# ACCU-CHEK® Inform II

***TESTS***

REF xxxxxxxxxxx

EN **Suitable for self-testing / For professional use**

## Intended Use

The Accu-Chek Inform II test strip is intended to be used with the Accu-Chek Inform II and Accu-Chek Performa blood glucose meters to quantitatively measure glucose in fresh venous, arterial, neonatal, and capillary whole blood from the finger as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Inform II test strips, used with these Accu-Chek meters provide complete test systems that are meant for in vitro diagnostic use by healthcare professionals in clinical settings and by people with diabetes at home. The systems are not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples. Venous, arterial, and neonatal blood testing is limited to healthcare professional use only.

## Consumer Information

**Important information:** These test strips are labeled with a green ▨ symbol to distinguish them from earlier test strips that were subject to a clinically relevant maltose interference.* The green symbol can be found on the test strip box and on the label of the test strip container.

*Data on file

**WARNING**

Choking hazard. Small parts. Keep away from children under the age of 3 years.

### Contents of the pack

Pack containing test strips, 1 code chip, and package inserts.

All items contained in the pack can be discarded in domestic waste. Because the reactive substances are in such small quantities, they are not considered to be hazardous materials under EU regulations. If you have any questions, contact the local Roche representative.

### Test strip storage and handling

- Store the test strips at temperatures between 2 and 30 °C. Do not freeze the test strips.
- Use the test strips at temperatures between 8 and 44 °C.
- Use the test strips between 10 and 90 % humidity. Do not store the test strips in high heat and moisture areas such as the bathroom or kitchen.
- Store the unused test strips in their original test strip container with the cap closed.
- Close the test strip container tightly immediately after removing a test strip to protect the test strips from humidity.
- Use the test strip immediately after removing it from the test strip container.
- Discard the test strips if they are past the use by date. Expired test strips can produce incorrect results. The use by date is printed on the test strip box and on the label of the test strip container next to ⏏. The test strips can be used until the printed use by date when they are stored and used correctly. This 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.

## Performing a Blood Glucose Test

### Getting ready to test a blood glucose

**If you have poor circulation, testing your own blood glucose may not be right for you. Ask your healthcare professional.**

**For the Accu-Chek Inform II System: Refer to the Accu-Chek Inform II Meter Operator's Manual.**

**For the Accu-Chek Performa System:**

1. The meter, a test strip, the code chip, and a disposable lancet or blood collection device are required.
2. Code the meter: Change the code chip every time a new test strip box is opened. Make sure the meter is off. Turn the meter over, remove the old code chip (if there is one in the meter), and discard it. Position the new code chip so the code number faces away from you. Push the code chip into the code chip slot until the code chip snaps into place. Leave the code chip in the meter until a new test strip box is opened.
3. Prepare the lancet or blood collection device.
4. Prepare the selected blood collection site per facility policy.

### Performing a Blood Glucose Test

**For the Accu-Chek Inform II System: Refer to the Accu-Chek Inform II Meter Operator's Manual.**

**For the Accu-Chek Performa System:**

1. Insert the test strip into the meter in the direction of the arrows. The meter turns on.
2. Make sure the code number on the display matches the code number on the test strip container. If the code number is overlooked, remove the test strip and reinsert it into the meter.
3. Obtain a blood from the patient per facility policy.
4. Touch the blood drop to the **front edge** of the yellow window of the test strip. Do not put blood on top of the test strip. When ⧗ flashes, sufficient blood is in the test strip.

## Understanding Test Results

The normal fasting blood glucose range for an adult without diabetes as related to plasma is 74–106 mg/dL (4.1–5.9 mmol/L).[1] 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).[2] Therefore, the meter displays blood glucose concentrations that refer to plasma although whole blood is always applied to the test strip.

### Unusual test results

If **LO** is displayed on the meter, blood glucose may be below 10 mg/dL (0.6 mmol/L).

If **HI** is displayed on the meter, blood glucose may be over 600 mg/dL (33.3 mmol/L).

For detailed information on error messages, refer to the Operator's Manual.

**If your blood glucose result does not match how you feel, follow these steps:**

1. Repeat the blood glucose test with a new test strip.
2. Perform a control test with an Accu-Chek Performa control solution.
3. Check this list to help solve the problem.
   - Check if the test strips were expired.
   - Check if the cap on the test strip container was always closed tightly.
   - Check if the test strip was used immediately after removing it from the test strip container.
   - Check if the test strips were stored in a cool, dry place.
   - Check if you followed the directions.
4. If you think your blood glucose results are too low, too high, or doubtful, contact your healthcare professional.

## Healthcare Professional Information

**Important information:** These test strips are labeled with a green ▨ symbol to distinguish them from earlier test strips that were subject to a clinically relevant maltose interference.* The green symbol can be found on the test strip box and on the label of the test strip container.

*Data on file

### Sample collection and preparation by healthcare professionals

- When using the Accu-Chek Inform II or Accu-Chek Performa meters, always follow the recognized procedures for handling objects that are potentially contaminated with human material. Practice the hygiene and safety policy of your laboratory or institution.
- A blood drop is required to perform a blood glucose test. Capillary blood can be used. Venous, arterial, or neonatal blood may be used, but must be obtained by healthcare professionals.
- Take caution to clear arterial lines before the blood sample is obtained and applied to the test strip.
- The system has been tested with neonatal blood. As a matter of good clinical practice, caution is advised in the interpretation of neonate blood glucose values below 50 mg/dL (2.8 mmol/L). Follow the recommendations for follow-up care that have been set by your institution for critical blood glucose values in neonates. Blood glucose values in neonates suspect for galactosemia should be confirmed by an alternative glucose methodology.
- To minimize the effect of glycolysis, venous or arterial blood glucose tests need to be performed within 30 minutes of obtaining the blood samples.
- Avoid air bubbles when using pipettes.
- Capillary, venous, and arterial blood samples containing these anticoagulants or preservatives are acceptable: EDTA, lithium heparin, or sodium heparin. Anticoagulants containing iodoacetate or fluoride are not recommended.
- Refrigerated samples should be brought to room temperature slowly prior to testing.

### Additional information for healthcare professionals

If the blood glucose result does not reflect the patient's clinical symptoms, or seems unusually high or low, perform a control test. If the control test confirms that the system is working properly, repeat the blood glucose test. If the second blood glucose result still seems unusual, follow facility guidelines for further action.

Discard items contained in the pack per facility guidelines. Consult local ordinances as they may vary by country.

## Limitations

- Blood concentrations of galactose >15 mg/dL (>0.83 mmol/L) will cause overestimation of blood glucose results.
- Lipemic samples (triglycerides) >1,800 mg/dL (>20.3 mmol/L) may produce elevated blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL (>0.17 mmol/L) will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary 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.
- Hematocrit should be between 10 and 65 %.
- This system has been tested at altitudes up to 3,094 meters.

## Performance Characteristics

The Accu-Chek Performa system complies with the requirements of EN ISO 15197 (In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).

**Calibration:** The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to a NIST standard.

**Detection limit (lowest value displayed):** 10 mg/dL (0.6 mmol/L) for the test strip

**System measurement range:** 10–600 mg/dL (0.6–33.3 mmol/L)

**Sample size:** 0.6 µL

**Test time:** 5 seconds

**Accuracy (method comparison):** The slopes obtained in external studies ranged between 0.94 and 1.06.

**System accuracy according to EN ISO 15197:** 199 out of 200 samples (99.5 %) are within the minimum acceptable performance criteria.

| Results for blood glucose concentrations <75 mg/dL (<4.2 mmol/L) | | |
|---|---|---|
| **within ±5 mg/dL (within ±0.28 mmol/L)** | **within ±10 mg/dL (within ±0.56 mmol/L)** | **within ±15 mg/dL (within ±0.83 mmol/L)** |
| 32/36 (88.9 %) | 34/36 (94.4 %) | 36/36 (100 %) |

| Results for blood glucose concentrations ≥75 mg/dL (≥4.2 mmol/L) | | | |
|---|---|---|---|
| **within ±5 %** | **within ±10 %** | **within ±15 %** | **within ±20 %** |
| 98/164 (59.8 %) | 150/164 (91.5 %) | 162/164 (98.8 %) | 163/164 (99.4 %) |

**Repeatability (within-series imprecision):** The mean imprecision is <3.5 %. In a typical series of tests, a coefficient of variation of 3.3 % was obtained.

**Reproducibility (day-to-day imprecision):** The mean imprecision is <1.7 %. In a typical series of tests, a coefficient of variation of 1.6 % was obtained.

**Test principle:** The enzyme on the test strip, mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH) from *Acinetobacter calcoaceticus*, recombinant in *E. coli*, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and environmental conditions are evaluated using AC and DC signals.

### 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)

**Note:** For an explanation of symbols used and a list of references, refer to the end of this package insert.

### Control and linearity test kits (if available)

Accu-Chek Performa control – Refer to the control package insert for details.

Accu-Chek linearity kit – Refer to the linearity kit package insert for details.

Visit our website at www.accu-chek.com or contact the local Roche representative for more information. Refer to the end of this package insert for addresses.

**LAST UPDATE:** 2012-02

### References


1 Stedman, TL. *Stedman's Medical Dictionary*, 28th Edition, 2006, APP 104.

2 D'Orazio et al.: "Approved IFCC Recommendation on Reporting Results for Blood Glucose (Abbreviated);" *Clinical Chemistry* 51:9 1573-1576 (2005).


[Country addresses]

| | |
|---|---|
| | Consult package insert |
| | Temperature limitation (store at) |
| | Use by (opened / unopened) |
| | Manufacturer |
| REF | Catalogue number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device. Do not ingest! |
| CE 0088 | This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices. |
| ▨ | These test strips deliver results that refer to plasma as per IFCC, and the symbol distinguishes them from earlier test strips that were subject to a clinically relevant maltose interference. |
| | Discard in domestic waste |

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CE 0088 IVD


Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-chek.com





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