

URGENT PRODUCT RECALL



Diagnostics

05-240
11/09/05

Attention: ACCU-CHEK® Aviva Meter User

ACCU-CHEK Aviva Meter – Potential for Erroneous Result

Recall Information

Roche Diagnostics is replacing specific ACCU-CHEK Aviva meters because of the potential for an electronic malfunction which can cause an erroneous result. If you use the ACCU-CHEK Aviva meter, please read this important information to determine if you have product subject to this recall. If your meter falls within the serial number range listed below, please call 1-888-591-5084 for a replacement.



ACCU-CHEK Aviva test strips are not affected by this recall.

NOTE

Affected Meters

Affected ACCU-CHEK Aviva Meters

Serial numbers **52500**000000 through **52510**999999

This recall affects a small percentage of ACCU-CHEK Aviva meters. It does not apply to meters with serial numbers 52511000000 and higher.

Please refer to the picture below for the location of the serial number on the back of your ACCU-CHEK Aviva meter.



Serial number

over...

Roche Diagnostics
Corporation

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Issues

If you use an affected ACCU-CHEK Aviva meter, Roche Diagnostics wants to make you aware of a possible electronic malfunction that could result in:

- an erroneous numerical result, **or**
- an erroneous “HI” or “LO” display, **or**
- the meter shutting down and being no longer usable

Actions Required

- **Roche Diagnostics will replace all affected ACCU-CHEK Aviva meters. If you have an affected meter, call toll free 1-888-591-5084 for a replacement.**
- File this Urgent Product Recall for future reference.

Unusual Test Results

If at any time your blood sugar result doesn't match the way you feel, Roche Diagnostics recommends that you follow these steps:

1. Run a control test, ACCU-CHEK Aviva Owner's Booklet, Chapter 2 “Control Testing.”
2. Repeat a blood sugar test, ACCU-CHEK Aviva Owner's Booklet, Chapter 3 “Testing Your Blood Sugar with Blood from Your Fingertip.”
3. If your blood sugar results still don't reflect the way you feel, call your doctor immediately.

Symptoms of High or Low Blood Sugar

Being aware of the symptoms of high or low blood sugar can help you understand your test results and decide what to do if they seem unusual. Here are the most common symptoms.

High blood sugar (hyperglycemia): fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

Low blood sugar (hypoglycemia): sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

Please note: Not all people with high or low blood sugar will have symptoms.

Questions

This notification is being made with the knowledge of the Food and Drug Administration (FDA). If you have any questions regarding the information contained in this Urgent Product Recall, please contact the ACCU-CHEK Customer Care Service Center at 1-800-858-8072.

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