McKESSON

Blood Glucose Test Strips

50 Test Strips. For self testing and professional use.

IMPORTANT: Please read this information and your McKesson blood glucose monitoring system user manual before using test strips. If you have any questions, contact technical support at 1-877-979-5454. To order, use MFR #ALL03AM0201GM for the McKesson blood glucose monitoring system.
NOTE: Your meter can show results either in "mg/dL" or "mmol/L" units. It is very important to use the correct unit of measurement to properly manage your diabetes.

- **If you live in the USA, you should use mg/dL; your result will NEVER have a decimal point.**
- **If you live in Canada and some European countries, you should use mmol/L; your result will ALWAYS have a decimal point.**

INTENDED USE
McKesson blood glucose test strips are used with McKesson blood glucose monitoring system for quantitatively measuring glucose in venous, arterial and capillary whole blood. Testing sites include traditional fingertip site along with palm, upper arm, forearm, thigh and calf. McKesson blood glucose test strips are for self-testing outside the body (*in vitro* diagnostic use). Self-testing blood glucose regularly can help you know how well your diabetes is being controlled. Diabetes should be managed under the guidance of a doctor or healthcare professional.

STORAGE AND HANDLING
- Store the package at temperatures between 36°F-86°F (2°C - 30°C). Avoid direct sunlight and excessive humidity.
- Always close the vial with the cap immediately after removing a test strip. If the test strip vial is left open for a long period of time, test strips will become unusable.
- Use the test strips immediately after removing it from the vial.
- Use all the test strips within 4 months after the first opening.
- Store your test strips only in their original vial; do not transfer them to a new bottle or any other container.
- Do not handle the test strips with wet hands.
- Do not bend, cut, or alter a test strip in any way.

WARNING: Keep the test strip vial away from the reach of children.
The vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

PRECAUTIONS:
- The McKesson blood glucose monitoring system is calibrated to produce values equivalent to plasma specimens on a laboratory analyzer.
- Self-monitoring of blood glucose level using these strips cannot substitute the medical examination and treatment. This product can only help the patient to consult a doctor with more information.
- McKesson blood glucose monitoring system is intended only for outside the body use (*in vitro* diagnostic use).
- McKesson blood glucose test strips are designed for use with the McKesson blood glucose monitoring system only.
- **Make sure that the displayed code number matches the number on the vial of test strips. Mismatching numbers will cause incorrect test results.**
- Do not use expired test strips.
- Do not reuse test strips.

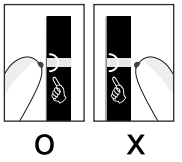
MATERIALS PROVIDED:
- McKesson blood glucose test strips

MATERIALS REQUIRED BUT NOT PROVIDED
- McKesson blood glucose monitoring system and user manual
- Lancing device and lancets

TEST PROCEDURE
For more detailed directions, see the McKesson blood glucose monitoring system USER MANUAL.
- Check that the expiration date for the test strips has not lapsed.
- Wash your hands with soap and warm water. Rinse and dry them thoroughly. Perspiration, dirt or water remaining on the finger may cause incorrect test results.

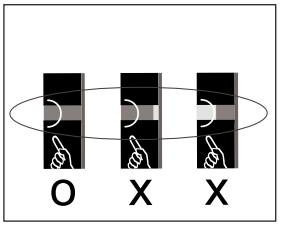
MEASURE YOUR GLUCOSE LEVEL
- Each time you test, check that the code number on the meter display matches the code number on the test strip vial.
- Remove a test strip from the vial.
- Recap the vial immediately. With the printed side facing up, insert the test strip firmly into the test port of your meter until it turns on automatically and beeps.
- The code, strip, and blood-shaped symbol will appear.
- Collect a drop of blood by using a lancing device. Touch and hold the drop of blood to the side edge of the test strip, where it meets the narrow channel (the reaction chamber).

IMPORTANT: Make sure you apply blood in the direction of the arrow.
- The test strip will automatically draw blood into the reaction chamber and the meter starts measuring.



IMPORTANT: Hold the blood drop to the reaction chamber of the test strip until blood has completely filled the confirmation window. If the confirmation window does not fill completely before the meter
begins to count down, do not add more blood to the test strips; discard the test strip and repeat the test.

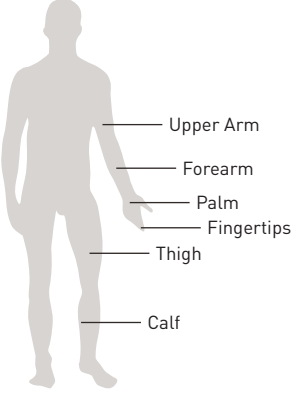
Adequate blood volume



- In the case of insufficient blood, Error message will be displayed. See the figure at right for the required blood volume and perform the test.
- The confirmation window must be filled by blood.
- If any yellow color of the confirmation window is still visible after the blood application or the window looks spotted irregularly, you should discard the test strips and repeat the test.

TEST PRINCIPLE
The McKesson blood glucose monitoring system is based on measurement of electrical currents caused by the reaction of glucose with the reagents on the gold electrode of the strip. The blood sample is drawn into the strip's reaction chamber through capillary action. Glucose in the sample reacts with glucose dehydrogenase and mediator.
This reaction creates electrical currents. The consequent electrical currents is proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the McKesson blood glucose monitoring system.

ABOUT ALTERNATE SITE TESTING (AST)



• Important: There are limitations for doing AST.
Please consult your healthcare professional before you do AST.

• What is AST?
Alternate site testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The McKesson blood glucose monitoring system allows you to test on your upper arm, forearm, palm, thigh and calf.

• What's the advantage?
Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous, and you will therefore not feel as much pain as you will experience at the fingertip.

• When to use AST?
Food, medication, illness, stress, and exercise all can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing your blood glucose level during or immediately after a meal, physical exercise, or stressful event, take the blood sample from your finger only, two hours or more after your last meal.

USE AST ONLY:
- Two hours or more after your last meal
- Two hours or more after taking insulin
- Two hours or more after exercise

DO NOT USE AST IF:
- You have reason to believe you have hypoglycemia or hyperglycemia
- Your routine glucose results are often fluctuating
- You are pregnant

MEASURE RANGE:
This test strip can measure blood glucose in the range 20-600 mg/dL (1.1-33.3 mmol/L). 'Lo' will be displayed when the glucose level is below 20 mg/dL (1.1 mmol/L). 'Hi' will be displayed when the glucose level is above 600 mg/dL (33.3 mmol/L). If 'Hi' or 'Lo' appears instead of a result, repeat the test. If the same message appears, consult your healthcare professional immediately.

EXPECTED VALUES (For people without diabetes)[1]

Status	Range
Fasting and Before meals	70 - 100 mg/dL (3.9-5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

IMPORTANT:
In the absence of unequivocal hyperglycemia these criteria should be confirmed by repeat testing on a different day. High or Low blood glucose results may have serious medical consequences. If your blood glucose result is Low or High, we recommend you consult a healthcare professional immediately.

QUALITY CONTROL
When to check the monitoring system with Control Solution:
- If you leave the cap off the vial of test strips
- When you open a new vial of test strips
- When you think our results are not accurate
- When you want to check the performance of the meter and test strip
- If you drop the meter

Test results using control solution should fall within an expected range of results that you will find printed on the vial of test strips that you are using. If control solution test results fall outside this range, repeat test. If the test result still is not acceptable, contact technical support at 1-877-979-5454. Monday through Friday, 9AM - 5PM EST.
Results that fall outside the range may be caused by:
- Error in performing the test
- Failure to shake the control solution vial well
- Expired or contaminated control solution
- Test strip deterioration
- A problem with the meter

Please refer to the user manual for instructions on how to perform a glucose control solution test.

HEALTHCARE PROFESSIONALS
Blood glucose determination with venous blood must be performed within 15 minutes of sample collection to avoid errors from glycolysis. The blood should be collected in EDTA or heparin vacutainer tubes. Do not shake the tube vigorously.

CHEMICAL COMPOSITION (per strip)

Glucose Dehydrogenase (Aspergillus oryzae)	7μg
Potassium Ferricyanide	26μg
Immobilizer	1.6μg
Stabilizer	0.5μg

LIMITATIONS
Serum or plasma will affect the measurement. Use the meter between 50°F-104°F (10°C-40°C) and below 85% relative humidity. McKesson blood glucose test strips may be affected by hematocrit value below 20% or above 60%. McKesson blood glucose test strips may be used to altitudes up to 8200 ft without an effect on test results. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose monitoring systems.

Depending on the concentration, below substances may affect the test results.

Ascorbic acid	> 4 mg/dL (0.2 mmol/L)
Uric acid	> 10 mg/dL (0.6 mmol/L)
Acetaminophen	> 6 mg/dL (0.4 mmol/L)
Total bilirubin	> 4 mg/dL (0.07 mmol/L)
Triglyceride	> 300 mg/dL (3.3 mmol/L)

PERFORMANCE CHARACTERISTICS
The performance of McKesson blood glucose test strips has been evaluated in clinical tests.[2]

Accuracy: The accuracy of the McKesson blood glucose monitoring system was assessed by comparing blood glucose results obtained by 130 diabetic patients with those obtained using a YSI Model 2300 STAT Plus Glucose Analyzer.

FOR GLUCOSE CONCENTRATION < 75mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Patient	50%	94%	100%
Technician	53%	88%	100%

FOR GLUCOSE CONCENTRATION ≥ 75mg/dL

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Patient	70.8%	93.4%	100%	100%
Technician	71.2%	93%	99%	100%

Correlation coefficient(R) should be more than 0.95.
The Correlation coefficient of the McKesson Blood Glucose Monitoring system was more than 0.95.

Repeatability (using venous whole blood):

Level	SD	CV
58 mg/dL	1.88 mg/dL	3.22%
103 mg/dL	1.95 mg/dL	1.89%
150 mg/dL	2.73 mg/dL	1.82%
190 mg/dL	3.72 mg/dL	1.96%
324 mg/dL	5.95 mg/dL	1.84%

Reproducibility (using control):

Level	SD	CV
39.8 mg/dL	2.32 mg/dL	5.82%
110 mg/dL	3.28 mg/dL	2.99%
311 mg/dL	9.20 mg/dL	2.96%

ACCURACY OF AST:
The accuracy of the McKesson Blood Glucose Monitoring System was assessed by comparing blood glucose results obtained by 51 diabetic patients with capillary blood obtained using a YSI Model 2300 STAT Plus Glucose Analyzer.

FOR GLUCOSE CONCENTRATION < 75mg/dL

	PATIENT			TECHNICIAN		
	Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
Finger	6/9(67%)	9/9(100%)	9/9(100%)	5/9(56%)	8/9(89%)	9/9(100%)
Palm	5/9(56%)	9/9(100%)	9/9(100%)	5/9(56%)	9/9(100%)	9/9(100%)
Upper arm	5/9(56%)	8/9(89%)	9/9(100%)	6/9(67%)	9/9(100%)	9/9(100%)
Forearm	6/9(67%)	9/9(100%)	9/9(100%)	5/9(56%)	9/9(100%)	9/9(100%)
Thigh	6/9(67%)	9/9(100%)	9/9(100%)	7/9(78%)	9/9(100%)	9/9(100%)
Calf	5/9(56%)	8/9(89%)	9/9(100%)	7/9(78%)	9/9(100%)	9/9(100%)

FOR GLUCOSE CONCENTRATION ≥ 75mg/dL

	Patient				Technician			
	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Finger	22/42(52%)	35/42(83%)	42/42(100%)	42/42(100%)	26/42(62%)	39/42(93%)	42/42(100%)	42/42(100%)
Palm	25/42(60%)	39/42(93%)	41/42(98%)	42/42(100%)	33/42(79%)	39/42(93%)	42/42(100%)	42/42(100%)
Upper arm	23/42(55%)	36/42(86%)	42/42(100%)	42/42(100%)	37/42(88%)	42/42(100%)	42/42(100%)	42/42(100%)
Forearm	26/42(62%)	39/42(93%)	42/42(100%)	42/42(100%)	34/42(81%)	41/42(98%)	42/42(100%)	42/42(100%)
Thigh	25/42(60%)	36/42(86%)	42/42(100%)	42/42(100%)	31/42(74%)	40/42(95%)	42/42(100%)	42/42(100%)
Calf	34/42(81%)	38/42(91%)	41/42(98%)	42/42(100%)	34/42(81%)	41/42(98%)	42/42(100%)	42/42(100%)

REFERENCE
1. ADA Clinical Practice Recommendations 2003.
2. All Medicus data on file.

Questions? Call toll-free 1-800-777-4908 Monday through Friday, 8am-5pm EST.
Technical Support? Call toll-free 1-877-979-5454 Monday through Friday, 9am-5pm EST.

Distributed by McKesson Medical-Surgical Inc.
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PVN A1025 AVN 09 A802DI800
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