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# Accutrend Glucose

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| REF | CONTENT | SYSTEM |
|---|---|---|
| **11447475** 160 | 25 test strips<br>1 code strip | Accutrend Plus<br>Accu-Chek® InstantPlus |

**For use in the USA only**

This is a CLIA Waived test system. A Certificate of CLIA Waiver (or higher) is required to perform the test. Information on obtaining CLIA certificates can be found at www.cms.hhs.gov/clia. Facilities performing testing must have a CLIA Certificate of Waiver. 42 USC 263a(c)(2).

Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1). Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a failure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements. All applicable state and local laws must be met.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online (at www.fda.gov/MedWatch/report.htm), by phone (1-800-FDA-1088), or by returning the postage-paid FDA form 3500 (which may be downloaded from www.fda.gov/MedWatch/getforms.htm) by mail to (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-1078).

### Intended use

Accutrend Glucose test strips are for the quantitative determination of glucose in capillary whole blood. For use by health care professionals and for home use by people with diabetes for glucose testing.
For use with Accutrend Plus and Accu-Chek InstantPlus meters. Before using these test strips read this method sheet and the User's Manual carefully.

### For in vitro diagnostic use

### Patient information

### Introduction

Almost anyone with diabetes can be helped by self-testing of blood glucose. Under a doctor's care, self-testing can help you achieve near-normal blood glucose levels.
The Accutrend Glucose test strip, used as directed with an Accutrend Plus or Accu-Chek InstantPlus meter, will accurately measure your blood glucose level. The strip changes color as it reacts to glucose in a drop of blood and the meter measures this color change. Your total blood glucose is then displayed on the meter display screen.

### Product updates

This section of your package insert may contain new information that has not yet been included in the Accutrend Plus or Accu-Chek InstantPlus User's Manuals. Refer to this section each time you get a new container of test strips for the latest revisions or updates.

### Reagent handling

- Tightly re-cap the container immediately after removing a test strip. Exposure to light and moisture may discolor the test strips which may lead to an error code.
- Do not cut or alter the test strips in any way. This will lead to an error code.

### Storage and stability

- Store strips at 36-86 °F (2-30 °C). Do not freeze.

### Tips for getting a good drop of blood

Accutrend Plus and Accu-Chek InstantPlus meters and strips **require a hanging drop of blood.** If you are new to self testing, or have had trouble getting enough blood in the past, you may want to review the following steps before you proceed with testing.

- Wash hands in warm, soapy water; rinse and dry completely. Warming the fingers can help increase blood flow. If you use an alcohol wipe to clean your finger, make sure the finger is completely dry before continuing.
- Let your arm hang down at your side briefly to allow blood to flow to fingertips.
- Grasp finger near area to be pricked and squeeze for three seconds.
- Keeping hand down, prick side of fingertip, and squeeze gently until you get a hanging drop of blood. For lancing the finger Roche Diagnostics recommends Accu-Chek Softclix, Accu-Chek Safe-T-Pro and Accu-Chek Safe-T-Pro Plus devices.

### Understanding your glucose test result

### What's normal?

The normal fasting adult blood glucose range for a non-diabetic is 70 - 105 mg/dL.[1] One or two hours after meals, normal blood glucose levels should be less than 140 mg/dL.[2] Your health care provider will determine the range that is appropriate for you.

### What if I get a low blood sugar reading?

If LO is displayed, your blood glucose result may be below 20 mg/dL. You may also observe symptoms of low blood glucose. If these symptoms—sweating, trembling, blurred vision, rapid heart beat, tingling or numbness around the mouth or fingertips are present— seek proper treatment immediately. If they are absent, YOU SHOULD REPEAT THE TEST. Be sure to check the test strip visually with the color chart on the container to confirm the test result.
If you repeat the test and obtain a low result again, **contact your physician immediately. Always, contact your physician before you change your therapy.**

### What if I get a high blood sugar reading?

If HI is displayed, your blood glucose result may be higher than 600 mg/dL. Be sure to check the test strip visually with the color chart on the container to confirm the test result.

### Caution

If your blood glucose value is high (above 240 mg/dL) for several days, your kidneys may excrete large amounts of water, causing excessive urination and dehydration. Dehydration may result in a glucose reading that is lower than the true value. We recommend that you contact your doctor if your glucose remains above 240 mg/dL for several days. If your blood glucose level is above 240 mg/dL, you should monitor your urine ketone levels with Chemstrip K or Chemstrip uGK test strips. Contact your doctor immediately if you detect moderate or high ketone levels, or if you experience thirst, abdominal pain, vomiting, difficulty in breathing or headaches. If you get an unusual test result, review the testing procedures. Repeat the test with a new test strip. If your blood glucose value still does not reflect your physical condition, contact your physician.

### Unusual test results

If your blood glucose value seems unusually high or low, and does not reflect the way you feel, there may be problems with your test procedure, test strip or meter, or the test strip code number may not match the code number on the meter. The following can cause unusually high or low results:

- Test strip was used after expiration date.
- Test strip was not stored in container with cap tightly sealed.
- Test strip was stored in extreme temperatures.
- Meter was not properly maintained or handled.
- Meter was not properly coded for the strips being used.
- Blood drop was too small.

If you get an unusual test result, review the testing procedures. Repeat the test with a new test strip. If your blood glucose value still does not reflect your physical condition, contact your physician.

### Return policy

If you have a problem with your Accutrend Glucose test strips, you may be asked to return them, with the code strip, to Roche Diagnostics. Before returning, call Technical Support at 1-800-440-3638. You will be mailed a return authorization label which must be put on your shipping carton. Cartons received without this label will be returned to you at your expense.

### Limitations of procedure

The limitations of the Accutrend Glucose test strips are listed in the Health care professional information section of this method sheet. **Please read the**

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**limitations carefully** and consult your health care professional if you have any questions.

**Additional supplies**

Additional Accutrend Glucose test strips, as well as Accutrend Glucose Control solutions, may be purchased directly from your medical supply distributor.

**Health care professional information**

This section of the method sheet contains information specific to health care professionals. If you are a person with diabetes who uses this product, read the Patient information section of this insert first. If you have questions about the Health Care Professional information listed in this section, ask your health care professional.

**Health care professionals**

Read the Patient information and the Health Care Professional information sections of this method sheet.

**Test principle**

Quinonediimine oxide is reduced by glucose to a hydroxylamine derivate. The reaction is catalyzed by glucose oxidase (GOD). The hydroxylamine derivative decomposes to quinonediimine spontaneously. Quinonediimine is reduced to phenylendiamine by glucose catalyzed by GOD. The phosphomolybdic acid oxidizer receives two electrons from phenylendiamine while regenerating quinonediimine. The reduced phosphomolybdic acid thus becomes molybdenum blue to give the color change measured by the meter.[3,4,5,6,7,8,9,10]

**Reagent composition**

See the outside of the test strip box for reagent composition.

**Precautions and warnings**

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

**Reagent handling**

Refer to the Patient information section of this Method Sheet.

**Storage and stability**

Refer to the Patient information section of this Method Sheet.

**Limitations of procedure**

Accutrend Glucose test strips give dependable test results when the following limitations are understood and followed:

1. System measurement range is 20-600 mg/dL.
2. Only fresh capillary whole blood is recommended for accuracy determinations. Do not use venous or arterial blood.
3. The test pad reacts only to D-glucose and not to other sugars which may be present in the blood.
4. Hematocrit values between 30-55 % do not significantly affect test results.
5. This system has not been proven for use with neonates.
6. In vitro bilirubin (unconjugated) up to 10 mg/dL, uric acid levels up to 13 mg/dL, and triglycerides up to 5,000 mg/dL showed no interference.
7. At altitudes above 6,000 ft., values obtained on the Accu-Chek InstantPlus and Accutrend Plus meters may be higher than the actual values.
8. In situations of decreased peripheral blood flow, fingerstick blood glucose testing may not be appropriate as it may not reflect the true physiological state. Examples would include, but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, shock or peripheral vascular disease.[11,12,13]
9. This system should be used at < 85 % relative humidity.
10. Intravenous infusion of ascorbic acid (Vitamin C) or dialysis treatment may affect test results.
11. Glucose measurements must be performed at 64-95 °F (18-35 °C).
12. Not for screening or diagnosis of diabetes.
13. Not for patients who are critically ill.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

**Performance characteristics**

The data shown represents typical performance results for the Accu-Chek InstantPlus and Accutrend Plus meters.

**Accuracy**

In studies conducted by trained technicians at two professional sites, patient results collected on Accu-Chek InstantPlus meters were compared to a whole blood glucose hexokinase reference, yielding the following linear regression statistics:

| | | | |
|---|---|---|---|
| n | 106 | correlation coefficient | 0.988 |
| slope | 0.973 | standard error | 13.4 |
| intercept | -0.4 | range, mg/dL | 59-510 |

**Precision:** Within-run precision testing was performed using aqueous materials. Results were very good at all levels of the dynamic range:

| | Low Level | High Level |
|---|---|---|
| n | 10 | 10 |
| mean, mg/dL | 72 | 184 |
| SD | 1.8 | 4.5 |
| % CV | - | 2.4 |

**References**


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13 Wickham HWR, Achar KN, et al. Unreliability of Capillary Blood Glucose in Peripheral Vascular Disease. Practical Diabetes 1986,3:100.

**Symbols**

| | |
|---|---|
| CONTENT | Contents of kit |
| SYSTEM | Analyzers/Instruments on which reagents can be used |
| | Consult instructions for use |
| | Use-by date |
| | Temperature limit |
| | Manufacturer |
| REF | Catalogue number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device |

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