ACCU-CHEK® Inform II

TESTS

REF 05942861

EN

Intended use

Accu-Chek Inform II:

The Accu-Chek Inform II test strip is intended to be used with the Accu-Chek Inform II 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 System is also intended for quantitative measurement of glucose (sugar) in venous whole blood, arterial whole blood, and neonate arterial and heel stick whole blood samples throughout all hospital and all professional healthcare settings including patients receiving intensive medical intervention/therapy.

The Accu-Chek Inform II test strips, used with these Accu-Chek Inform II 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.

This product is for monitoring hypoglycemia in neonates diagnosed with laboratory glucose methods.

Accu-Chek Performa:

The Accu-Chek Inform II test strip is intended to be used with the Accu-Chek Performa (with code chip slot) 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 Performa 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.

This product is for monitoring hypoglycemia in neonates diagnosed with laboratory glucose methods.

Materials provided

For details see material table in header section.

Materials required (but not provided)

- Accu-Chek Inform II meter or
- Accu-Chek Performa meter or
- Lancing device (e.g. Accu-Chek Softclix)
- Lancets (e.g. Accu-Chek Safe-T-Pro or Accu-Chek Softclix lancets)

In addition, other suitable control material can be used.

Precautions and warnings

⚠ Choking Hazard. Small Parts. Keep away from children under the age of 3 years.

⚠ Do not ingest! Seek immediate medical attention if swallowed.

The solution can stain fabric. Wash with soap and water.

Dispose in domestic waste. All items contained in the pack can be disposed of in domestic waste. Because the reactive substances are in such small quantities, they are not considered to be hazardous materials under EU Regulations.

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.

If you have any questions, please contact the local Roche representative.

Healthcare Professional Information

Important information: These test strips are labelled 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.

Sample collection and preparation by healthcare professionals

- When using the Accu-Chek Inform II or Accu-Chek Performa (with code chip slot) meters, always follow the recognised 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 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.

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 components of the pack per facility guidelines. Consult local ordinances as they may vary by country.

Consumer Information

Important information: These test strips are labelled 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.

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 components of 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 your local Roche representative.

Test strip storage and handling

- If the container is open or damaged before using the test strips for the first time, if the cap is not fully closed, if you see any damage to the cap or container, or if anything prevents the cap from closing properly, do not use the test strips. Contact Roche.
- Store the test strips at temperatures between 2-30 °C. Do not freeze the test strips.
- Use the test strips at temperatures between 10 °C to 40 °C.
- Use the test strips between 10-85 % 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 perform a blood glucose test

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 (with code chip slot) system:

Note: The Accu-Chek Performa (with code chip slot) meter comes with a pre-inserted black activation chip. The black activation chip is not for use with Accu-Chek Inform II test strips. Remove the black activation chip and proceed with Step 1.

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 (with code chip slot) 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 sample 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 glucose level for a non-diabetic adult is below 5.6 mmol/L. A criterion for the diagnosis of diabetes in adults is a fasting glucose level of 7.0 mmol/L or higher confirmed in two tests.[1,2,3] Adults with a fasting glucose level between 6.1 and 6.9 mmol/L are defined as having impaired fasting glucose (prediabetes).[1,2]

Other diagnostic criteria for diabetes exist. Consult your healthcare professional to determine if you have diabetes or not.

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).[4] 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 0.6 mmol/L.

If **HI** is displayed on the meter, blood glucose may be over 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.

Limitations

- Blood concentrations of galactose > 0.83 mmol/L will cause overestimation of blood glucose results.
- Lipemic samples (triglycerides) > 20.3 mmol/L may produce elevated blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid > 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 hyperglycaemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- Haematocrit should be between 10 and 65 %.
- This system has been tested at altitudes up to 3094 meters.
- Intravenous administration of N-acetylcysteine which results in blood concentrations > 5 mg/dL will cause overestimation of blood glucose results. Do not use during intravenous infusion of N-acetylcysteine.
- Fresh whole blood samples should not be collected from an indwelling line.
- Possible interferences could be observed with Methotrexate hydrate (> 91 mg/dL).

Performance Characteristics

The Accu-Chek Inform II system complies with the requirements of EN ISO 15197:2013 (In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).[a]

a) The system also complies with the requirements of EN ISO 15197:2003.

Calibration and traceability: The system (meter and test strips) is calibrated with venous blood containing various glucose concentrations as a calibrator. The reference values are obtained using the hexokinase method which is calibrated using the ID-GCMS method. The ID-GCMS method as the method of highest metrological quality (order) is traceable to a primary NIST standard. Using this traceability chain, the results obtained with these test strips for control solutions can also be traced back to the NIST standard.

Measuring range

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

System measurement range: 0.6 - 33.3 mmol/L

Sample size: 0.6 µL

Test time: 5 seconds

Neonatal blood study:

Studies conducted gave the following results:

N = 191

y = 1.011x + 0.1

r = 0.976

range = 1.00 - 8.49 mmol/L

HCT range = 23 - 58 %

HCT mean = 40 %

System accuracy:

System Accuracy Study #1

System accuracy results for glucose concentrations less than 5.55 mmol/L:

within ± 0.28 mmol/L	within ± 0.56 mmol/L	within ± 0.83 mmol/L
138/174 (79.3 %)	171/174 (98.3 %)	174/174 (100 %)

System accuracy results for glucose concentrations equal to or greater than 5.55 mmol/L:

within ± 5 %	within ± 10 %	within ± 15 %
258/426 (60.6 %)	387/426 (90.8 %)	421/426 (98.8 %)

System accuracy results for glucose concentrations between 1.2 mmol/L and 30.4 mmol/L:

within ± 0.83 mmol/L or within ± 15 %
595/600 (99.2 %)

System Accuracy Study #2

This clinical studies were conducted according to the FDA's Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use (finalized Sept. 30, 2020) guidance. For Study #a, the prospective study accuracy was assessed within 11 clinical study sites on 1056 patients receiving intensive medical intervention/therapy. The studies included patients involving 1612 distinct medical conditions. The study patients received over 743 different medications. Glucose results were referenced to the hexokinase method and are traceable to a NIST standard. For Study #b[5], the retrospective study accuracy was collected from 3 clinical study sites using 596 samples, where the subjects were considered critically ill by the study site.

For Study #c, this retrospective study collected 104 venous samples from one site. All samples were less than 4.16 mmol/L.

Venous blood study (combined all sites):

Results for venous glucose concentrations < 4.16 mmol/L

Study a

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
3/8 (38 %)	6/8 (75 %)	6/8 (75 %)	6/8 (75 %)	6/8 (75 %)	2/8 (25 %)

Study b

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
5/8 (62.5 %)	8/8 (100 %)	8/8 (100 %)	8/8 (100 %)	8/8 (100 %)	0/8 (0 %)

Study c

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
102/104 (98 %)	103/104 (99 %)	104/104 (100 %)	104/104 (100 %)	104/104 (100 %)	0/104 (0 %)

Results for venous glucose concentrations ≥ 4.16 mmol/L

Study a

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
217/369 (59 %)	336/369 (91 %)	355/369 (96 %)	357/369 (97 %)	364/369 (99 %)	368/369 (100 %)	1/369 (0 %)

Study b

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
75/127 (59.1 %)	120/127 (94.5 %)	125/127 (98.4 %)	125/127 (98.4 %)	127/127 (100 %)	127/127 (100 %)	0/127 (0 %)

Arterial blood study (combined all sites):

Results for arterial glucose concentrations < 4.16 mmol/L

Study a

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
3/3 (100 %)	3/3 (100 %)	3/3 (100 %)	3/3 (100 %)	3/3 (100 %)	0/3 (0 %)

Study b

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
12/13 (92.3 %)	13/13 (100 %)	13/13 (100 %)	13/13 (100 %)	13/13 (100 %)	0/13 (0 %)

Results for arterial glucose concentrations ≥ 4.16 mmol/L

Study a

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
204/358 (57 %)	326/358 (91 %)	340/358 (95 %)	342/358 (96 %)	350/358 (98 %)	358/358 (100 %)	0/358 (0 %)

Study b

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
277/431 (64.3 %)	404/431 (93.7 %)	419/431 (97.2 %)	423/431 (98.1 %)	428/431 (99.3 %)	430/431 (99.8 %)	1/431 (0.2 %)

Neonate heel stick blood study (combined all sites):

Results for venous glucose concentrations < 4.16 mmol/L

Study a

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
26/37 (70 %)	37/37 (100 %)	37/37 (100 %)	37/37 (100 %)	37/37 (100 %)	0/37 (0 %)

Results for neonate heel stick glucose concentrations ≥ 4.16 mmol/L

Study a

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
24/63 (38 %)	54/63 (86 %)	59/63 (94 %)	62/63 (98 %)	63/63 (100 %)	63/63 (100 %)	0/63 (0 %)

Neonate arterial blood study (combined all sites):

Results for neonate arterial glucose concentrations < 4.16 mmol/L

Study a

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.66 mmol/L	Within ± 0.69 mmol/L	Within ± 0.83 mmol/L	Exceeds ± 0.83 mmol/L
11/15 (73 %)	15/15 (100 %)	15/15 (100 %)	15/15 (100 %)	15/15 (100 %)	0/15 (0 %)

Results for neonate arterial glucose concentrations ≥ 4.16 mmol/L

Study a

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
22/85 (26 %)	55/85 (65 %)	69/85 (81 %)	74/85 (87 %)	83/85 (98 %)	85/85 (100 %)	0/85 (0 %)

Precision

Repeatability:

Mean value [mmol/L]	2.3	3.7	6.8	10.4	17.6
Standard deviation [mmol/L]	0.1	0.2	0.3	0.4	0.6
Coefficient of variation [%]	—	—	3.9	4.0	3.6

Intermediate precision:

Mean value [mmol/L]	2.5	6.5	17.0
Standard deviation [mmol/L]	0.1	0.1	0.3
Coefficient of variation [%]	—	1.8	1.7

Performance assessment by the user: A study evaluating glucose values from fingertip capillary blood samples obtained by 325 lay persons showed the following results:

- For glucose concentrations less than 5.55 mmol/L, 100 % of the test results were within ± 0.83 mmol/L of the results obtained through laboratory testing.
- For glucose concentrations equal to or greater than 5.55 mmol/L, 98.6 % of the test results were within ± 15 % of the results obtained through laboratory testing.

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[b)]

Mediator	6.72 %
Quinoprotein glucose dehydrogenase[c)]	15.27 %
Pyrroloquinoline quinone	0.14 %
Buffer	34.66 %
Stabiliser	0.54 %
Non-reactive ingredients	42.66 %

b) Minimum at time of manufacture

c) From *A. calcoaceticus*, recombinant in *E. coli*, detailed description in patent application WO 2007/118647 (as "mutant 31" in table 4)

Control and linearity test kits (if available)

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

Accu-Chek linearity test kit – Refer to the linearity test 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.

References

1 Punthakee Z, Goldenberg R and Katz P. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: Definition, Classification and Diagnosis of Diabetes, Prediabetes and Metabolic Syndrome. Can J Diabetes 2018; 42 (Suppl 1): S10-S15.

2 Ekoe J, Goldenberg R and Katz P. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: Screening for Diabetes in Adults. Can J Diabetes 2018; 42 (Suppl 1): S16-S19.

3 Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. WHO, Geneva 2006 (ISBN 92 4 159493 4, ISBN 978 92 4 159493 6).

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

5 Louie, et al, Performance Evaluation of a Glucose Monitoring System for Point-of-Care Testing With the Critically Ill Patient Population—A Multicenter Study.

Canada

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

SYSTEM	Analyzers/Instruments on which reagents can be used
	Consult package insert
	Temperature limitation (store at)
	Use by (opened / unopened)
	Manufacturer
REF	Catalogue number
LOT	Batch code
IVD	In vitro diagnostic medical device
GTIN	Global Trade Item Number
CE 0123	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.
	All components of the pack can be discarded in domestic waste. Discard used test strips according to local regulations.

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