

ONE DROP

8100-10235 Rev A

One Drop Test Strips

IMPORTANT: Please read this information and your One Drop Owner's Guide before using One Drop Test Strips.

IMPORTANT: Only use One Drop Test Strips with The One Drop Meter.

IMPORTANT SAFETY INSTRUCTIONS

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed disinfection.

Please refer to your One Drop Owner's Guide for instructions on disinfecting your One Drop Meter.

The FDA and CDC have issued warnings regarding the risk of bloodborne pathogen transmission when blood glucose meters have been used by more than one person. Please read the following references for more information:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)¹
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)²

INTENDED USE

One Drop Test Strips are intended for use with The One Drop Meter for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Meter is intended to be used by a single patient and should not be shared.

The One Drop Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

Limitations:

- Do not use for the diagnosis of or screening of diabetes mellitus.
- Do not use for patients who are dehydrated, hypotensive, in shock, critically ill, or in a hyperosmolar state.
- Do not use for persons undergoing Oxygen therapy.
- Do not use for testing the glucose levels in neonates (children under 4 weeks).
- Do not use for testing glucose levels in arterial or venous blood samples.
- Do not use for testing glucose from sites other than samples drawn from the fingertip.

TEST PRINCIPLE

The test strip contains glucose oxidase (GOx) enzyme with a redox chemical mediator that produces an electrochemical signal in proportion to the glucose concentration in the blood sample. The blood glucose meter measures this signal, using dynamic electrochemistry to correct for common analytical interferences such as hematocrit.

CHECK METER AND TEST STRIP PERFORMANCE USING ONE DROP CONTROL SOLUTIONS

One Drop Control Solutions contain a known amount of glucose that reacts with a One Drop Test Strip in combination with The One Drop Meter to make sure they are working together properly.

Control solution tests should be performed when you:

- First get your meter.
- Suspect that your meter or test strips are not working properly.
- Think your test results are not accurate.
- Have dropped or damaged your meter or exposed your meter to liquids.
- Are advised by your healthcare professional to do so.

If your control solution test results do not fall within the target range printed on the test strip vial for the control solution you are using (Level 2 or Level 4), repeat the test.

Out-of-range results may be due to one or more of the following factors:

- Expired or defective control solution.
- Expired or defective test strip.
- Error in performing test.
- Watered-down control solution.
- Meter malfunction.
- Control solution test performed outside of the system operating

temperature range of 50°F to 104°F (10°C to 40°C).

- Control solution test performed outside the system operating humidity range of 10% to 90%.
- Failure to shake the control solution bottle vigorously before using.
- Failure to discard the first drop of control solution and to wipe the bottle tip clean.

If results continue to fall outside the appropriate target range printed on your One Drop Test Strip vial, the test strip and meter may not be working properly. If so, do not use your system and contact 24-Hour Customer Service toll free: 1-800-828-8888.

CAUTION: To ensure accurate results, wash your hands with warm, soapy water and dry before every test. Unwashed hands may lead to inaccurate results. Make sure there is no grease, oil, or lotion on the test site. Use lancets only once. Do not use any lancing device or lancet that has been used by another person.

The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed disinfection.

TEST PROCEDURE

1. To ensure accurate results, wash your hands with soap and water. Make sure there is no grease, oil, or lotion on the test site. Thoroughly dry your hands.
2. Snap the cap off the lancing device, insert a new lancet and twist off the lancet cover. Replace the lancing device cap, set the lancing level and cock the handle.
3. Insert a new test strip.
4. Lance your fingertip.
5. When the meter displays the "Apply Sample to Test Strip" animation, bring the blood sample to the tip of the One Drop Test Strip.
6. When your blood glucose test result is shown on the display, the test is completed and stored in the memory.
7. Remove the used One Drop Test Strip from the meter and follow your healthcare professional's instructions for disposal. The meter will automatically be deactivated.
8. Wash your hands thoroughly with soap and water after handling meter, lancing device and test strips.

See your One Drop Owner's Guide for a more detailed, step-by-step guide on how to perform the test.

WHAT DO YOUR TEST RESULTS MEAN?

Results below 20 mg/dL: If the test result is below 20 mg/dL, a message will appear on the display indicating hypoglycemia (low blood glucose). The meter will display <20 mg/dL. You should perform another test immediately. If your result is below 20 mg/dL again, follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.

Results above 600 mg/dL: If the test result is above 600 mg/dL, a message will appear on the display indicating hyperglycemia (high blood glucose). The meter will display >600 mg/dL. You should perform another test immediately. If your result is above 600 mg/dL again, follow your healthcare professional's recommendation to treat hyperglycemia. Checking ketones may be advisable.

Expected Values/Reference Range

Expected blood glucose levels for people without diabetes: Fasting <100 mg/dL, two hours after meals <140 mg/dL.3

Always consult your healthcare professional for your recommended target ranges.

TESTING PRECAUTIONS

- Results below 70 mg/dL may mean low blood glucose levels (hypoglycemia).
- Results over 240 mg/dL may mean high blood glucose levels (hyperglycemia). Checking ketones may be advisable.
- If you get results below 70 mg/dL or above 240 mg/dL and do not have symptoms of hypoglycemia or hyperglycemia, repeat the test. If you have symptoms, or continue to get results that fall below 70 mg/dL or rise above 240 mg/dL, follow the treatment plan recommended by your healthcare team or contact your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test and you have followed all instructions described in your Owner's Guide, follow your healthcare professional's recommendations.
- Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- Always follow your healthcare professional's recommendations.

STORAGE AND HANDLING

- Store the One Drop Test Strip vial in a cool, dry place at 46°F to 86°F (8°C to 30°C) and at a relative humidity of 10% to 90%.
- Keep away from direct sunlight and heat.
- Store your One Drop Test Strips in their original vial only; never store them in another vial, any other container or outside the vial.
- After removing a One Drop Test Strip from the vial, immediately close the vial cap tightly.

- With clean, dry hands, you may gently handle the One Drop Test Strip when removing it from the vial or inserting it into the meter.
- Do not use One Drop Test Strips beyond the expiration date or 180 days after first opening the vial. This may cause inaccurate results. Write the discard date (180 days from the first opening) on the test strip vial.
- Do not bend, cut or alter One Drop Test Strips.
- Apply only fresh capillary blood or control solution to the sample area of the One Drop Test Strip.

WARNINGS AND PRECAUTIONS

- Keep test strips and the test strip vial away from children. The test strips may be choking hazards. The vial contains drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse. Discard used test strips properly.
- If test strip will not receive a blood sample, contact 24-Hour Customer Service toll free: 1-800-421-1234.

PERFORMANCE CHARACTERISTICS

System Measurement Range: 20 to 600 mg/dL (1.1 to 33.3 mmol/L)
 Hematocrit Range: 20% to 60%
 Maximum Altitude: 10,000 feet
 System Operating Temperature Range: 50°F to 104°F (10°C to 40°C)
 Operating Relative Humidity Range: 10% to 90%
 Sample: Whole blood, capillary
 Calibration: Plasma equivalent
 Blood Sample Size: 0.5 microliters
 Average Glucose Test Time: 5 seconds

The analytical performance of the One Drop Test Strips has been evaluated in both clinical and laboratory settings.

System Accuracy:

The accuracy of the system was evaluated by using blood glucose results obtained from whole blood samples. The system is calibrated to yield results equivalent to plasma glucose concentrations. Whole blood glucose results obtained with the meter were compared to the plasma glucose results obtained using the YSI Model 2300 Glucose Analyzer.

Accuracy for Lay Users:

Capillary blood glucose results obtained by 100 lay users to assess the performance of the system in the hands of the intended user. The blood glucose results obtained by the participants were compared to the YSI 2300 reference results.

The results were:

n: 100
 Slope: 1.04 (+/- 0.03)
 y-int: 2.10 (+/-5.79)
 Sy,x: 11.20
 Correlation Coefficient (r): 0.99
 Range of Reference Values: 42.8-396.0 mg/dL

User results for glucose concentrations < 75 mg/dL (< 4.2 mmol/L)

Within ± 5 mg/dL (± 0.28 mmol/L)	Within ± 10 mg/dL (± 0.56 mmol/L)	Within ± 15 mg/dL (± 0.83 mmol/L)
4/4 (100%)	4/4 (100%)	4/4 (100%)

User results for glucose concentrations ≥ 75 mg/dL (≥ 4.2 mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
48/96 (50%)	77/96 (80%)	91/96 (95%)	95/96 (99%)

Summary of total number of acceptable results

Total (percent)
99/100 (99%)

Precision:

The repeatability of the strips was evaluated with blood samples and control solutions in the laboratory:

Repeatability (Within Run)

Blood	Level 1	Level 2	Level 3	Level 4	Level 5
Average, mg/dL	32.2	98.0	130.2	223.6	382.7
SD, mg/dL	2.9	4.2	4.1	7.7	15.3
CV, %	9.0	4.3	3.2	3.5	4.0

Intermediate Precision (Day to Day)

Control Solution	Level 1	Level 2	Level 4
Average, mg/dL	57.3	135.4	343.8
SD, mg/dL	1.9	3.6	8.3
CV, %	3.3	2.7	2.4

CHEMICAL COMPOSITION

Each One Drop Test Strip contains:

- Glucose oxidase (*Aspergillus niger*) (2.7 IU)
- Hexaamineruthenium (III) chloride (45.7 µg)

LIMITATIONS

Interfering Substances

If you are taking Vitamin C (ascorbic acid) >3 mg/dL you may get inaccurate results with this system.

Manufacturer:

AgaMatrix, Inc.
 7C Raymond Avenue
 Salem, NH 03079 USA

References:

1. <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm>
2. <http://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html>
3. American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes—2016. Diabetes Care 2016;39 (Suppl. 1): S13–S22

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