ACCU-CHEK® SmartView

Test Strips

FOR SELF-TESTING ONLY

Cat. No. 06334059, 06337538, 06337546, 06337554, 06337562, 07214090, 06333796

Important Information

Note: In this package insert the term "blood glucose" is used when referring to "blood sugar."

Intended use

The Accu-Chek Nano SmartView blood glucose monitoring system is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm. The Accu-Chek Nano SmartView blood glucose monitoring system is intended to be used by a single person and should not be shared.

The Accu-Chek Nano SmartView 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. The Accu-Chek Nano SmartView blood glucose monitoring system should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternate site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Accu-Chek SmartView test strips are for use with the Accu-Chek Nano blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm.

For in vitro diagnostic use

Introduction

Testing your blood glucose regularly may help you better manage your diabetes, which can prevent or slow the development of diabetes complications. Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay in your target range. If your blood glucose is too low, you may experience anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion. If your blood glucose is too high, you may experience increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

Important Safety Information

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.[1,2]
- The Accu-Chek Nano meter and the lancing device should never be used by more than one person. Do not share them with anyone, including other family members, due to the risk of infection from bloodborne pathogens.[1,2]
- Disinfect the Accu-Chek Nano meter and the lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. Read and follow the meter and lancing device cleaning and disinfecting instructions found in the Accu-Chek Nano Owner's Booklet.
- Wash and dry hands thoroughly using soap and water before and after handling the meter, lancing device, and test strips.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

WARNING:

- Failure to follow testing instructions or test strip storage and handling instructions can lead to an incorrect test result that may lead to improper therapy. 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 the Accu-Chek Customer Care Service Center. Damaged test strips can cause inaccurate results, which could lead to improper therapy.
- Do not eat the test strips. They are only for use outside the body (in vitro).
- Choking hazard. Small parts. Keep away from children under the age of 3 years.

Before You Start Testing

- Your hematocrit should be between 10–65 %. Ask your healthcare professional if you do not know your hematocrit.
- If you have poor circulation, testing your own blood glucose may not be right for you. Ask your healthcare professional.
- This system has been tested at altitudes up to 10,000 feet.

Test Strip Storage and Handling

- Use the test strips at temperatures between 57–104 °F.
- Use the test strips between 10–80 % relative humidity. Humidity is the amount of dampness in the air.
- Do not expose the test strip to heat, moisture, or humidity. Temperatures outside the required range, as well as moisture and humidity, can damage the test strips and produce incorrect results.
- Use the test strip immediately after removing it from the container.
- Discard the test strips if they are past the **Use By** date printed on the test strip container. If the **Use By** date is missing or cannot be read, do not use the test strips.
- Store the test strip container at room temperature between 36–86 °F. Do not freeze. Do not store the test strip container in rooms where the air is humid such as kitchen, laundry room, or bathroom.
- Store the test strips in their original container with the cap closed.
- Close the container tightly immediately after removing a test strip to protect the test strips from humidity.

Step 1 Getting Ready to Test

1. Get your supplies together. You need the meter, a test strip, a lancing device, and a lancet.
2. Prepare the lancing device.

Step 2 Performing a Control Test

What control solution to use

Use the Accu-Chek SmartView control solution.

How the control solution works

The control solution contains a known amount of glucose that acts like blood when you apply it to the test strip. Performing a control test lets you know that the meter and test strips are working properly.

When to perform a control test

- You open a new box of test strips
- You think the test strips are damaged
- The test strips were stored at extreme temperatures or humidity
- You want to check if the meter and the test strips are working properly
- You dropped the meter
- Your blood glucose result does not agree with how you feel
- You want to check if you are testing correctly

How to perform a control test

Please refer to the control solution package insert or the Owner's Booklet for instructions. If you need control solution, talk to your pharmacist or visit accu-chek.com to order online.

What the control results mean

Compare the control result to the range on the label of the test strip container. If the control result is within the range, you know that the meter and test strips are working properly. You can now test your blood glucose.

If the control result is NOT within the range…

Check the following list to see what may be causing the problem:

- Are the test strips or control solution past the **Use By** or discard date?
- Did you wipe the tip of the control solution bottle with a tissue before and after use?
- Were the test strip container and control solution bottle closed tightly?
- Did you use the test strip immediately after removing it from the container?
- Were the test strips and control solution stored in a cool, dry place?
- Did you follow all of the testing steps?

For more information, refer to the control solution package insert or the Owner's Booklet.

If you still have problems, call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Step 3 Performing a Blood Glucose Test

You are now ready to test your blood glucose. Read the "Getting a good blood drop" section of this package insert if you have problems or are new to testing.

Procedure

1. Wash hands with warm soapy water and dry thoroughly.
2. Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.
3. Insert the test strip into the meter in the direction of the arrows. The meter turns on.
4. A test strip and flashing blood drop symbol appear on the display.
5. Use the lancing device to get a blood drop.
6. Touch the blood drop to the **front edge** of the yellow window of the test strip. **Do not put blood on the top of the test strip**. When you see flash, you have enough blood in the test strip.
7. Your blood glucose result appears on the display.
8. Take the test strip out of the meter. Put the lancet and test strip in a puncture-proof container such as a biohazard container.
9. Wash hands with warm soapy water and dry thoroughly.

Getting a good blood drop

If you have trouble getting a good blood drop, here are some tips:

Fingertip testing

- Wash your hands in warm, soapy water, then rinse and dry thoroughly. (Warming your fingers can increase blood flow.)
- If you use an alcohol wipe, make sure the testing site is dry before getting a blood drop.
- Let your hand hang by your side. (This increases blood flow.)
- Squeeze your finger at the knuckle for 3 seconds, then let go. Repeat.
- Prick your finger, then squeeze at the knuckle to form a blood drop. Do not squeeze too hard.

Alternate site testing

- Rub the skin prior to lancing to increase blood flow.

Step 4 Your Blood Glucose Results

The normal fasting glucose level for a non-diabetic adult is below 100 mg/dL. The normal glucose level for a non-diabetic adult 2 hours post 75 g Oral Glucose Tolerance Test (OGTT) is less than 140 mg/dL.[3,4]

For people with diabetes: Please consult your healthcare professional for the blood glucose level appropriate for you.

You should treat your low or high blood glucose as recommended by your healthcare professional.

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). Therefore, the meter displays blood glucose concentrations that refer to plasma although you always apply whole blood to the test strip.

Symptoms of low or high blood glucose

Being aware of the symptoms of low or high blood glucose can help you understand your blood glucose results and decide what to do if they seem unusual.

Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

If you are having any of these symptoms, test your blood glucose. If your blood glucose result is displayed as LO or HI, and you have symptoms of low or high blood glucose, follow your healthcare professional's instructions or contact your healthcare professional. For example, if your healthcare professional has advised you to immediately treat a low blood glucose result (such as by eating something), then do so.

WARNING: Follow the advice of your healthcare professional before you change your therapy!

Unusual test results

If **LO** is displayed on the meter, blood glucose may be below 20 mg/dL.

If **HI** is displayed on the meter, blood glucose may be over 600 mg/dL.

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

1. Perform a control test.
2. Review the test procedure and repeat the test with a new test strip.
3. If your blood glucose result still does not match the way you feel, follow your healthcare professional's instructions or contact your healthcare professional immediately.

Do not change your treatment because of just one result.

NEVER ignore symptoms of low or high blood glucose.

For detailed information on error codes, please refer to the Owner's Booklet.

Testing from Alternate Sites

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternate sites include two palm testing sites. The two palm testing sites are the fleshy areas under the thumb (thenar) and under the little finger (hypothenar). Blood obtained from the fingertip can be used at any time to test blood glucose. If blood from an alternate site is used, there are certain times when testing is not appropriate (see next section). This is because your blood glucose level changes faster in your fingertip than in the alternate sites. These differences may cause you to make the wrong therapeutic decision, producing adverse health effects. Please read the following section before you test from alternate sites.

IMPORTANT

- Talk to your healthcare professional before you test from alternate sites.
- Do not use an alternate site testing measurement to calibrate a continuous glucose monitoring (CGM) device or to make insulin dosing calculations.

Tests from the palm may be performed

- Immediately before a meal
- Fasting

Tests from the palm may NOT be performed

- Two hours or less after eating
- After exercising
- If you are sick
- If you think your blood glucose is low
- If you often do not notice when your blood glucose is low
- During peak action time of short-acting insulin or rapid-acting insulin analogues
- Up to 2 hours after injecting a short-acting insulin or a rapid-acting insulin analogue

If your blood glucose does not match how you feel, perform a fingertip test to confirm your result. If the fingertip result still does not match how you feel, contact your healthcare professional. For more information on testing from alternate sites, call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Limitations

- The Accu-Chek SmartView test strips are for testing fresh capillary whole blood.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of fresh capillary whole 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 hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.

Performance Characteristics

Test principle

The Accu-Chek Nano SmartView system is plasma calibrated to allow easy comparison of results with laboratory methods. Blood from your fingertip reacts with the chemicals in the test strip to create a harmless electrical current in the test strip. The meter reads the current and gives you the blood glucose result.

Sample size: 0.6 µL
Test time: 5 seconds
System measurement range: 20–600 mg/dL

Accuracy (method comparison)

Capillary blood study: Study conducted at 1 physician site for capillary blood samples. Data across the entire reportable range meets the criteria of 95 % of individual values within ±15 mg/dL glucose concentrations <75 mg/dL and within ±20 % glucose concentrations ≥75 mg/dL.

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 17/19 (89.5 %)	**Within ±10 mg/dL** 19/19 (100 %)
Within ±15 mg/dL 19/19 (100 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 57/81 (70.4 %)	**Within ±10 %** 77/81 (95.1%)
Within ±15 % 81/81 (100.0 %)	**Within ±20 %** 81/81 (100.0 %)

User performance study: In a study conducted with the Accu-Chek Nano SmartView system at 1 office site with capillary blood samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL 3/3 (100 %)	**Within ±10 mg/dL** 3/3 (100 %)
Within ±15 mg/dL 3/3 (100 %)	

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 % 33/57 (57.9 %)	**Within ±10 %** 48/57 (84.2 %)
Within ±15 % 55/57 (96.5 %)	**Within ±20 %** 57/57 (100 %)

Alternate site testing study: In a study conducted with the Accu-Chek Nano SmartView system at 2 office sites with capillary blood samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL

Alternate site	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Palm	15/20 (75.0 %)	18/20 (90.0 %)	19/20 (95.0 %)

Results for glucose concentrations greater than or equal to 75 mg/dL

Alternate site	Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
Palm	76/166 (45.8 %)	132/166 (79.5 %)	160/166 (96.4 %)	166/166 (100.0 %)

Precision

Precision studies using control solutions (day-to-day precision) and blood (within-lot precision) are shown below:

Control solutions	Low	Mid	High
N	10	10	10
mean [mg/dL]	44.9	116.6	303.4
SD [mg/dL]	1.0	1.6	4.9
CV [%]	2.2	1.4	1.6

Blood	1	2	3	4	5
N	100	100	100	100	100
mean [mg/dL]	47.7	88.4	134.6	208.3	341.2
SD [mg/dL]	1.9	3.8	5.0	8.5	11.1
CV [%]	4.0	4.3	3.7	4.1	3.2

Reagent composition†

Mediator ..... 6.72 %
Quinoprotein glucose dehydrogenase‡ ..... 15.27 %
Pyrroloquinoline quinone ..... 0.14 %
Buffer ..... 34.66 %
Stabilizer ..... 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)

Limited Warranty

Roche warrants that your Accu-Chek SmartView test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are used and stored in the manner described in this package insert and in your Accu-Chek blood glucose meter Owner's Booklet. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, Roche will replace the test strips free of charge. Your sole and exclusive remedy with respect to the test strips shall be replacement. Any warranty claim should be directed to the Accu-Chek Customer Care Service Center at 1-800-858-8072.

ACCU-CHEK® SmartView

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Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

Additional Information

The Owner's Booklet contains more information. If you need help, call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

References

1. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, Update November 29, 2010. http://wayback.archive-it.org/7993/20161022010458/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed April 26, 2019.
2. CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed April 26, 2019.
3. American Diabetes Association website; Diagnosing Diabetes and Learning about Prediabetes. http://www.diabetes.org/diabetes-basics/diagnosis/. Accessed April 26, 2019.
4. American Diabetes Association: Classification and Diagnosis of Diabetes. Sec. 2. Standards of Medical Care in Diabetes-2019. Diabetes Care, 42 (Suppl. 1): S13-S28, 2019.

Explanation of Symbols

GTIN	Global Trade Item Number
SN	Serial Number

Problems or Questions?

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. We offer assistance in many languages.

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Manufactured in the U.S.A. of U.S. and imported content.
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