emVia™ Pro Blood Glucose Test Strips

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IMPORTANT
Please read this information and the meter's user manual before using the emVia Pro Blood Glucose Test Strips.

INTENDED PURPOSE
The emVia Pro Blood Glucose Test Strips are for use with the emVia Pro Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood from the fingertip.
In the clinical and hospital setting, venous, arterial, and neonatal whole blood may be used to measure blood glucose when drawn by trained healthcare professionals.

TEST PRINCIPLE
Glucose in blood samples reacts with the chemical in the test strip to produce a small electrical current. The compatible meters detect the electrical current which reflects the amount of glucose in the blood sample.

STORAGE AND HANDLING
- Store the vial or foil packet in a cool and dry place at a temperature between 1–30 °C and 10–90 % relative humidity. Do not freeze.
- Keep the vial or foil packet of test strips away from direct sunlight or heat.
- Store unused test strips in their original vial or foil packet to avoid damage or contamination.
- Close the vial immediately after taking out a test strip.
- Avoid getting any liquid or moisture in the test strip vial or foil packet. This can affect the test strips and cause inaccurate test results.
- Do not apply samples other than capillary, venous, neonatal, or arterial whole blood or control solution to the test strip.
- Handle test strips only with clean and dry hands.
- Use the test strip immediately after taking it out of the vial or foil packet.
- Do not bend, cut, or alter the test strips in any way.
- Do not force a test strip into the meter. Gently push it into the meter's test strip port.
- Use all of the test strips within the expiration date printed on the test strip box and vial label or foil packet.
- Dispose of expired test strips immediately. Using test strips past their expiration date can produce incorrect test results.
- Test strips in both unopened and opened vials, and unopened foil packet can be used up until the expiration date printed on the test strip box and vial label or foil packet if the test strips are used and stored according to its storage and handling methods.

WARNINGS AND PRECAUTIONS
- Use only the meters that are compatible with the test strips, otherwise it may lead to an error message.
- Keep the test strips, test strip vial, and test strip box away from children. There is a choking hazard from the test strips, foil packet and vial cap when swallowed. Drying agents in the vial cap may be harmful if inhaled or swallowed, and may cause skin or eye irritation.
- Test strips are for single use only. Do not reuse.
- In the event of any serious incident with the emVia Pro Blood Glucose Test Strip, please report to manufacturer and the competent authority of the Member State.
- If the test strip does not absorb the blood sample properly, please contact your authorised embecta sales representative.

TEST PROCEDURE
Fingertip Site Blood Sampling
1) Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before collecting the blood sample with a lancing device.
2) Insert the test strip into the port with contact bars facing upwards. Push the test strip in gently until the meter beeps.
3) The blood insertion symbol will appear. For control solution testing, you must activate the Control Solution Test Mode by pressing and holding ▶ on the meter for three seconds. If control solution testing is performed without the control solution flag, an Er8 message may appear or the results may fall outside the range printed on the test strip vial or box.
4) Use lancing device to get blood sample. Sample must be at least 0.5 µL (actual size: ●) to fill the test strip confirmation window.
5) Apply blood sample to the sample inlet of the test strip until the meter beeps. If the confirmation window is not filled completely, an Er4 message may appear.
6) Meter will count down from five-to-one on the display. Test result, time, and date will appear and automatically be stored in the meter's memory. Remove used test strip from port. Meter will turn off after three seconds.

TEST RESULTS
The emVia Pro Blood Glucose Meter will display results between 10 and 600 mg/dL (0.6 and 33.3 mmol/L).

Normal Blood Glucose Results
Normal blood glucose levels for an adult without diabetes are below 100 mg/dL (5.5 mmol/L) before meals and fasting* and are lower than 140 mg/dL (7.8 mmol/L) two hours after meals.[1]
*Fasting is defined as no caloric intake for at least eight hours.

Severely Low Blood Glucose Results
If the test result is below 10 mg/dL (0.6 mmol/L), **Lo** will appear on the display, showing severe hypoglycemia (very low blood glucose levels).
Wash and dry your hands thoroughly, then repeat the test with a new test strip. If the result repeats, contact your healthcare professional immediately for advice and treatment.

Severely High Blood Glucose Results
If the test result is above 600 mg/dL (33.3 mmol/L), **HI** will appear on the display, showing severe hyperglycemia (much higher than normal blood glucose levels).
Wash and dry your hands thoroughly, then repeat the test with a new test strip. If the result repeats, contact your healthcare professional immediately for advice and treatment.

Unexpected Results
Severely low or severely high blood glucose readings can indicate a potentially serious medical condition. If your results are unusually high or low, or do not match the way you feel, repeat the test with a new test strip. If your reading is inconsistent with your symptoms or your result is lower than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), contact your healthcare professional.

LIMITATIONS
- An abnormally high or low red blood cell count (hematocrit level over 70 % or below 15 %) may produce inaccurate results.
- Severe dehydration (excessive water loss) may cause inaccurate results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
- The emVia Pro Blood Glucose Test Strips should be used with fresh capillary whole blood samples and neonatal heelstick capillary whole blood samples immediately after drawn, or with venous and arterial whole blood samples within 30 minutes after drawn. Venous, neonatal, and arterial whole blood samples should be drawn by healthcare professionals. Besides whole blood samples, serum or plasma samples can affect test results.
- Venous and arterial whole blood specimens containing the anticoagulants EDTA and Heparin are acceptable. Iodoacetate or fluoride/oxalate should not be used.
- Heel stick neonatal capillary whole blood specimens containing the anticoagulants EDTA and Heparin are acceptable. The system is not for testing neonatal cord blood samples.
- Altitude of up to 3,000 m above sea level has no effect on the performance of the test strip.
- Interferences: Acetaminophen, ascorbic acid (vitamin C), uric acid 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 inaccurate high results.
- Do not use during or within 24 hours of receiving xylose absorption testing as it may cause inaccurate results.
- Discard used test strips safely in appropriate containers according to the regulations applicable in your country.

METER AND TEST STRIP PERFORMANCE CHECK
The emVia Glucose Control Solution (Control L and/or H) contains a known amount of glucose that reacts with the emVia Pro Blood Glucose Test Strips in combination with the emVia Pro Blood Glucose Meter to make sure they are working properly together and the correct testing procedure is being followed.
You may run a check when you:
- Want to practice the test procedure using the control solution instead of blood.
- Use the meter for the first time.
- Open a new vial or box of test strips.
- Have symptoms that are inconsistent with your blood glucose test results.
- Believe your test results are not accurate.
- Suspect your meter and test strips are not performing properly.
- Drop or damage the meter.

If your control solution test results do not fall within the range printed on the test strip vial or box, repeat the test. Out of range results may be due to one or more of the following factors:
- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Failure to shake control solution bottle.
- Failure to discard first drop of control solution.
- Failure to wipe the bottle tip clean.

If results continue to fall outside the range printed on the test strip vial or box, the test strip and the compatible meter may not be working properly. If so, do not use your system and contact your authorised embecta sales representative.

CHEMICAL COMPOSITION
Each emVia Pro Blood Glucose Test Strip contains the following reagents:
- Glucose dehydrogenase (FAD-dependent): 3.1 units
- Hexaammineruthenium(III) chloride: 7.8 µg
- Thionine acetate: 0.7 µg

PERFORMANCE CHARACTERISTICS
The performance of emVia Pro Blood Glucose Test Strips has been evaluated in laboratory and clinical tests. For the performance characteristics (including the perspective of professional use) of your compatible meters, please refer to your meter's user manual.

emVia™ Pro Blood Glucose Test Strips

Accuracy

The accuracy of the emVia Pro Blood Glucose Test Strip using the YSI Model 2300 Glucose Analyzer (laboratory instrument) as the comparator method are described below. The results are calibrated to be equivalent to plasma glucose concentrations. The following results were obtained by diabetic patients at clinic centers.

Slope	1.00
Y-intercept	5.60 mg/dL (0.3 mmol/L)
Correlation coefficient (r)	1.00
Number of tests	600
Range tested	35–453 mg/dL (1.96–25.1 mmol/L)

Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.56 mmol/L)	Within ±15 mg/dL (Within ±0.83 mmol/L)
100/174 (57.5 %)	165/174 (94.8 %)	173/174 (99.4 %)

Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %
206/426 (48.4 %)	385/426 (90.4 %)	420/426 (98.6 %)

System accuracy results for glucose concentrations between 35 mg/dL (1.96 mmol/L) and 453 mg/dL (25.1 mmol/L)

Within ±15 mg/dL (Within ±0.83 mmol/L) and Within ±15 %
593/600 (98.8 %)

Precision

Within Run Precision		
Blood average	38 mg/dL (2.1 mmol/L)	SD = 2.0 mg/dL (0.1 mmol/L)
	83 mg/dL (4.6 mmol/L)	SD = 3.6 mg/dL (0.2 mmol/L)
	130 mg/dL (7.2 mmol/L)	CV = 3.2 %
	192 mg/dL (10.7 mmol/L)	CV = 2.8 %
	312 mg/dL (17.3 mmol/L)	CV = 2.5 %

Between Run Precision		
Control average	35 mg/dL (2.0 mmol/L)	SD = 1.5 mg/dL (0.1 mmol/L)
	120 mg/dL (6.7 mmol/L)	CV = 4.0 %
	347 mg/dL (19.3 mmol/L)	CV = 4.1 %

This study shows that there could be variation of up to 4.1 %.

Influence Quantities

1) Packed cell volume (Hematocrit)
   Packed cell volume evaluation was conducted in various hematocrit levels. The range of hematocrit levels within the acceptance criteria is 15–70 %.
2) Interferences
   The effect of various interfering substances was evaluated in whole blood samples. The presence of the following substances within the given concentrations does not affect blood glucose measurements. Higher concentrations of the substances shown below may cause inaccurate blood glucose results.

No.	Interferent	Concentration
1	Acetaminophen (paracetamol)	20 mg/dL (1.32 mmol/L)
2	Ascorbic acid	6 mg/dL (0.34 mmol/L)
3	Bilirubin (conjugated)	50 mg/dL (0.59 mmol/L)
4	Bilirubin (unconjugated)	40 mg/dL (0.68 mmol/L)
5	Cholesterol	500 mg/dL (12.93 mmol/L)
6	Creatinine	15 mg/dL (1.33 mmol/L)
7	Dopamine	0.1 mg/dL (0.01 mmol/L)
8	EDTA	0.1 mg/dL (0.003 mmol/L)
9	Galactose	60 mg/dL (3.33 mmol/L)
10	Gentisic acid	1.8 mg/dL (0.12 mmol/L)
11	Glutathione (reduced)	93 mg/dL (3.03 mmol/L)
12	Hemoglobin	1,000 mg/dL (0.62 mmol/L)
13	Heparin	330 U/dL
14	Ibuprofen	50 mg/dL (2.42 mmol/L)
15	Icodextrin	1,095 mg/dL
16	L-Dopa	0.75 mg/dL (0.04 mmol/L)
17	Maltose	480 mg/dL (14.02 mmol/L)
18	Methyldopa	2.25 mg/dL (0.11 mmol/L)
19	Pralidoxime Iodide	25 mg/dL (0.95 mmol/L)
20	Salicylate	60 mg/dL (4.34 mmol/L)
21	Tolazamide	9 mg/dL (0.29 mmol/L)
22	Tolbutamide	72 mg/dL (2.66 mmol/L)
23	Triglycerides	1,500 mg/dL (16.94 mmol/L)
24	Uric acid	23.5 mg/dL (1.40 mmol/L)
25	Xylose	12.4 mg/dL (0.83 mmol/L)

Compounds of xylose ≥ 12.4 mg/dL (0.83 mmol/L) may cause overestimation of blood glucose results.

User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 102 lay persons showed the following results:
100 % within ±15 mg/dL (0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 97.5 % within ±15 % of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

Metrological Traceability

The system has been evaluated using the YSI glucose analyzer as the reference method and traceable to the NIST Standard Reference Material (SRM) 917d. Using the traceability chain, the results obtained with test strips for control solutions can also be traced back to the NIST standard.

DESCRIPTION OF SYMBOLS

IVD	*In vitro* diagnostic medical device
	Do not re-use
	Consult instructions for use
	Temperature limit
	Manufacturer
	Importer
LOT	Batch code
	Use-by date
	Device for self-testing

REFERENCE

1. American Diabetes Association (Standards of Medical Care in Diabetes – 2021. *Diabetes Care*), January 2021, vol. 44 (Supplement 1): S15-S33.

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