ACCU-CHEK® Inform II

TESTS

REF 05942861

(EN) **Device for self-testing**
Device for near-patient testing

Intended use

The Accu-Chek Inform II test strips with the dedicated blood glucose meters (Accu-Chek Inform II, Accu-Chek Performa (with code chip slot), and Accu-Chek Performa Nano) are intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal whole blood. They are indicated as an aid in monitoring the effectiveness of glucose control for self-testing by people with diabetes and for near-patient testing by healthcare professionals. For specific instructions for your meter refer to your User's Manual.

The test strip is 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

Introduction

Read this package insert and the User's Manual before performing a blood glucose test.

The package insert contains warnings and precautions:

A **WARNING** indicates a foreseeable serious hazard.

A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

⚠ WARNING

Risk of suffocation

This product contains small parts that can be swallowed.

Keep the small parts away from small children and people who might swallow small parts.

⚠ WARNING

Risk of a serious health incident

Failure to follow testing instructions or test strip storage and handling instructions can lead to an incorrect test result.

Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions.

Risk of infection: Human blood is a potential source for the transmission of infection. Avoid exposing other people to contaminated components.

Discard the used test strip as potentially infectious material according to the regulations applicable in your country.

Contents of the pack

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

All components of the pack can be discarded in domestic waste.

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 8 °C to 44 °C (46 °F to 111 °F).
- Use the test strips between 10-90 % 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 already opened by the user.
- Use a test strip only once. Test strips are for single use only.

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. Clean the puncture site before obtaining a blood drop. 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) and Accu-Chek Performa Nano systems:

Note: The Accu-Chek Performa (with code chip slot) and Accu-Chek Performa Nano meters may come with a pre-inserted black activation chip. The black activation chip is not for use with Accu-Chek Inform II test strips. If present, 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. Remove your finger from the Test strip when 🩸 appears.

Understanding Test Results

The normal fasting glucose level for a non-diabetic adult is below 5.6 mmol/L (100 mg/dL).[1] The normal glucose level for a non-diabetic adult 2 hours post-meal, e.g. simulated by 75 g Oral Glucose Tolerance Test (OGTT), is less than 7.8 mmol/L (140 mg/dL).[2] A criterion for the diagnosis of diabetes in adults is a fasting glucose level of 7.0 mmol/L (126 mg/dL) or higher confirmed in two tests.[1,3,4] Adults with a fasting glucose level between 5.6 mmol/L (100 mg/dL) and 6.9 mmol/L (125 mg/dL) are defined as having impaired fasting glucose (prediabetes).[1]

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.

For information on the effects and prevalence of diabetes in your area, visit the International Diabetes Federation website at www.idf.org or send an email to info@idf.org. For further advice or helpline information, refer to the national diabetes organization for your country.

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).[5] 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 (10 mg/dL).

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

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 have 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.

⚠ PRECAUTION

Risk of a serious health incident

Never ignore symptoms or make significant changes to your diabetes therapy without talking to your healthcare professional.

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

- Repeat the blood glucose test with a new test strip.
- Perform a control test as described in the User's Manual.
- Refer to the User's Manual for other causes.

If your symptoms still do not match your blood glucose results, contact your healthcare professional.

Healthcare Professional Information

The system can be used in non-critical and critical professional healthcare environments such as general practitioner's offices, hospital wards, intensive care units and emergency units.

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 (below 50 mg/dL). 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 components of the pack per facility guidelines. Consult local ordinances as they may vary by country.

Limitations

Certain health conditions can lead to an incorrect test result. If one or more of the following health conditions apply, do not use the test strip.

- Blood concentrations of galactose > 0.83 mmol/L (> 15 mg/dL) will cause overestimation of blood glucose results.
- Lipemic samples (triglycerides) > 20.3 mmol/L (> 1800 mg/dL) may produce elevated blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid > 0.17 mmol/L (> 3 mg/dL) 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 (> 307 µmol/L) will cause overestimation of blood glucose results. Do not use during intravenous infusion of N-acetylcysteine.

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 (10 mg/dL) for the test strip

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

Sample size: 0.6 µL

Test time: 5 seconds

System accuracy:

The minimum requirements for the system accuracy with capillary blood according to ISO 15197:2013 are also met for venous blood anticoagulated with lithium heparin or sodium heparin or EDTA, arterial blood, and neonatal blood. The tables below show the results for capillary blood.

System accuracy results for glucose concentrations less than 5.55 mmol/L (less than 100 mg/dL)

within ±0.28 mmol/L (within ±5 mg/dL)	within ±0.56 mmol/L (within ±10 mg/dL)	within ±0.83 mmol/L (within ±15 mg/dL)
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 (equal to or greater than 100 mg/dL)

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 (21 mg/dL) and 30.4 mmol/L (547 mg/dL)

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

Repeatability:

Mean value	[mg/dL]	41.6	67.5	122.4	186.7	316.8
	[mmol/L]	2.3	3.7	6.8	10.4	17.6
Standard deviation	[mg/dL]	1.8	3.0	4.8	7.4	11.3
	[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	[mg/dL]	44.9	117.9	306.4
	[mmol/L]	2.5	6.5	17.0
Standard deviation	[mg/dL]	1.2	2.1	5.1
	[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 (less than 100 mg/dL), 100 % of the test results were within ±0.83 mmol/L (within ±15 mg/dL) of the results obtained through laboratory testing.
- For glucose concentrations equal to or greater than 5.55 mmol/L (equal to or greater than 100 mg/dL), 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.

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

LAST UPDATE: 2021-07

References

1 American Diabetes Association: 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2019. *Diabetes Care*, 42, (Suppl. 1): S13-S28 (2019).

2 American Diabetes Association website: Diagnosing Diabetes and Learning about Prediabetes.http://www.diabetes.org/diabetes-basics/diagnosis/. Accessed April 22, 2019.

3 IDF Clinical Guidelines Task Force. Global guideline for Type 2 diabetes. Brussels: International Diabetes Federation, 2012.

4 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).

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

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	Consult instructions for use.
	Caution, refer to safety-related notes in the instructions for use accompanying this product.
	Temperature limitation (store at)
	Use by (opened / unopened)
	All components of the pack can be discarded in domestic waste. Discard used test strips according to local regulations.
	Date of manufacture
	Manufacturer
IVD	In vitro diagnostic medical device
	Device for self-testing
	Device for near-patient testing
UDI	Unique device identifier
REF	Catalogue number
LOT	Batch code
CE	Complies with the provisions of the applicable EU Legislation

ACCU-CHEK® Inform II

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CE 0123 IVD

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ACCU-CHEK® Inform II

TESTS

REF 05942861

(ZH) **本器材適用於血糖自我檢測**
本器材適用於病人身邊檢測

效能/預定用途

帶專用血糖機的 Accu-Chek Inform II 試紙（Accu-Chek Inform II、Accu-Chek Performa [帶密碼晶片/密碼牌槽] 及 Accu-Chek Performa Nano）適用於定量測量新鮮微血管、靜脈、動脈及新生兒血液中的血糖。它們在監測血糖控制的有效性中作為輔助器材，用於糖尿患者的血糖自我檢測以及由專業醫護人員執行的病人身邊檢測。有關血糖機的具體說明，請參閱《使用者手冊》。
本試紙不適用於糖尿病的診斷或篩查，亦不適用於檢測新生兒臍帶血樣本。靜脈、動脈及新生兒血液檢測僅限專業醫護人員使用。

消費者資訊

簡介

在執行血糖檢測之前，請先閱讀本說明書（仿單）和《使用者手冊》。
說明書（仿單）包含警告和預防措施：
警告 是指可預見的嚴重危害。
預防措施是指安全且有效地使用產品或防止產品損壞而應採取的措施。

⚠ 警告
窒息的風險
本產品內含可能被吞下的小物品。
請將小物品放置在遠離可能吞下小物品的幼童和成人之處。

⚠ 警告
發生嚴重健康事件的風險
未能遵循檢測說明或試紙保存和使用的說明可能會導致檢測值不正確。
仔細閱讀並遵循《使用者手冊》以及試紙和品管/質控液說明書（仿單）中的說明。

感染風險：人血是傳播感染的潛在來源。避免其他人暴露於受污染的組件。
根據您所在國家和地區的適用法規，將用過的試紙作為潛在傳染性材料丟棄。

包裝內容

包裝盒內含試紙、1 個密碼晶片/密碼牌及說明書（仿單）。由於其中反應物質含量極低，故依據歐盟法規不視為危險材料。如有任何疑問，請聯絡當地羅氏糖尿病照護部門/客戶服務部。
包裝盒內的所有物品都能當作一般家用垃圾丟棄。

試紙保存和使用

- 如果在首次使用試紙之前，試紙瓶已打開或損壞、瓶蓋未蓋緊、發現瓶蓋或瓶子有任何損壞或者無法正確蓋緊瓶蓋，請勿使用試紙。請聯絡羅氏。
- 將試紙保存在 2-30 °C 溫度下。切勿冷凍試紙。
- 在 8 °C 至 44 °C（46 °F 至 111 °F）溫度下使用試紙。
- 在 10-90 % 濕度下使用試紙。切勿將試紙保存在高溫和潮濕區域，例如浴室或廚房。
- 將未使用的試紙保存原始試紙瓶內，並擰緊瓶蓋。
- 取出試紙後立即蓋緊試紙瓶，以防試紙受潮。
- 從試紙瓶中取出試紙後應立即使用。
- 如果試紙超過保存期限，請予以丟棄。過期的試紙可能產生不正確的結果。保存期限印在試紙盒及試紙瓶標籤上的 ⏏ 旁邊。如果正確保存和使用試紙，那麼在所印的保存期限之前均可使用試紙。這適用於從新的未開封的試紙瓶中取出的試紙，以及從使用者已打開的試紙瓶中取出的試紙。
- 試紙只能使用一次。試紙僅供單次使用。

執行血糖檢測

準備執行血糖檢測

如果您的血液循環不暢，則您可能不適合自行檢測血糖。先清潔輸注部位，再獲取血滴。請諮詢您的專業醫護人員。
對於 Accu-Chek Inform II 系統：請參閱《Accu-Chek Inform II 血糖機使用者手冊》。
對於 Accu-Chek Performa（帶密碼晶片/密碼牌槽）及 Accu-Chek Performa Nano 系統：
注意：Accu-Chek Performa（帶密碼晶片/密碼牌槽）及 Accu-Chek Performa Nano 血糖機可能隨附有預先插入的黑色啟用晶片。黑色啟用晶片不適用於 Accu-Chek Inform II 試紙。如果有，請取出黑色啟用晶片，並繼續執行第 1 步。

1. 需要使用血糖機、試紙、密碼晶片/密碼牌及拋棄式採血針或採血裝置。
2. 為血糖機編碼：每次打開新的試紙盒時應更換密碼晶片/密碼牌。確保血糖機已關閉。開閉血糖機，取出舊的密碼晶片/密碼牌（如果血糖機中有一個），然後丟棄它。放入新的密碼晶片/密碼牌，使密碼背對著您。將密碼晶片推入密碼晶片/密碼牌槽中，直到密碼晶片/密碼牌卡入到位。將密碼晶片/密碼牌留在血糖機中，直到打開新的試紙盒。
3. 準備採血針或採血裝置。
4. 根據機構政策，準備選定的採血部位。

執行血糖檢測

對於 Accu-Chek Inform II 系統：請參閱《Accu-Chek Inform II 血糖機使用者手冊》。
對於 Accu-Chek Performa（帶密碼晶片/密碼牌槽）系統：

1. 按箭頭方向將試紙插入血糖機中。開啟血糖機。
2. 確保螢幕上的密碼與試紙瓶上的密碼相匹配。如果未看到密碼，請取出試紙，再重新插入血糖機中。
3. 根據機構政策，獲取患者的血樣。
4. 將血滴抹到試紙黃色反應區的**前緣**。請勿將血液抹在試紙頂部。當顯示 ⧗ 時，從試紙上拿開手指。

解讀血糖檢測值

非糖尿病成人空腹時的正常血糖水平為 5.6 mmol/L (100 mg/dL) 以下。[1] 非糖尿病成人飯後 2 小時的正常血糖水平（例如透過 75 g 口服耐糖試驗 [OGTT] 模擬）為 7.8 mmol/L (140 mg/dL) 以下。[2] 成人糖尿病的診斷標準是經兩次檢測確認，空腹血糖水平為 7.0 mmol/L (126 mg/dL) 或以上。[1,3,4] 空腹血糖水平在 5.6 mmol/L (100 mg/dL) 至 6.9 mmol/L (125 mg/dL) 之間的成人被定義為空腹血糖異常（糖尿病前期）。[1]
還存在其他糖尿病診斷標準。諮詢您的專業醫護人員，確定自己是否患有糖尿病。對於糖尿病患者：諮詢您的專業醫護人員適合您的血糖範圍。您應遵循專業醫護人員的建議治療低血糖或高血糖。
有關您所在區域糖尿病的影響和患病率的資訊，請造訪 International Diabetes Federation 網站：www.idf.org，或者傳送電子郵件至 info@idf.org。有關更多建議或專線資訊，請諮詢您所在國家和地區的糖尿病組織。
根據國際臨床化學和檢驗醫學聯合會 (IFCC) 的建議，這些試紙可提供與血漿中血糖濃度相對應的結果。[5] 因此，儘管試紙上始終使用全血，但血糖機仍會顯示血漿的血糖濃度。

異常血糖檢測值

如果血糖機上顯示 **LO**，則血糖可能低於 0.6 mmol/L (10 mg/dL)。
如果血糖機上顯示 **HI**，則血糖可能超過 33.3 mmol/L (600 mg/dL)。
有關錯誤訊息的詳細資訊，請參閱《使用者手冊》。
如果您的血糖檢測值與您的感覺不符，請執行以下步驟：

1. 使用新的試紙再次進行血糖檢測。
2. 使用 Accu-Chek Performa 品管/質控液執行品管/質控檢測。
3. 檢查以下項目將有助於解決問題。
   - 檢查試紙是否已過期。
   - 檢查試紙瓶的瓶蓋是否始終蓋緊。
   - 檢查從試紙瓶中取出試紙後是否立即使用試紙。
   - 檢查試紙是否存放在陰涼、乾燥的地方。
   - 檢查您是否遵循指示。
4. 如果您認為血糖檢測值太低、太高或存疑，請聯絡您的專業醫護人員。

⚠ 預防措施
發生嚴重健康事件的風險
切勿在未告知專業醫護人員的情況下，忽略症狀或對糖尿病治療方案進行重大變更。
如果您的血糖檢測值與您的感覺不符，請執行以下步驟：

- 使用新的試紙再次進行血糖檢測。
- 按照《使用者手冊》所述執行品管/質控檢測。
- 請參閱《使用者手冊》瞭解其他原因。

如果您的症狀仍與您的血糖檢測值不符，請聯絡您的專業醫護人員。

專業醫護人員資訊

系統可用於非關鍵和關鍵專業醫療保健環境，例如全科醫生辦公室、醫院病房、重症監護室及急診室。

由專業醫護人員執行的樣本採集和準備

- 當使用 Accu-Chek Inform II 或 Accu-Chek Performa（帶密碼晶片/密碼牌槽）血糖機時，請始終遵循公認的程序來處理可能被人源性材料污染的物件。
- 執行您所在實驗室或機構的衛生和安全政策。
- 需要使用血滴執行血糖檢測。既可以使用微血管血液，也可以使用靜脈、動脈或新生兒血液，但必須由專業醫護人員採集。
- 在採集血樣並將其抹到試紙上之前，請小心清理動脈管線。
- 系統已使用新生兒血液進行測試。作為良好的臨床實踐，在解讀低於 2.8 mmol/L（低於 50 mg/dL）的新生兒血糖值時，建議保持謹慎。遵循您所在機構針對新生兒的臨界血糖值制定的後續護理建議。疑似患有半乳糖血症的新生兒的血糖值應透過另一種血糖檢測方法進行確認。
- 為了最小化糖解作用，需要在採集血樣後 30 分鐘內執行靜脈或動脈血糖檢測。
- 使用移液管時避免有氣泡。
- 含以下抗凝劑或防腐劑的微血管、靜脈和動脈血樣是可以接受的：EDTA、肝素鋰或肝素鈉。不建議使用含碘乙酸鹽或氟化物的抗凝劑。
- 冷藏的檢體在檢測前應緩慢恢復到室溫。

針對專業醫護人員的附加資訊

如果血糖檢測值未反映患者的臨床症狀，或者異常高或低，請執行品管/質控檢測。如果品管/質控檢測確認系統正常工作，請再次執行血糖檢測。如果第二次血糖檢測值仍有異常，則遵循機構指引採取進一步行動。
根據機構指引丟棄包裝盒的組件。因不同國家有不同規定，請參考當地法規。

限制

某些健康狀況會導致檢測值不正確。如果以下一個或多個健康狀況適用，則請勿使用試紙。

- 血液中的半乳糖濃度 > 0.83 mmol/L (> 15 mg/dL) 會導致高估血糖檢測值。
- 血脂樣本（三酸甘油脂）> 20.3 mmol/L (> 1800 mg/dL) 可能會導致血糖檢測值升高。
- 靜脈注射抗壞血酸會導致血液中的抗壞血酸濃度 > 0.17 mmol/L (> 3 mg/dL)，從而導致高估血糖檢測值。
- 如果未稱循環不暢，則不建議從經批准的採樣部位採集微血管血液，因為檢測值可能無法真實反映生理性血糖值。這在以下情況下可能適用：因糖尿病酮酸血症或高血糖高滲透壓非酮體性症候群、低血壓、休克、NYHA 第 IV 類非代償性心衰竭或周邊動脈阻塞性疾病導致的嚴重脫水。
- 血球容積比應介於 10 % 至 65 % 之間。
- 本系統已在最高 3094 米的海拔下進行測試。
- 靜脈注射 L-酪氨酸會導致血液濃度 > 5 mg/dL (> 307 µmol/L)，從而導致高估血糖檢測值。切勿在靜脈輸注 N-乙醯半胱胺酸期間使用。

效能特性

Accu-Chek Inform II 系統符合 EN ISO 15197:2013 的要求（體外診斷檢測系統 – 在管理糖尿病時用於進行血糖自我檢測的血糖監測系統的要求）。[a]

a) 系統還符合 EN ISO 15197:2003 的要求。

校正和可回溯性：將含各種血糖濃度的靜脈血液用作校準品來校正系統（血糖機和試紙）。參考值使用己糖激酶法獲得，該方法使用 ID-GCMS 法進行了校正。ID-GCMS 法作為計量質量最高（最高階）的方法，可回溯到主要美國國家標準與技術局 (NIST) 標準。使用此可回溯性鏈，這些用於品管/質控液的試紙所獲得的結果也可回溯到美國國家標準與技術局 (NIST) 標準。

檢測範圍

偵測極限（顯示的最低值）：0.6 mmol/L (10 mg/dL)（試紙）
系統檢測範圍： 0.6–33.3 mmol/L (10–600 mg/dL)
樣本量：0.6 µL
檢測時間：5 秒

系統精度：

對於含肝素鋰、肝素鈉或 EDTA 抗凝劑的靜脈血液、動脈血液及新生兒血液，還符合 ISO 15197:2013 對使用微血管血液的系統精度的最低要求。下表顯示了微血管血液的檢測值。

血糖濃度小於 5.55 mmol/L（小於 100 mg/dL）的系統精度值

±0.28 mmol/L 以內（±5 mg/dL 以內）	**±0.56 mmol/L 以內（±10 mg/dL 以內）**	**±0.83 mmol/L 以內（±15 mg/dL 以內）**
138/174 (79.3 %)	171/174 (98.3 %)	174/174 (100 %)

血糖濃度等於或大於 5.55 mmol/L（等於或大於 100 mg/dL）的系統精度值

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

血糖濃度介於 1.2 mmol/L (21 mg/dL) 至 30.4 mmol/L (547 mg/dL) 之間的系統精度值

±0.83 mmol/L 以內或 ±15 % 以內（±15 mg/dL 以內或 ±15 % 以內）
595/600 (99.2 %)

可重複性：

平均值	[mg/dL]	41.6	67.5	122.4	186.7	316.8
	[mmol/L]	2.3	3.7	6.8	10.4	17.6
標準差	[mg/dL]	1.8	3.0	4.8	7.4	11.3
	[mmol/L]	0.1	0.2	0.3	0.4	0.6
變異係數 [%]		—	—	3.9	4.0	3.6

中間精密度：

平均值	[mg/dL]	44.9	117.9	306.4
	[mmol/L]	2.5	6.5	17.0
標準差	[mg/dL]	1.2	2.1	5.1
	[mmol/L]	0.1	0.1	0.3
變異係數 [%]		—	1.8	1.7

使用者進行的效能評估：一項評估血糖值的研究顯示了以下結果，樣本來自 325 名非專業人士採集的指尖微血管血液：

- 對於小於 5.55 mmol/L（小於 100 mg/dL）的血糖濃度，100 % 的檢測結果在透過實驗室檢測獲得的結果的 ±0.83 mmol/L 以內（±15 mg/dL 以內）。
- 對於等於或大於 5.55 mmol/L（等於或大於 100 mg/dL）的血糖濃度，98.6 % 的檢測結果在透過實驗室化驗獲得的結果的 ±15 % 以內。

檢測原理：試紙上的酶，即來自*醋酸鈣不動桿菌*的喹啉葡萄糖脫氫酶的突變體 (Mut.Q-GDH)，在*大腸桿菌*中重組，會將血樣中的血糖轉化為葡萄糖酸內脂。該反應會產生可供血糖機解讀為血糖檢測值的無害直流電流。其後，血糖機使用交流和直流訊號對樣本和環境條件進行評估。

試劑成分[b)]

媒介物	6.72 %
喹啉葡萄糖脫氫酶[c)]	15.27 %
吡咯喹啉醌	0.14 %
緩衝劑	34.66 %
穩定劑	0.54 %
非反應成分	42.66 %

b) 出廠時最小

c) 來自*醋酸鈣不動桿菌*，在*大腸桿菌*中重組，詳見專利申請 WO 2007/118647（表 4 中的「突變 31」）

品管/質控及線性檢測套件（如可用）

Accu-Chek Performa 品管/質控液 – 詳見品管/質控液說明書（仿單）。
Accu-Chek 線性檢測套件 – 詳見線性檢測套件說明書（仿單）。
請造訪我們的網頁www.accu-chek.com，聯絡當地羅氏糖尿病照護部門/客戶服務部，以獲取詳細資訊。請參閱本說明書（仿單）末尾的地址。

嚴重事件通報

對於歐盟內的患者/使用者/第三方以及具有完全相同監管制度的國家；如果在使用本器材期間或由於其使用發生了嚴重事件，請將其通報到製造商和您的國家機關。

最近更新日期：2021-07

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www.accu-chek.com

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Customer Support and Service Centre:
Toll-Free Line: 1-800-88-1313
www.accu-chek.com.my

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製造廠地址：9115 Hague Road
Indianapolis, IN 46256 USA
藥商名稱：台灣羅氏醫療診斷設備股份有限公司
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(+63) 917 897 8000
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	查詢使用說明。
	小心，是指本產品隨附的使用說明中的安全相關註釋。
	溫度限制（保存）
	保存期限（已開封/未開封）
	包裝盒內的所有物品都能當作一般家用垃圾丟棄。根據本地法規丟棄用過的試紙。
	製造日期
	製造廠
IVD	體外診斷醫療器材
	本器材適用於血糖自我檢測
	本器材適用於病人身邊檢測
UDI	醫療器材單一識別系統
REF	物料型號
LOT	批號
CE	符合適用的歐盟法規的規定

CE 0123 IVD

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