




## ACCU-CHEK 07453701 Test Strips Instruction Manual

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### ACCU-CHEK 07453701 Test Strips Instruction Manual



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## Important Information

**NOTE:** In this package insert the term “blood glucose” is used when referring to “blood sugar.”

### Intended Use for the Accu-Chek Guide Meter

The Accu-Chek Guide Blood Glucose Monitoring System is comprised of the Accu-Chek Guide meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

### Intended Use for the Accu-Chek Guide Link Meter

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and Accu-Chek Guide test strips. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Link Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed™ 770G system with Bluetooth® wireless technology through the use of Bluetooth low energy communication.

### Intended Use for the Accu-Chek Guide Me Meter

The Accu-Chek Guide Me Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Me meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Me Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes. The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Me Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

## **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.<sup>1,2</sup>
- Meters and lancing devices 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.<sup>1,2</sup> Do not use on multiple patients!
- Clean and disinfect the 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 meter User's Manual.
- Wash and dry hands thoroughly using soap and water before and after handling the meter, lancing device, and test strips.

### **Warning**

- 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.
- 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.

## **Limitations**

- Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.
- Not for use in diagnosis or screening of diabetes mellitus.
- Not for neonatal use.
- Abnormally high concentrations of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate results. If you are not sure please check with your doctor.
- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular

collapse (severe shock) or decreased peripheral blood flow.

- Do not use this system during xylose absorption test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.
- This system has not been tested at altitudes higher than 10,150 feet.

## **Before You Start Testing**

- Carefully read and follow all instructions in the package insert when testing your blood glucose.
- The Accu-Chek Guide test strips are for testing fresh capillary whole blood.
- 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.

## **Test Strip Storage and Handling**

- Use the test strips at temperatures between 43–113 °F.
- Use the test strips between 10–90 % relative humidity. Humidity is the amount of dampness in the air.
- Do not expose the test strips 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 temperatures between 39–86 °F. Do not freeze. Do not store the test strip container in rooms where the air is humid such as the 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.
- Store the test strip container between 10–90 % relative 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.
3. Check the Use By date on the test strip container. Do not use test strips past the Use By date.

## **STEP 2 Performing a Control Test**

### **What control solution to use**

Use the Accu-Chek Guide control solutions.

### **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 test strip box

- You left the test strip container open
- You think the test strips are damaged
- You want to check the meter and test strips
- The test strips were stored in extreme temperatures, humidity, or both
- You dropped the meter
- Your test result does not match how you feel
- You want to check if you are performing the test correctly

### **How to perform a control test**

Refer to the control solution package insert or User's Manual for instructions. If you need control solutions, talk to your pharmacist or visit [accu-chek.com](http://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...**

- Were the test strips or control solutions past the Use By or discard date?
- Did you wipe the tip of the control solution bottle before use?
- Were the caps on the test strip container and the control solution bottle always closed tightly?
- Was the test strip used immediately after it was removed from the test strip container?
- Were the test strips and control solutions stored in a cool, dry place?
- Did you follow the directions?
- Did you choose the correct control solution level, either 1 or 2, when you performed the control test?

For more information, refer to the control solution package insert or User's Manual. For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. We offer assistance in many languages.

## **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. Insert the metallic end of the test strip into the meter. The meter turns on.  
On the Accu-Chek Guide and Accu-Chek Guide Link meters, Preparing to test appears on the display.  
On the Accu-Chek Guide Me meter, a flashing drop appears on the display.
3. Check the Use By date on the test strip container. Do not use test strips past the Use By date.
4. Use the lancing device to get a blood drop.
5. Touch the yellow edge of the test strip to the blood drop. Do not put blood on top of the test strip.  
On the Accu-Chek Guide and Accu-Chek Guide Link meters, remove your finger from the test strip when Analyzing appears on the display.

On the Accu-Chek Guide Me meter, remove your finger from the test strip when the flashing hourglass appears on the display. Failure to move your finger away from the test strip could give inaccurate results.

6. The test result appears on the display.
7. Take the test strip out of the meter. Put the lancet and the test strip in a puncture-proof container, such as a biohazard container.
8. Wash hands thoroughly with soap and water.

### 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, and then squeeze at the knuckle to form a blood drop. Do not squeeze too hard.

**Alternative site testing—Rub** the skin prior to lancing to increase blood flow.

### 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.<sup>3,4</sup> 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.

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, your 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!

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, refer to the User's Manual.

### **Testing from Alternative Sites with the Accu-Chek Guide, Accu-Chek Guide Link, and Accu-Chek Guide Me Meters**

**Warning:** Do not use alternative site testing to calibrate a continuous glucose monitoring system or to make insulin dosing calculations. Warning: Alternative site testing should be done only during steady-state times (when blood glucose is not changing rapidly).

Alternative site testing is **ONLY** approved for the Accu-Chek Guide test strips when used with the Accu-Chek Guide, Accu-Chek Guide Link, or Accu-Chek Guide Me meters.

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm and upper arm. Blood obtained from the fingertip can be used at any time to test blood glucose. If blood from an alternative site is used, there are certain times when testing is not appropriate (see below). This is because your blood glucose level changes faster in your fingertip than in the alternative sites. These differences may cause you to make the wrong therapeutic decision, producing adverse health effects. Read the following section before you test from alternative sites.

### **IMPORTANT**

- Talk to your healthcare professional before you test from alternative sites.
- Only fingertip samples should be used to calibrate a continuous glucose monitoring (CGM) device or to make insulin dosing calculations.

#### **You may perform a test from the palm or upper arm:**

- immediately before a meal.
- while fasting.

#### **You may NOT perform a test from the palm or upper arm:**

- up to 2 hours following a meal, when blood glucose values can rise quickly.
- after injecting bolus insulin, when blood glucose values can decrease rapidly.
- after exercise.
- if you are sick.
- if you think your blood glucose is low (hypoglycemia).
- if you sometimes do not notice when your blood glucose is low.

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

### **Performance Characteristics**

**Test principle:** The blood glucose monitoring systems are 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  $\mu$ L

**Test time:** <4 seconds

**System measuring range:** 20–600 mg/dL

**User performance study:** In a study conducted at 2 sites with capillary blood samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL		
within $\pm 5$ mg/dL	within $\pm 10$ mg/dL	within $\pm 15$ mg/dL
8/12 (66.7 %)	12/12 (100 %)	12/12 (100 %)

Results for glucose concentrations greater than or equal to 75 mg/dL			
within $\pm 5$ %	within $\pm 10$ %	within $\pm 15$ %	within $\pm 20$ %
63/108 (58.3 %)	103/108 (95.4 %)	107/108 (99.1 %)	108/108 (100 %)

**User performance study:** In a study conducted at 1 site with Palm AST samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL			
Alternative Site	within $\pm 5$ mg/dL	within $\pm 10$ mg/dL	within $\pm 15$ mg/dL
Palm	8/9 (88.9 %)	9/9 (100 %)	9/9 (100 %)



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

<b>Alternative Site</b>	<b>within ±5 %</b>	<b>within ±10 %</b>	<b>within ±15 %</b>	<b>within ±20 %</b>
Palm	175/363 (48.2 %)	308/363 (84.8 %)	356/363 (98.1 %)	362/363 (99.7 %)

**User performance study:** In a study conducted at 1 site with Upper Arm AST samples, the following results were obtained by untrained patients:

**Results for glucose concentrations less than 75 mg/dL**

<b>Alternative Site</b>	<b>within ±5 mg/dL</b>	<b>within ±10 mg/dL</b>	<b>within ±15 mg/dL</b>
Upper Arm	7/10 (70 %)	10/10 (100 %)	10/10 (100 %)

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

<b>Alternative Site</b>	<b>within ±5 %</b>	<b>within ±10 %</b>	<b>within ±15 %</b>	<b>within ±20 %</b>
Upper Arm	156/355 (43.9 %)	281/355 (79.2 %)	337/355 (94.9 %)	351/355 (98.9 %)

**Precision**

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

Control solutions	Low	Mid	High
N	300	300	300
mean [mg/dL]	44.9	116.6	297.4
SD [mg/dL]	1.4	2.8	6.8
CV [%]	3.1	2.4	2.3

Blood	1	2	3	4	5
N	300	300	300	300	300
mean [mg/dL]	40.5	81.7	132.1	206.7	330.2
SD [mg/dL]	1.4	2.0	2.8	5.4	8.6
CV [%]	3.5	2.4	2.1	2.6	2.6

**Reagent composition†**

Mediator	6.6 %
FAD-GDH enzyme	21.3 %
Buffer	22.6 %
Stabilizer	2.3 %
Non-reactive ingredients	47.2 %

†Minimum at time of manufacture

## Warranty

Roche warrants that your Accu-Chek Guide 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 User's Manual. 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.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE TEST STRIPS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

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 User's Manual contains more information.

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



## References

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## Explanation of Symbols

	Global Trade Item Number
	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.

Manufactured in the U.S.A. using U.S. and imported materials.

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U.S. Pat.: <http://www.roche-diagnostics.us/patents>

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## Documents / Resources

	<a href="#">ACCU-CHEK 07453701 Test Strips</a> [pdf] Instruction Manual Test Strips, 07453701, 07453710, 07453736, 07453744, 08053707, 08053723
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