SCREEN

SCREEN IFA TEST HBA1C
(Whole Blood)
Package Insert

REF: SC-1347	English

A rapid test for measuring HbA1c value in whole blood with the use of SCREEN® fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The HbA1c Test Cassette (Whole Blood) is based on Fluorescence immunoassay for the quantitative detection of HbA1c in whole blood.The measure of HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus. This test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.

SUMMARY

The human erythrocyte is freely permeable to glucose. Within each erythrocyte a slow, continuous, non-enzymatic process between hemoglobin A and various sugars takes place. The product formed is known as glycated hemoglobin, or glycohemoglobin1.
The chronic elevated blood sugar level of persons with diabetes mellitus will over time cause damage to the small vessels of the body. This damage develops slowly over years and is known to cause late complications. Good metabolic control, i.e. lowering the HbA1c concentration, has proven to delay the onset and slow the progression of diabeteslate complications2,3,4.
It is concluded that measurements of HbA1c can be used to diagnose diabetes mellitus. When in agreement with national regulations, HbA1c Test can be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabete.

PRINCIPLE

The HbA1c Test Cassette (Whole Blood) detects HbA1c based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. HbA1c in the sample, attaches to the HbA1c antibody which is conjugated with fluorescent microspheres. Then captured by hemoglobin(Hb) antibody coated on the nitrocellulose membrane.The concentration of HbA1c in the sample correlates linearly with the fluorescence signal intensity. According to the two fluorescence intensity, SCREEN® Fluorescence Immunoassay Analyzer could calculate the value of HbA1c percentage in the sample.

REAGENTS

The test includes HbA1c antibody coated fluorphores, Rabbit IgG coated fluorphoers, Hb antibody and Goat anti Rabbit IgG coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.

The HbA1c Test Cassette should only be used with the SCREEN® Analyzer by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze**.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15-30℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

Blood Sample Taking
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within half-day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing.
4. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

Sample Dilution / Sample Stability
1. The specimen (10ul of whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample rest for approximately 1 minute.
4. It is best to test the diluted sample immediately.

MATERIALS

Materials Provided
- Test Cassettes
- Specimen Collection Tubes with Dilution Buffer
- ID Card
- Package Insert

Materials Required But Not Provided
- Timer
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Turn on the Analyzer power. Then according to the need, select "**Standard test**" or "**Quick test**" mode.
2. Take out the ID card and insert it into the Analyzer port.
3. **Whole blood:** Transfer **10 μL whole blood** into the buffer tube with pipette; mix the specimen and the buffer throughly.
4. **Add diluted specimen with a Pipette:** Pipette **75μl diluted specimen** into the sample well of the test cassette. Start the timer at the same time.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

Quick test" mode: Insert the test cassette into the Analyzer at **10 minutes** after sample application and click "**Test**", the Analyzer will automatically give the test result after a few seconds.

"**Standard test**" mode: Insert the test cassette into the Analyzer immediately after sample application, click "**New test**" at the same time, the Analyzer will automatically counting down 10 minutes. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for HbA1c is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyze.
Linearity range of HbA1c Test is 4~ 14.5%.
Reference range:4.0~6.0%.

QUALITY CONTROL

Each HbA1c Test Cassette contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The HbA1c Test Cassette (Whole Blood) is for professional in vitro diagnostic use, and should only be used for the quantitative detection of HbA1c.
2. The HbA1c Test Cassette (Whole Blood) will only indicate the HbA1c level in the specimen and should not be used as the sole criterion for evaluating Diabetes. Laboratories can have their separate reference values for HbA1c to be under control.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
   The results of HbA1c Tests are based on measuring the levels of HbA1c in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

The following cut-off points have been established by the Diabetes Control and Complications Trail Research Group and have been adapted by many countries for the evaluation of the degree blood glucose control in diabetic patients.

Concentrations	Clinical Reference
4 ~ 6%	Non diabetics
6 ~ 6.5%	Goal
6.5 ~ 8%	Good control
> 8%	Action suggested

It is recommended that each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the HbA1c results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The HbA1c Test Cassette (Whole Blood) can detect levels of HbA1c as low as 4% inl whole blood.
3.Detection range
4~ 14.5%
4. Linearity range
4~ 14.5% , R≥0.990
5. Precision
Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 5%, 10% of HbA1c. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 5%, 10% of HbA1c. C.V. is ≤15%.

6.Interfering Substances

The following potentially interfering substances were added to 5% and 10% HbA1c specimens, respectively.

Ascorbic Acid: 50mg/dL Bilirubin: 200mg/dL

Glucose: 600mg/dLTriglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay

LITERATURE REFERENCES

1. Bunn F et al. The Biosynthesis of Human Hemoglobin A1c. Slow glycosylation of hemoglobin in vivo. J Clin Invest 1976; 57:1652-1659.
2. The Diabetes Control and Complications Trial Research Group, The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329:977-986.
3. Sacks DB et al., Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. ClinChem 2002; 48:436-472.
4. Stratton IM et al., Association of glycemia with macrovascular and microvascular complications of type 2 diabetes: prospective observational study (UKPDS 35). BMJ 2000; 321:405-412.

INDEX OF SYMBOLS

	Consult Instructions for Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

SCREEN ITALIA S.r.l.
Via dell'Artigianato, 16
06089 - Torgiano - Perugia - Italia
www.screenitalia.it **info@screenitalia.it**

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