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EN TITEL

ACCU-CHEK® Mobile

07141254 / 07203233

TIP OF THE CASSETTE HAS CHANGED

TITEL

EN Test cassette

Read this package insert and the User's Manual of the Accu-Chek Mobile blood glucose meter before testing your blood glucose with this test cassette. The User's Manual contains all the information you need to perform a test. If you have any questions, contact your customer support and service centre.

This package insert features the following 2 symbols:

⚠ This symbol indicates **a possible risk of injury or of damage to your health**.

ⓘ This symbol draws your attention to **important information**.

New: Tip of the cassette has changed

The test cassette was changed to include two guidance tabs at the tip of the cassette. The guidance tabs are intended to help you touch the test area with the blood drop only and not with your finger. Place your finger lightly on the guidance tabs at the tip of the cassette and do not exert any pressure.

Intended use

- The test cassette is intended for quantitatively measuring blood glucose in fresh capillary blood.
- The test cassette may only be used with Accu-Chek Mobile meters and may only be used outside of the body.
- The system, comprising of meter and test cassette, is only suitable for self-testing. People with diabetes can use this system to self-test their blood glucose.
- The system must not be used to diagnose or rule out diabetes.

Additional information

⚠
- Self-testing is not a substitute for visits to your healthcare professional. You must receive proper instruction from a qualified healthcare professional before you start self-testing your blood glucose. Your healthcare professional will determine the appropriate blood glucose range jointly with you.
- Keep the blood glucose monitoring system with all its components away from small children and vulnerable persons. There is a risk of suffocation if small parts (e.g. covers, caps or similar objects) are swallowed.

ⓘ
- All components of the pack can be discarded in domestic waste. Discard used test cassettes according to local regulations.
- This test cassette delivers results that correspond to blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) [1]. Therefore, your meter displays blood glucose values that refer to plasma although you always apply whole blood to the test area.

The normal fasting glucose level for a non-diabetic adult is below 5.6 mmol/L. 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, 3, 4]. 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.

Contents of the pack

- 1 or 2 test cassettes
- 1 package insert

Additional materials required for blood glucose testing

- Accu-Chek Mobile meter with User's Manual
- Finger pricker and lancets

⚠ The Accu-Chek Mobile meter and Accu-Chek FastClix finger pricker are intended for patient self-monitoring by an individual person only. They must not be used to collect blood from more than one person as they do not incorporate any features to guard against cross-infection.

Blood volume and test time

The meter requires approximately 0.3 µL of blood (1 µL (microlitre) = 1 thousandth of a millilitre) per blood glucose test. The test takes approximately 5 seconds (test time depends on the blood glucose concentration).

Storing and using test cassettes properly

⚠ Test cassettes which are not stored or used properly can lead to incorrect test results. Incorrect test results can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects.

- Always store the test cassettes in the unopened plastic container.
- Store the test cassettes at a temperature between +2 and +30 °C in a dry place away from direct sunlight.
- If you store the test cassette in a refrigerator, leave the unopened plastic container to stand at an ambient temperature. Only remove the test cassette once the plastic container has warmed up to ambient temperature. This prevents condensation from forming in the test cassette.
- The test areas are sensitive to humidity. Only transport the test cassettes in the unopened plastic container or in the meter. When you open the plastic container, you must use up the test cassette within 90 days (use by period). After the period of 90 days, the test cassette can deliver incorrect test results.
- Do not use test cassettes if the plastic container or foil cover is damaged.
- If you take a partly used test cassette out of the meter, keep it in a dry place away from light.
- When you perform a test, the temperature must be between +10 and +40 °C.

Test principle

Each test area contains reagents. When blood is applied to the test area, the glucose dehydrogenase enzyme (Mut. Q-GDH 2, EC 1.1.5.2) reacts with the blood glucose. The subsequent chemical reaction changes the colour of the test area. The meter registers this colour change and converts it into a blood glucose value.

Control test

Carry out regular control tests with the Accu-Chek Mobile control solutions to ensure that your meter and test cassette are functioning properly and that you are carrying out tests correctly. Read the package insert for the control solutions and the User's Manual for your meter.

Performance characteristics of the Accu-Chek Mobile system

The Accu-Chek Mobile system complies 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 cassette) is calibrated with whole 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 this test cassette for control solutions can also be traced back to the NIST standard.

Detection limit (lowest value displayed): The detection limit is 0.6 mmol/L.

Measuring interval: The method is linear within the interval from 0.6–33.3 mmol/L.

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
167/186 (89.8 %)	185/186 (99.5 %)	186/186 (100 %)

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

within ± 5 %	within ± 10 %	within ± 15 %
360/414 (87.0 %)	411/414 (99.3 %)	414/414 (100 %)

System accuracy results for glucose concentrations between 2.1 mmol/L and 25.3 mmol/L

within ± 0.83 mmol/L or within ± 15 %
600/600 (100 %)

Repeatability:

Mean value					
[mmol/L]	2.2	5.1	7.3	11.8	19.3
Standard deviation					
[mmol/L]	0.1	0.1	0.1	0.2	0.4
Coefficient of variation					
[%]	—	—	1.8	1.9	1.9

Intermediate precision:

Mean value			
[mmol/L]	2.2	6.6	19.6
Standard deviation			
[mmol/L]	0.1	0.2	0.5
Coefficient of variation			
[%]	—	2.4	2.3

Performance assessment by the user:
A study evaluating glucose values from fingertip capillary blood samples obtained by 107 lay persons showed the following results:

- For glucose concentrations less than 5.55 mmol/L, 100 % 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, 99.0 % of the test results were within ± 15 % of the results obtained through laboratory testing.

Sources of error which may produce incorrect test results

⚠ Incorrect test results can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects.

- Parenteral administration of galactose and galactosemia can lead to falsely elevated test results. Concentrations of galactose in the blood equal to or greater than 1.2 mmol/L lead to falsely elevated test results.
- Do not use when undergoing ceftriaxone treatment. Ceftriaxone in the blood may lead to falsely lowered test results.
- If peripheral circulation is impaired, capillary blood 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 a hyperglycaemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA class IV or peripheral arterial occlusive disease.
- You may use blood with a haematocrit of 25 to 55 %.

Reagent composition

Minimum content per cm^2 at time of manufacture	
Mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH 2, modified variant of EC 1.1.5.2), *acinetobacter spec.*	6.7 U
Pyrroloquinoline quinone	0.4 µg
Bis-(2-hydroxyethyl)-(4-hydroximino-cyclohexa-2,5-dienylidene)-ammonium chloride	8.5 µg
2,18-phosphomolybdic acid, sodium salt	88 µg
Stabiliser	0.17 mg
Non-reactive ingredients	2.1 mg

Last update

2019-05

Customer support and service centre

Hong Kong
Enquiry hotline: +852-2485 7512 (office hours)
www.accu-chek.com.hk

United Kingdom
Roche Diabetes Care Limited
Charles Avenue, Burgess Hill
West Sussex, RH15 9RY, **United Kingdom**
Accu-Chek Customer Careline [1)]
UK Freephone number: 0800 701 000
ROI Freephone number: 1 800 709 600
[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

References

[1] D'Orazio et al.: Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated); *Clinical Chemistry* 51:9, 1573–1576, 2005

[2] American Diabetes Association: Classification and diagnosis of diabetes. Sec. 2. Standards of Medical Care in Diabetes–2017. *Diabetes Care* 2017; 40 (Suppl. 1): S11–S22

[3] IDF Clinical Guidelines Task Force. Global guideline for Type 2 diabetes. Brussels: International Diabetes Federation, 2012

[4] 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)

	Consult package insert
⚠	Caution, refer to safety-related notes in the package insert accompanying this product.
	Temperature limitation (store at)
	Use by
90D	Use-by period of the test cassette after opening the foil-sealed plastic container: 90 days
	All components of the pack can be discarded in domestic waste. Discard used test cassettes according to local regulations.
	Manufacturer
REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
CE	This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

CE 0123

IN VITRO DIAGNOSTIC MEDICAL DEVICE

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