaminated or broken.
12. Place the analyzer on a flat surface when in use.
13. Wash your hands in warm, soapy water. Rinse well and dry completely before testing.
14. Discard the used test kit according to the proper method.
15. Mix the blood specimen and extraction buffer well. And then, collect all of the mixed solution.
16. Check the expiration date printed at the pouch or package.
17. Blood specimen, HbA1c latex tablet and extraction buffer should be well mixed by using the rubber at the top of the Spoit™. And then, immediately apply the specimen at the test device within 1 minute at least.
18. Use the STANDARD F HbA1c at 15-30°C / 59-86°F.
19. Mix well to avoid bubble forming and do not put bubbles in the specimen well of the test device.
20. All kit components must be at room temperature (15-30°C / 59-86°F) 30 minutes before running the assay.
21. Do not write on the barcode or damage the barcode of the test device.

PERFORMANCE CHARACTERISTICS

■ ANALYTICAL PERFORMANCE

1. Analytical Sensitivity – LoB, LoD and LoQ

The analytical sensitivity [Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)] of **STANDARD™ F HbA1c** is shown below;

HbA1c (%)		
LoB	**LoD**	**LoQ**
2.4	2.8	4.0

2. Precision

The following precision results of **STANDARD™ F HbA1c** meet the acceptance criteria of both repeatability and reproducibility (CV ≤3%).

Repeatability													
HbA1c (%)		**Within-run**			**Between-run**			**Between-day**			**Total CV**		
Ref, value	**N**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**
5.2	50	5.2	0.09	1.7%	5.2	0.10	1.9%	5.2	0.03	0.6%	5.2	0.10	1.9%
6.9	50	7.0	0.14	2.0%	7.0	0.12	1.7%	7.0	0.06	0.9%	7.0	0.13	1.9%
10.2	50	10.2	0.20	1.9%	10.2	0.18	1.7%	10.2	0.11	1.1%	10.2	0.20	2.0%

Reproducibility													
HbA1c (%)		**Between-Site**			**Between-Lot**			**Between-Operator**			**Between-Analyzer**		
Ref, value	**N**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**	**Mean**	**SD**	**CV**
5.2	30	5.3	0.12	2.2%	5.2	0.11	2.1%	5.2	0.13	2.4%	5.2	0.10	1.9%
6.9	30	6.9	0.20	2.8%	7.0	0.19	2.7%	6.9	0.19	2.7%	6.9	0.15	2.1%
10.2	30	10.3	0.21	2.0%	10.3	0.22	2.2%	10.2	0.23	2.2%	10.3	0.22	2.2%

3. Interference Substances

The following substances do not interfere the test result up to the indicated concentrations;

Substance	Concentration
Acetaminophen	30mg/dL
Ibuprofen	50mg/dL
Rheumatoid Factor	600IU/mL
Metformim	5.1mg/dL
Glibenclamide	0.2mg/dL
Labile A1C	2,000mg/mL
Carbamylated hemoglobin	20mg/mL
Acetylated hemoglobin	200mg/mL
Acetylsalicylic acid	30mg/dL
Ascorbic acid	10mg/dL
Bilirubin	20 mg/dL
Caffeine	30mg/dL
Hydroxyzine dihydrocholoride	30mg/dL
Triglyceride	900mg/dL
Glyburide	20mg/dL
Dopamine	2mg/dL

QUALITY CONTROL

■ Calibration

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzers' manual.

[When to use calibration set]

1. Before using the analyzer for the first time.
2. When you drop the analyzer.
3. Whenever you do not agree with your result.
4. When you want to check the performance of an analyzer and test device.

[How to use calibration set]

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

The STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with test device. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

■ External quality control

Quality control testing should be run to check the performance of STANDARD F HbA1c and STANDARD F Analyzers. SDB HbA1c Control manufactured by SD BIOSENSOR should be used for quality control testing. Control test should be conducted in accordance with the instructions of SDB HbA1c Control.

Control test should be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in instructions for use of SDB HbA1c Control and in accordance with local, state and federal regulations or accreditation requirements.

BIBLIOGRAPHY

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5. Brooks DE, Devine DV, Harris PC, et al. RAMP(TM): A rapid, quantitative whole blood immunochromatographic platform for point-of-care testing. Clin Chem 1999;45:1676-1678.
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8. Rohlfing CL et al., Use of GHb (HbA1c) in Screening for Undiagnosed Diabetes in the U.S. Population. Diabetes Care 2000; 23(2):187-191.

CE IVD

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REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE This product fulfills the requirements of the European Directive 98/79/EC.