

3. Interference testing

A variety of potentially interfering conditions can affect the accuracy of a blood glucose result, depending on the type of chemistry used in a bGM system.

Interfering substances can be a significant source of error in measurements.

The ISO 15197:2013 standards require that BGM systems are tested for the influences of at least 23 substances that might potentially be interfering with the test results.⁴

Each Accu-Chek bGM system is tested for an additional 150 possible interfering influences during its development phase using a variety of substances, including Oxygen and Hematocrit.⁷

USE ACCU-CHEK FOR RESULTS THAT YOU CAN TRUST.

- A high level of accuracy when comparing bGM test results with the lab reference.⁵
- Accurate bG values for all four types of blood samples (capillary, venous, arterial and neonatal).⁶
- Ensures accurate results under robust ranges of environmental conditions - humidity, altitude, temperature.⁶
- Real-life accuracy - No significant influence of increased or decreased partial pressure of oxygen.^{8,9}
- Wide haematocrit range.⁶
- Tested for more than 170 interfering substances.⁷

Contact your Roche Diabetes Care sales representative for more information.



Accuracy Matters



1. Knapp S et al. Self-monitoring of blood glucose: Advice for providers and patients. Cleve Clin J Med. 2016; 83(8):355-360.
 2. Freckmann G et al. System Accuracy Evaluation of 43 Blood Glucose Monitoring Systems for Self-Monitoring of Blood Glucose According to DIN EN ISO 15197. J Diabetes Sci Technol. 2012;6(5):1060-75.
 3. Diabetes Technology: Standards of Medical Care in Diabetes-2021 American Diabetes Association. Diabetes Care. 2021 Jan; 44(Supplement 1):S85-S99.
 4. The International Organization for Standardization (ISO). In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self testing in managing diabetes mellitus. ISO 15197:2013.
 5. Breitenbeck et al. Accuracy Assessment of a Blood Glucose Monitoring System for Self-Testing with Three Test Strip Lots Following ISO 15197:2013/ISO 15179:2015. J Diabetes Sci Technol. 2017 Jul;11(4) 854-855.
 6. Accu-Chek Instant [Package Insert]. Roche Diabetes Care.
 7. Accu-Chek Instant System Evaluation. 2016. Internal Roche Diabetes Care report; unpublished.
 8. Schmid C et al. Impact of Partial Pressure of Oxygen in Blood Samples on the Performance of Systems for Self-Monitoring of Blood Glucose. Diabetes Technol Ther. 2014;16(3):156-165.
 9. Baumstark A et al. Influence of Partial Pressure of Oxygen in Blood Samples on Measurement Performance in Glucose-Oxidase-Based Systems for Self-Monitoring of Blood Glucose. J Diabetes Sci Technol. 2013;7(6):1513-1521.

www.rochediabetescare.com

Roche Diabetes Care Middle East FZCO | Jebel Ali Free Zone | PO Box 263990 | Dubai | UAE
 ACCU-CHEK and ACCU-CHEK INSTANT are trademarks of Roche.
 ©2023 Roche Diabetes Care Middle East FZCO. All Rights Reserved.

Distributed by Cobel Darou Company No.39, Alvand St, 1516673115, Tehran, Iran Tel: +98(21)455 98 000
 Roche Pars Ltd. 9th Floor, No.3, Madiaran Building, Aftab St., Vanak Sq., 1994834592 Tehran-Iran Tel: +98(21) 860 92 100

09/2026

29.7cm

Self-monitoring of blood glucose (SMBG) is recommended for all people with diabetes, particularly for the adjustment of insulin in patients with multiple daily injections (MDI).¹

The accuracy of SMBG measurements is imperative for the reliability of results:²

- Making therapeutic decisions such as insulin dosing.
- Identifying hypoglycaemic episodes.
- For healthcare professionals to make decisions regarding necessary therapy change.

AMERICAN DIABETES ASSOCIATION (ADA) 2021 RECOMMENDATIONS REGARDING METER ACCURACY³

- Providers should be aware of the differences in accuracy among glucose meters.
- Only meters with proven accuracy should be used (fulfilling ISO 15192:2013 or FDA criteria).
- Test strips should only be purchased from a pharmacy or licensed distributor.
- Only unopened and unexpired vials of glucose test strips should be used to ensure SMBG accuracy.
- Healthcare providers should be aware of factors that can interfere with glucose meter accuracy (e.g. oxygen, temperature and interfering substances).

ISO 15197: 2013⁴

The ISO (International Organization for Standardization) 15197 standard establishes requirements for in-vitro bGM Systems intended for self-testing by people with diabetes to manage their condition.

WHAT ARE THE REQUIREMENTS?

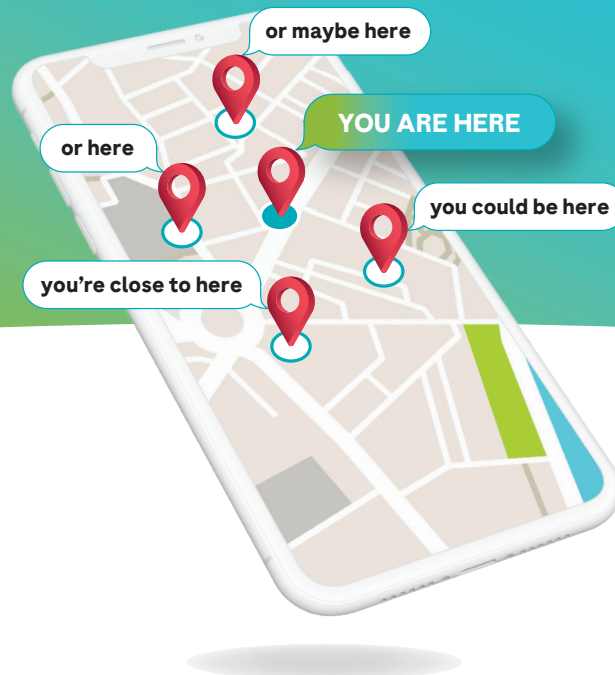
1. Analytical Accuracy

(The analytical accuracy of a BGM system expresses how closely its bG measurements match the true values.)

| | REQUIREMENTS | ACCU-CHEK INSTANT RESULTS |
|---|--------------|---------------------------|
| At blood glucose concentrations of <100 mg/dL | +/- 15 mg/dL | +/- 10 mg/dL |
| At blood glucose concentrations of ≥100 mg/dL | +/- 15 % | +/- 10 % |

The ISO 15197:2013 standard require that 95% of measured blood glucose values shall fall within the following reference values:⁴

The Accu-Chek Instant system exceeds these performance criteria and delivers 10/10 accuracy.^{5,6}

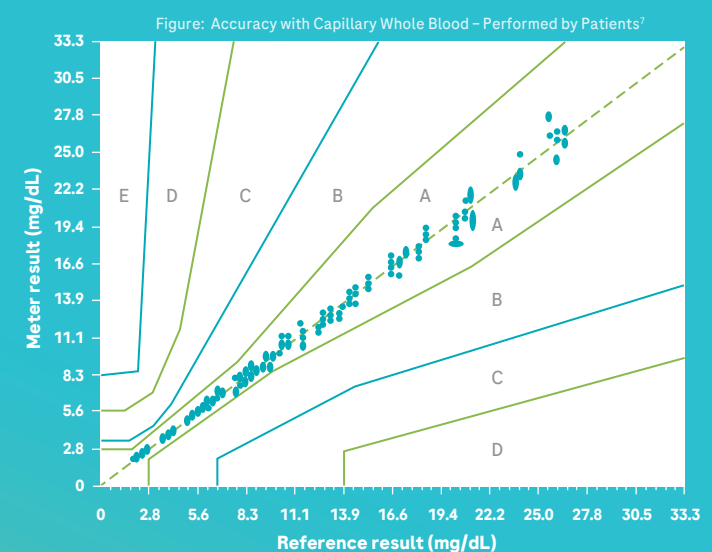


2. Clinical Accuracy

(Clinical accuracy is a measure of how well bG measurements enable correct therapy decisions.)

The ISO 15197:2013 standards require that ≥99 % of all blood glucose values must be within zones A and B of the Consensus Error Grid for type 1 diabetes.⁴

With the Accu-Chek Instant system 100% of results fall within zone A of the consensus error grid.⁵



21cm

The Accu-Chek Instant system delivers 10/10 accuracy

9.9cm

9.9cm

9.9cm