

ABRA BLOOD GLUCOSE TEST STRIPS

Instruction for use

For Testing Glucose in Capillary Whole Blood

IN VITRO DIAGNOSTIC MEDICAL DEVICE.

DEVICE FOR SELF-TESTING. FOR EXTERNAL USE ONLY.

IMPORTANT: Please read this information and your ABRA Blood Glucose Monitoring System user’s manual before using ABRA Test Strips. Call Customer Service Phone number (depends on country) immediately if these instructional materials or your meter results seem unclear.

INTENDED USE

The ABRA Blood Glucose Test Strips are used with the ABRA Blood Glucose Meter for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm and forearm. The ABRA Blood Glucose Monitoring System is intended for use by lay users and should only be used by a single person. The ABRA Test Strips are for testing outside the body (in vitro diagnostic use).

TEST PRINCIPLE

On each test strip there is a test area containing reaction chemicals. When blood is applied to this area, a chemical reaction takes place, then a transient electrical current is formed. The blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is showed on the display. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The ABRA Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

PRECAUTIONS

- For in vitro diagnostic use (outside the body) only.

Do not reuse test strips.

Do not use test strips beyond the expiration date printed onthe package since this may cause inaccurate results.

Discard the vial and any unused test strips 3 months after you first open it. Constant exposure test strips to air may destroy chemicals in the test strip. This damage can cause incorrect readings.

The sample must only be applied to the tip of the test strip.

Do not apply blood or control solution to the top, left or right sides of the test strip. This may cause inaccurate test results.

Use only the ABRA Blood Glucose Meter with the ABRA Test Strips.

Keep the test strip vial away from children. The cap is a choking hazard. The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Any change in medication based on the ABRA blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended. Consult your physician or healthcare professional before making changes in your treatment plan based on your blood glucose test results.

Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.

All devices contaminated with blood should be disposed of properly.

- If you get ABRA Control Solution test results that fall outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the ABRA may not be working properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label.

Alternate site testing (AST) should ONLY be used in the following intervals:

- In a pre-meal or fasting state. (more than 2 hours since the last meal)
- Two hours or more after taking insulin.
- Two hours or more after exercise.

DO NOT USE AST IF:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- If you are pregnant.

When using the Meter, Standard precautions must be taken by the users for their own safety. To assure that you are not placing yourself or other people at risk, always remember:

- The Meter and Lancing Device are for single person use. Do not share them with anyone including other family members.
- All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between each user, even after you have performed cleaning and disinfection.
- Refer to your user's manual section "Clean and Storage" for how to clean your meter and lancing device.



STORAGE AND HANDLING

- Store at room temperature between 4-30°C (39-86°F). Do not refrigerate or freeze. Avoid exposing test strips to extreme temperatures.
- Store away from direct sunlight and heat.
- Use each strip immediately after removing it from the vial.
- Store your test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- Do not bend, cut, or alter the Test Strip in any way.
- With clean, dry hands you may gently touch the test strip anywhere when removing it from the vial or inserting it into the meter.

HOW TO DO THE TEST

See your User’s Manual for a step-by-step guide on how to do the test.

1. Select the Puncture Site to Obtain Blood

Usually, sample is obtained from fingertip. It is possible to use blood from alternative sites (AST). For details refer to User’s Manual of ABRA Blood Glucose Monitoring System.

2. Blood Glucose Testing

Insert a Test Strip to the meter. The meter will turn on. Use the Lancing Device to obtain the right size blood drop. Refer to your Lancing Device User’s Instruction for how to lance your finger, forearm and palm. Then obtain a blood sample about the size of a pinhead. Gently touch only one edge of the Test Strip to the blood sample. Do not press the edge of the strip against the test site. When the strip is full of blood, the meter will “beep” or you will see the test strip chamber area completely filled.

3. Read Results

Read the test results in an average of 5 seconds. The result will be stored in the meter memory. Results are displayed as mg/dL (milligrams per deciliter of blood) or mmol/L (millimoles per liter of blood) depending on the units you chose when you set up your meter. To change the units displayed, see your User’s Manual section “Setting Up the Meter.” Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

WHAT DO YOUR RESULTS MEAN?

NORMAL GLUCOSE VALUES

The normal fasting glucose range for a diabetic adult is 70 to 130 mg/dL (3.9 to 7.2 mmol/L). One to two hours after meals, normal glucose values should be less than 180 mg/dL (10.0 mmol/L).1 For people with diabetes, consult your physician or healthcare professional for the target glucose values that are right for you.

LOW GLUCOSE VALUES

The ABRA Meter displays results between 20 and 600 mg/dL (1.1 and 33.3 mmol/L). If your test result is lower than 20, “Low” (LO) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). You should immediately treat low blood sugar as recommended by your healthcare professional.

HIGH GLUCOSE VALUES

If your test result is above 600 mg/dL (33.3 mmol/L), “High” (HI) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). You should immediately treat high blood sugar as recommended by your healthcare professional.

UNEXPECTED RESULTS

Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. **If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.**

LIMITATIONS

The ABRA Blood Glucose Test Strips give accurate results when the following limitations are observed:

- Use only the ABRA Test Strip with the ABRA Meter.
- Use only capillary whole blood from finger, palm and forearm. Do not use plasma or serum.
- Do not use neonate samples. ABRA Test Strips are not validated for and should not be used for testing neonatal blood specimens.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20 to 600mg/dL (1.1-33.3 mmol/L).
- This system can be used up to an altitude of 7545 feet (2300 m.n.p.m).
- The test strips are for single use only. Do not reuse test strips.
- ABRA Test Strip does not interfere with the hematocrit at a normal range (35-55%) of blood glucose. High (above 55%) and low (below 35%) hematocrit can cause false results. Patients with higher hematocrit values (above 55%) will usually test lower whiles patients with lower hematocrit values (below 35%) will test higher. Please ask your healthcare professional if you do not know your Hematocrit level.
- Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.

- Lipemic samples; Cholesterol up to 375 mg/dL or triglycerides up to 2,000 mg/dL do not significantly affect test results. However, glucose values in specimens beyond these levels, should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- Antiglycolysis and anticoagulants in blood samples may affect the test results.
- Severe dehydration, diabetic ketoacidosis, hyperosmolar non-kitotic state, hypotension, shock, or peripheral vascular disease 2,3,4 may cause inaccurate results.
- Critically ill patients should not be tested with home use blood glucose monitors as it may lead to inaccurate results.

Summary of Substances with Interference		
Interferents	Limiting Concentration	Therapeutic Concentration
Acetaminophen	> 3 mg/dL	2 mg/dL
Ascorbic acid	> 7.5 mg/dL	2 mg/dL
Cholesterol	> 375 mg/dL	30 mg/dL
Creatinine	> 30 mg/dL	1.5 mg/dL
Ibuprofen	> 40 mg/dL	4.2 mg/dL
Maltose	> 40 mg/dL	120 mg/dL
Salicylate	> 125 mg/dL	30 mg/dL
Tolazamide	> 3.75 mg/dL	2.5 mg/dL
Tolbutamide	> 100 mg/dL	10 mg/dL
Triglyceride	>2000 mg/dL	190 mg/dL
Uric acid	>15 mg/dL	7.7 mg/dL

QUALITY CONTROL

The control solutions are used to check the performance of the ABRA meter, Test Strips, and your testing technique. The system is performing correctly if the control solution test result falls within the specific control solution range listed on your Test Strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- error in performing the test,
- expired or contaminated control solution,
- test strip deterioration or meter malfunction.

If the problem persists, the system may not be working properly. DO NOT continue to use the system to test your blood glucose level. If you continue to get results that fall outside the specified range, please call Customer Service.

Note: ABRA Control Solutions are required but not supplied with Test Strips for checking the system. For order information, please contact Customer Service.

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

20–600mg/dL (1.1mmol/L to 33.3 mmol/L)

SYSTEM ACCURACY

The accuracy of the ABRA System was compared with YSI 2300 Stat Plus glucose analyzer with fingertip testing done by persons with diabetes. The linear regression statistics are derived from a plot of the ABRA capillary data (y) versus YSI glucose analyzer (x). The linear regression equation for the study was y=0.99x+1.78. The coefficient was 0.9826. The sample numbers were 104. The glucose range of the sample was 46–442mg/dL.

ISO 15197: 2013 requirement: 95% of individual glucose results falling within ±15mg/dL at glucose concentration for samples <100mg/dL and within ±15% at glucose concentrations ≥100mg/ dL. The accuracy study was performed with a total of 104 persons and 3 lots of Test Strips. The total number of measured values is 624, There are 622 of 624 values (99.7%) are within the system accuracy criteria.

Accuracy results for glucose concentration < 100mg/dL(5.55 mmol/L)		
Within ± 5mg/dL (0.27 mmol/L)	Within ± 10mg/dL (0.55 mmol/L)	Within ± 15mg/dL (0.83 mmol/L)
58.3%(119/204)	89.7%(183/204)	100.0%(204/204)

Accuracy results for glucose concentration ≥100mg/dL (5.55 mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
52.1%(215/420)	86.9%(365/420)	99.5%(418/420)

Accuracy results for glucose concentrations between 46–442mg/dL	
Within ±15mg/dL(0.83 mmol/L) or ±15 %	
99.7% (622/624)	

Consensus Error Grid of Three Lots						
Region	A+B	A	B	C	D	E
Points	624	623	1	0	0	0
CEG %	100%	99.8%	0.2%	0%	0%	0%

USER PERFORMANCE EVALUATION

The layer user study of the ABRA system was assessed with 1 lots of Test Strip and 104 lay users by comparing one meter’s reading of capillary blood from fingertip, palm and forearm respectively with YSI 2300 glucose analyzers. A study evaluating glucose values from fingertip capillary blood samples obtained by 104 lay persons showed the following results: 96.6 % within ±15mg/dL (±0.83mmol/L) of the medical laboratory values at glucose concentrations below 100mg/dL (5,55mmol/L), and 98.7 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100mg/dL (5,55mmol/L).

Accuracy results for glucose concentration < 100mg/dL(5.55 mmol/L)			
	Within ± 5mg/dL (0.27 mmol/L)	Within ± 10mg/dL (0.55 mmol/L)	Within ± 15mg/dL (0.83 mmol/L)
Fingertip	51.7%(15/29)	86.2%(25/29)	96.6%(28/29)
Palm	62.1%(18/29)	86.2%(25/29)	96.6%(28/29)
Forearm	58.6%(17/29)	75.9%(22/29)	96.6%(28/29)

Accuracy results for glucose concentration ≥100mg/dL (5.55 mmol/L)			
	Within ± 5%	Within ± 10%	Within ± 15%
Fingertip	52.0%(39/75)	84.0%(63/75)	98.7%(74/75)
Palm	50.7%(38/75)	88.0%(66/75)	100.0%(75/75)
Forearm	50.7%(38/75)	76.0%(57/75)	97.3%(73/75)

Accuracy results for glucose concentrations between 74–442mg/dL	
Within ±15mg/dL(0.83 mmol/L) or ±15 %	
Fingertip	99.0% (103/104)
Palm	99.0% (103/104)
Forearm	97.1%(101/104)

REPEATABILITY AND PRECISION

Between-run precision of ABRA test strips was measured with venous blood samples in the laboratory. The results for total three hundred test strips from 3 lots (n=300) concluded the following repeatability and precision estimates.

Mean Blood Glucose (mg/dL)	43.8	80.8	129.	222	351
SD (mg/dL) or CV%	2.7	3.7	4.3%	2.6%	2.0%

INTERMEDIATE PRECISION

Ten replicate assays drawn from 3 strip lots were run on ABRA Blood Glucose Meters each day for a total of 10 days. Control solutions at three concentration levels were used in the testing. The results concluded the following intermediate precision estimates










Mean of Control Solution (mg/dL)	45.7	113.2	341.1
SD (mg/dL) or CV%	2.8	2.9%	2.5%

CHEMICAL COMPOSITION

Glucose oxidase (Aspergillus niger)	1.4% w/w
Potassium ferricyanide	2.6%w/w
Non-reactive ingredients	96%w/w

REFERENCES

1. American Diabetes Association Clinical Practice Recommendations, Diabetes Care, 2008:31(supplement 1) S12–S54.
2. Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingerstick glucose determination in shock. Ann Int Med 114: 1020–1024. 1991
3. Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990
4. Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease.Practical Diabetes 3: 100. 1986.

 4 °C	Storage Temperature		For single use only	IVD	In vitro diagnostic medical device - only for external use
	Consult instructions for use		Number of test kit	LOT	Batch code
	Use by		Keep dry	REF	Catalogue Number
	Manufacturer		Do not use if package is damaged		
Rev.	Last revision of the instruction for use		Keep away from sunlight		

 0470






 0197

 4 °C

 30 °C





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