ACCU-CHEK® Active

Roche

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# TEST STRIPS

## ADDITIONAL INFORMATION FOR USE WITH THE ACCU-CHEK SUGARVIEW APP

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# 1 Before You Get Started

Read this additional information before testing your blood glucose with the Accu-Chek SugarView app and the Accu-Chek Active test strips. The User's Manual of the Accu-Chek SugarView app contains all the information you need to perform a test and to understand your test results. If you have questions, contact customer support. Contact information for your country can be found in the main menu. Open the app, and go to: *PROFILE > Support Information > Support Contact.*

**⚠ WARNING**

The package insert contains warnings:

A WARNING indicates a foreseeable serious hazard.

Self-testing is not a substitute for visits to your doctor. 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 target range jointly with you.

The cap of the test strip container contains a non-toxic silicate-based drying agent. If you accidentally swallow any of this, drink plenty of water!

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) [1]. Therefore, the Accu-Chek SugarView app displays blood glucose values that refer to plasma although you always apply whole blood to the test strip.

The normal fasting glucose level for a non-diabetic adult is below 100 mg/dL (5.6 mmol/L). A criterion for the diagnosis of diabetes in adults is a fasting glucose level of 126 mg/dL or higher (7.0 mmol/L or higher) confirmed in two tests [2, 3, 4]. Adults with a fasting glucose level between 100 and 125 mg/dL (5.6 and 6.9 mmol/L) are defined as having impaired fasting glucose (prediabetes) [2]. Other diagnostic criteria for diabetes exist. Consult your doctor or diabetes nurse to determine if you have diabetes or not.

# 1 Before You Get Started

The User's Manual of the Accu-Chek SugarView app includes details on where to get information on the effects and prevalence of diabetes.

**⚠ 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.

# 2 Contents of the Accu-Chek Active Test Strip Box

- 1 or 2 containers with test strips; on the container label is a color chart, the concentration table for the control solutions and the code number
- 1 package insert inside the test strip box*

*The package insert refers only to the use of the test strips with a blood glucose meter. For information on how to use the test strips with the app, open the app and go to: *PROFILE > Support Information > Additional Test Strip Information.*

# 3 Additional Materials Required for Blood Glucose Testing

- The Accu-Chek SugarView app and User's Manual (available in the app)
- Finger pricker and lancets
- Accu-Chek SugarView color card

# 4 Blood Volume and Test Time

The test strip requires 1–2 µL of blood (1 µL (microliter) = 1 thousandth of a milliliter) per blood glucose test. The blood glucose test takes approximately 13–45 seconds.

# 5 Storing and Using Test Strips Properly

**⚠ WARNING**

**Risk of a serious health incident**

If the test strips are not stored or used properly, they can deliver incorrect test results. This can lead to a serious health incident.

- Store the test strips at temperatures between +2 and +30 °C in a dry place away from direct sunlight.

Also note the following instructions:

- The drying agent contained in the cap of the test strip container protects the test strips from moisture. Always store the test strips in their original test strip container with the cap closed.
- Close the test strip container tightly with its original cap after removing a test strip. Do not remove test strips from the test strip container with moist hands. This enables the drying agent to retain its effect.
- If you store the test strip container in a refrigerator, leave the closed container to stand at an ambient temperature. Only remove a test strip once the test strip container has warmed up to ambient temperature. This prevents condensation from forming in the test strip container.
- Do not store any other objects such as cleaning cloths or used test strips in a test strip container that contains unused test strips. This could make the test strips unusable.
- When you perform a blood glucose test with the app, the temperature must be between +15 and +40 °C.
- Do not test in direct sunlight.
- Use only test strips which are within the use by date. The use by date is printed next to the ⌛ symbol on the packaging and on the label of the test strip container. The use by date applies for test strips from a new, unopened test strip container and for test strips from a test strip container that has already been opened.
- Use a test strip only once. Test strips are for single use only.

# 6 Test Principle

On each test strip there is a test area containing reagents. When blood is applied to the test area, the glucose dehydrogenase enzyme (Mut. Q-GDH 2) reacts with the blood glucose. The subsequent chemical reaction changes the color of the test area. The app performs a digital visual test of the color of the control window, interprets the color change on the test strip using the standard color information provided by the accessory color card. The app indicates on the display of the smartphone if your test result falls above, below, or within your target range. Displayed will be a semi-quantitative blood glucose range.

# 7 Blood Glucose Ranges

| mg/dL | mmol/L | Description |
|---|---|---|
| greater than 600 | greater than 33.3 | outside the measuring range, blood glucose cannot be properly detected |
| 301 to 600 | 16.7 to 33.3 | very high, exercise and doctor visit recommended |
| 181 to 300 | 10.0 to 16.6 | high, exercise recommended |
| 131 to 180 | 7.3 to 10.0 | after a meal (within 2 hours): within target range, good blood glucose result<br>before meal or fasting: slightly high blood glucose result, exercise recommended |
| 71 to 130 | 3.9 to 7.2 | within target range, good blood glucose result |
| 20 to 70 | 1.1 to 3.9 | low or very low, eating or drinking something sugary and immediate doctor visit recommended |
| lower than 20 | lower than 1.1 | out of measuring range, blood glucose cannot be properly detected |

Source: see [5]

# 8 Checking the Test Result

### Check by Color Comparison

The test strip itself allows you to estimate the test result through color comparison and thus check the displayed test result in addition. The color comparison serves only as a plausibility check of the test result.

- Before the test: On the back of the test strip, there is a round, colored control window. Compare the color of this window with the colored dots on the label of the test strip container. The color of the control window must match the color of the top dot (0 mg/dL, 0 mmol/L). If the control window is a different color, do not perform a test with that test strip.
- After the test: The label on the test strip container shows blood glucose values in mg/dL and mmol/L next to each colored dot. Within 30 to 60 seconds after applying blood to the test strip, compare the color of the control window on the back of the test strip with the dot that comes closest to your test result. If the color deviates significantly, repeat the test. If the color still deviates in further tests, contact customer support.

### Check Performed by the App

The app automatically tests your mobile device's camera and system every time you scan a test strip and lets you know if something is wrong. Additionally, the app checks the quality of the test strip and rejects an unsuitable test strip. In this way, the app ensures that the blood glucose result is measured correctly.

# 9 Performance Characteristics

For performance characteristics of the app in combination with test strips refer to the Accu-Chek SugarView app User's Manual. Go to *PROFILE > Support Information > App Manual*.

# 10 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.

- Intravenous administration of ascorbic acid may lead to falsely elevated test results. Concentrations of ascorbic acid in the blood greater than 8 mg/dL (greater than 0.45 mmol/L) lead to falsely elevated blood glucose test results.
- Parenteral administration of galactose and galactosemia can lead to falsely elevated test results. Concentrations of galactose in the blood greater than 15 mg/dL (greater than 0.83 mmol/L) lead to falsely elevated test results. Test results for neonates exhibiting symptoms of galactosemia must be confirmed by laboratory tests.
- Concentrations of bilirubin in the blood up to 40 mg/dL (680 µmol/L) do not interfere. Higher concentrations have not been tested.
- Do not use when undergoing ceftriaxone treatment. Concentrations of ceftriaxone in the blood greater than 100 µg/mL (greater than 180 µmol/L) lead to falsely lowered blood glucose test results.
- If peripheral circulation is impaired, capillary blood 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 hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA class IV, or peripheral arterial occlusive disease.
- You may use blood with a hematocrit of 20 to 55 %.
- Visually impaired people must not use the Accu-Chek SugarView app, the test strips, and the control solutions.
- For any limitations on using blood samples from other sites on your body besides the fingertip (AST testing), refer to the package insert inside the test strip box.

# 10 Limitations

- If you are on insulin therapy or if you take hypo-inducing oral antidiabetics (for example, sulfonylureas), this may lead to incorrect test results. In such a case do not use the app for testing your blood glucose. Do **not** use test results of the app as a basis for making therapy decisions.

# 11 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.* | 3.0 U |
| Pyrroloquinoline quinone | 0.2 µg |
| Bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidene)-ammonium chloride | 7.9 µg |
| 2,18-phosphomolybdic acid, sodium salt | 85 µg |
| Stabilizer | 0.13 mg |
| Non-reactive ingredients | 1.6 mg |

# 12 Discarding the Test Strip

**⚠ WARNING**

**Risk of infection**

A used test strip can transmit infections. Discard a used test strip as infectious material according to the regulations applicable in your country.

For information on how to discard a used test strip correctly, contact your local council or authority.

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

# 13 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.

# 14 Explanation of Symbols

| Symbol | Description |
|---|---|
| | 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 (unopened or opened test strip container) |
| | All components of the pack can be discarded in domestic waste. Discard used test strips according to local regulations. |
| | Date of manufacture |
| | Device for self-testing |
| | Device for near-patient testing |
| | Manufacturer |
| UDI | Unique device identifier |
| REF | Catalogue number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device |
| CE | Complies with the provisions of the applicable EU Legislation |

# 15 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: 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes–2020. *Diabetes Care* 2020, 43, (Supplement 1): S14–S31

[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)

[5] American Diabetes Association. Glycemic targets. Sec. 6. Standards of Medical Care in Diabetes–2017. *Diabetes Care* 2017; 40 (Suppl. 1): S48–S56

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