ACCU-CHEK® Performa

TESTS

REF 06453996 / 06454011 / 08966648

EN

Device for self-testing

Device for near-patient testing

Intended Use

The Accu-Chek Performa system consists of the Accu-Chek Performa family of meters, Accu-Chek Performa test strips, Accu-Chek Performa control solution and Accu-Chek linearity test kit.

The test strips with the dedicated blood glucose meter are indicated to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal whole blood as an aid in monitoring the effectiveness of glucose control. They are intended for self-testing by people with diabetes and for near-patient testing by healthcare professionals. They are intended for in vitro diagnostic use by healthcare professionals in clinical settings and by people with diabetes at home. Meters used in combination with an insulin pump are for home use only. For specific instructions for your meter refer to your User's Manual.

Testing sites for the Accu-Chek Performa family of meters include the finger, palm, forearm, and upper arm. Meters used in combination with an insulin pump should use fingertip testing only.

The systems are not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples. Venous, arterial, and neonatal whole blood testing is limited to healthcare professional use only.

Consumer Information

Important information: These test strips are labelled with a green ▤ symbol to distinguish them from earlier test strips that were subject to a clinically relevant maltose interference.* The green symbol can be found on the test strip box and on the label of the test strip container.

*Data on file

Introduction

Read this package insert and the User's Manual before performing a blood glucose test.

Testing your blood glucose regularly may help you better manage your diabetes. Medical studies show that you and your healthcare professional can manage your blood glucose to near normal levels.[1] This can prevent or slow the development of complications from diabetes.

The package insert contains warnings and precautions:

A **WARNING** indicates a foreseeable serious hazard.

A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

⚠ WARNING

Risk of suffocation

This product contains small parts that can be swallowed.

Keep the small parts away from small children and people who might swallow small parts.

Risk of a serious health incident

Failure to follow testing instructions or test strip storage and handling instructions can lead to an incorrect test result.

Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions.

Inspect the test strip container before using the test strips for the first time. If you see any damage to the container, if anything prevents the cap from closing properly, or if the container was open before using for the first time, do not use the test strips. Do not perform a control test. Contact Roche. Damaged test strips can cause inaccurate results, which could lead to improper therapy.

Risk of infection

Human blood is a potential source for the transmission of infection. Avoid exposing other people to contaminated components. Discard a used test strip as infectious material according to the regulations applicable in your country.

Contents of the pack

Pack containing test strips and package inserts.

Because the reactive substances are in such small quantities, they are not considered to be hazardous materials under EU regulations. If you have any questions, contact Roche.

All components of the pack can be discarded in domestic waste.

Test strip storage and handling

- Store the test strips at temperatures between 2 and 30 °C. Do not freeze the test strips.
- Use the test strips at temperatures between 8 and 44 °C.
- Use the test strips between 10 and 90 % humidity. Do not store the test strips in high heat and moisture areas such as the bathroom or kitchen.
- Store the unused test strips in their original test strip container with the cap closed.
- Close the test strip container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the test strip container.
- Discard the test strips if they are past the use by date. Expired test strips can produce incorrect results. The use by date is printed on the test strip box and on the label of the test strip container next to ⏳. The test strips can be used until the printed use by date when they are stored and used correctly. This applies for test strips from a new, unopened test strip container and for test strips from a test strip container already opened by the user.
- Use a test strip only once. Test strips are for single use only.

Performing a Blood Glucose Test

Note: If your meter requires an activation chip, contact Roche to obtain one.

If you have poor circulation, testing your own blood glucose may not be right for you. Ask your healthcare professional.

Clean the puncture site before obtaining a blood drop.

1. Wash your hands in warm, soapy water. Rinse and dry completely.
2. Prepare the finger pricker.
3. Check the use by date on the test strip container. Do not use test strips past the use by date.
4. Insert the test strip into the meter in the direction of the arrows. The meter turns on.
5. Obtain a blood drop using the finger pricker.
6. Touch the blood drop to the **front edge** of the yellow window of the test strip. Remove your finger from the test strip when ⧗ appears. Do not put blood on top of the test strip.
7. Remove and discard the used test strip.

Note: If the control bottle symbol and the flashing **L** appear on the display with your blood glucose result, an error has occurred.

Do not act on the blood glucose result. Repeat the blood glucose test with a new test strip.

Alternative Site Testing

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm, forearm, and upper arm. If you are interested in alternative site testing (AST), talk to your healthcare professional first. Additional information on how to conduct AST and its limitations may be found in the User's Manual.

If you use your meter in combination with an insulin pump, only use fingertip testing.

⚠ WARNING

Risk of a serious health incident

Your blood glucose level changes faster in your fingertip and palm than in the AST site (forearm and upper arm). Performing a blood glucose test with blood from the forearm or upper arm may cause you to misinterpret your actual blood glucose level, leading to improper therapy.

- Do not use AST to calibrate a continuous glucose monitoring system.
- Do not use AST to make insulin dosing calculations.
- Alternative Site Testing should be done only during steady-state times (when glucose is not changing rapidly).

Understanding Test Results

The normal fasting glucose level for a non-diabetic adult is below 5.6 mmol/L.[2] The normal glucose level for a non-diabetic adult 2 hours post-meal, e.g. simulated by 75 g Oral Glucose Tolerance Test (OGTT), is less than 7.8 mmol/L.[3] A criterion for the diagnosis of diabetes in adults is a fasting glucose level of 7.0 mmol/L or higher confirmed in two tests.[2,4,5] Adults with a fasting glucose level between 5.6 and 6.9 mmol/L are defined as having impaired fasting glucose (prediabetes).[2] Other diagnostic criteria for diabetes exist. Consult your healthcare professional to determine if you have diabetes or not. For people with diabetes: Consult your healthcare professional for the blood glucose range appropriate for you. You should treat your low or high blood glucose as recommended by your healthcare professional.

For information on the effects and prevalence of diabetes in your area, visit the International Diabetes Federation website at www.idf.org or send an email to info@idf.org. For further advice or helpline information, refer to the national diabetes organisation for your country.

Unusual test results

If **LO** is displayed on the meter, your blood glucose may be below 0.6 mmol/L.

If **HI** is displayed on the meter, your blood glucose may be over 33.3 mmol/L.

If you receive an E-3 error message refer to your User's Manual.

⚠ PRECAUTION

Risk of a serious health incident

Never ignore symptoms or make significant changes to your diabetes therapy without talking to your healthcare professional.

If your blood glucose result does not match how you feel, follow these steps:

- Repeat the blood glucose test with a new test strip.
- Perform a control test as described in the User's Manual.
- Refer to the User's Manual for other causes.

If your symptoms still do not match your blood glucose results, contact your healthcare professional.

Healthcare Professional Information

The system can be used in doctors' offices, general wards, in suspected cases of diabetes and in emergency cases.

Sample collection and preparation by healthcare professionals

- When using the Accu-Chek Performa family of meters, always follow the recognised procedures for handling objects that are potentially contaminated with human material. Practice the hygiene and safety policy of your laboratory or institution.
- A blood drop is required to perform a blood glucose test. Capillary blood can be used. Venous, arterial, or neonatal blood may be used, but must be obtained by healthcare professionals.
- Take caution to clear arterial lines before the blood sample is obtained and applied to the test strip.
- The system has been tested with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonate blood glucose values below 2.8 mmol/L. Follow the recommendations for follow-up care that have been set by your institution for critical blood glucose values in neonates. Blood glucose values in neonates suspect for galactosaemia should be confirmed by an alternative glucose methodology.
- To minimise the effect of glycolysis, venous or arterial blood glucose tests need to be performed within 30 minutes of obtaining the blood samples.
- Avoid air bubbles when using pipettes.
- Capillary, venous, and arterial blood samples containing these anticoagulants or preservatives are acceptable: EDTA, lithium heparin, or sodium heparin. Anticoagulants containing iodoacetate or fluoride are not recommended.
- Refrigerated samples should be brought to room temperature slowly prior to testing.

Additional information for healthcare professionals

If the blood glucose result does not reflect the patient's clinical symptoms, or seems unusually high or low, perform a control test. If the control test confirms that the system is working properly, repeat the blood glucose test. If the second blood glucose result still seems unusual, follow facility guidelines for further action.

Discard components of the pack per facility guidelines. Consult local ordinances as they may vary by country.

Limitations

Certain health conditions can lead to an incorrect test result. If you know that one or more of the following health conditions apply to you, do not use the test strip. If you are unsure whether any of the health conditions apply to you, contact your healthcare professional.

- Blood concentrations of galactose >0.83 mmol/L will cause overestimation of blood glucose results.
- Lipaemic samples (triglycerides) >20.3 mmol/L may produce elevated blood glucose results.
- Intravenous administration of ascorbic acid, which results in blood concentrations of ascorbic acid >0.17 mmol/L, will cause overestimation of blood glucose results.
- Intravenous administration of N-acetylcysteine, which results in blood concentrations of N-acetylcysteine >307 µmol/L, will cause overestimation of blood glucose results. Do not use during intravenous administration of high-dose N-acetylcysteine.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: Severe dehydration as a result of diabetic ketoacidosis or due to hyperglycaemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- Haematocrit should be between 10 and 65 %. Ask your healthcare professional if you do not know your haematocrit.
- The accuracy of the system has been tested at altitudes up to 3,094 metres. Do not use the system at altitudes above 3,094 metres.

Performance Characteristics

The Accu-Chek Performa family of meters, and their systems, comply with the requirements of ISO 15197:2013 (In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).

Calibration and traceability: The system (meter and test strips) is calibrated with venous blood containing various glucose concentrations as a calibrator. The reference values are obtained using the hexokinase method which is calibrated using the ID-GCMS method. The ID-GCMS method as the method of highest metrological quality (order) is traceable to a primary NIST standard. Using this traceability chain, the results obtained with these test strips for control solutions can also be traced back to the NIST standard.

Detection limit (lowest value displayed): 0.6 mmol/L for the test strip

System measuring range: 0.6–33.3 mmol/L

Sample size: 0.6 µL

Test time: 5 seconds

System accuracy:

System accuracy results for glucose concentrations less than 5.55 mmol/L

within ±0.28 mmol/L	within ±0.56 mmol/L	within ±0.83 mmol/L
137/168 (81.5 %)	163/168 (97.0 %)	167/168 (99.4 %)

System accuracy results for glucose concentrations equal to or greater than 5.55 mmol/L

within ±5 %	within ±10 %	within ±15 %
256/432 (59.3 %)	393/432 (91.0 %)	428/432 (99.1 %)

System accuracy results for glucose concentrations between 0.67 mmol/L and 29.1 mmol/L

within ±0.83 mmol/L or within ±15 %
595/600 (99.2 %)

Repeatability:

Mean value	[mmol/L]	2.4	5.0	6.8	10.4	17.4
Standard deviation	[mmol/L]	0.1	0.2	0.2	0.4	0.6
Coefficient of variation [%]		—	—	3.5	3.9	3.7

Intermediate precision:

Mean value	[mmol/L]	2.5	6.6	17.2
Standard deviation	[mmol/L]	0.09	0.2	0.3
Coefficient of variation [%]		—	2.3	2.0

Performance assessment by the user: A study evaluating glucose values from fingertip capillary blood samples obtained by 209 lay persons showed the following results:

- For glucose concentrations less than 5.55 mmol/L, 97.6 % of the test results were within ±0.83 mmol/L of the results obtained through laboratory testing.
- For glucose concentrations equal to or greater than 5.55 mmol/L, 97.0 % of the test results were within ±15 % of the results obtained through laboratory testing.

Test principle: The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH) from *Acinetobacter calcoaceticus*, recombinant in *E. coli*, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and environmental conditions are evaluated using AC and DC signals.

These test strips deliver results that correspond to blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).[6] Therefore, the meter displays blood glucose concentrations that refer to plasma although whole blood is always applied to the test strip.

Reagent composition¤

Mediator	6.72 %
Quinoprotein glucose dehydrogenase¤¤	15.27 %
Pyrroloquinoline quinone	0.14 %
Buffer	34.66 %
Stabiliser	0.54 %
Non-reactive ingredients	42.66 %

¤Minimum at time of manufacture

¤¤From *A. calcoaceticus*, recombinant in *E. coli*, detailed description in patent application WO 2007/118647 (as "mutant 31" in table 4)

Note: For an explanation of symbols used and a list of references, refer to the end of this package insert.

Control and linearity test kits (if available)

Accu-Chek Performa control solution – Refer to the control solution package insert for details.

Accu-Chek linearity test kit – Refer to the linearity test kit package insert for details.

Visit our website at www.accu-chek.com or contact the local Roche representative for more information.

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

LAST UPDATE: 2022-01

Indicates updated content

References

1. Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, Rossing P, Tsapas A, Wexler DJ, Buse JB. Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2018 Dec;41(12):2669-2701.
2. American Diabetes Association: "2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2020." *Diabetes Care* 2020, 43 (Supplement 1): S14-S31.
3. American Diabetes Association website; Diagnosing Diabetes and Learning about Prediabetes. http://www.diabetes.org/diabetes-basics/diagnosis/. Accessed January 25, 2019.
4. IDF Clinical Guidelines Task Force. Global guideline for Type 2 diabetes. Brussels: International Diabetes Federation, 2012.
5. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. WHO, Geneva 2006 (ISBN 92 4 159493 4, ISBN 978 92 4 159493 6).
6. D'Orazio et al.: "Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated);" *Clinical Chemistry* 51:9 1573-1576 (2005).

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[1)] calls may be recorded for training purposes
Some mobile operators may charge for calls to these numbers.

www.accu-chek.co.uk
www.accu-chek.ie

	Consult instructions for use or consult electronic instructions for use
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Temperature limit
	Use by (opened / unopened)
	All components of the pack can be discarded in domestic waste. Discard used test strips according to local regulations.
	Date of manufacture
IVD	In vitro diagnostic medical device
	Device for self-testing
	Device for near-patient testing
	Manufacturer
UDI	Unique device identifier
REF	Catalogue number
SN	Serial number
LOT	Batch code
CE	Complies with the provisions of the applicable EU Legislation
	These test strips deliver results that refer to plasma as per IFCC, and the symbol distinguishes them from earlier test strips that were subject to a clinically relevant maltose interference.

ACCU-CHEK® Performa 07667531061B-0322

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