THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR cobas® pulse GLUCOSE MONITORING SYSTEM IVD, POINT OF CARE

Version number 2.0, 09/09/2024

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1. Introduction

cobas® pulse is a class C In-vitro diagnostic device belonging to the Clinical Laboratory. It is approved in Tanzania as a device system, for use in adults, children and elderly by healthcare professionals and general public.

1.1. Administrative Information

Registration number	TAN 23 MDR 0277
Brand Name (if relevant)	cobas® pulse
Common name	Glucose Monitoring System IVD, Point Of Care
Class of the device and rule applied	Class C according to classification rule No. 4
GMDN code and term	62646, Glucose Analyzer IVD, point-of-care
Name and complete address of the Market Authorization Holder	Sciex Ltd, Plot 328 Mikocheni Senga Road off Garden Road, P. O. BOX 33974, Kijitonyama, Dar-Es- salaam, Tanzania
Name and address (es) of local responsible person (LRP).	Sciex Ltd, Plot 328 Mikocheni Senga Road off Garden Road, P. O. BOX 33974, Kijitonyama, Dar-Es- salaam, Tanzania

1.2. Assessment Procedure

The application for registration of cobas® pulse was submitted on 17/03/2022. The product underwent full assessment. Assessment was completed in three (3) rounds of evaluation. cobas® pulse was registered on 04/12/2023.

2. Technical information

2.1. Intended use

The intended use of cobas® pulse as declared by the manufacturer and approved by TMDA is; it provides an in vitro diagnostic test that quantitatively measures glucose in venous whole blood, arterial whole blood, capillary whole blood, neonatal heel stick, and neonatal arterial whole blood samples. The cobas® pulse meters are intended for near-patient testing, in non-critical and critical professional healthcare environments such as general wards, outpatient clinics, intensive care units, and emergency departments and are indicated for use in determining dysglycemia.

cobas® pulse is approved for use in healthcare settings and in point of care testing by Healthcare professionals and persons with diabetes and/or at point-of-care.

2.2. Device details and features

cobas® pulse is a single device with accessories. cobas® pulse has been registered as a system which consists of Pack of cobas® pulse Meter, Blood Lancets, Cobas 2x2.5 ml QC solution, cobas GLU linearity kit, cobas GLU test strips and user manual. It is a closed system.

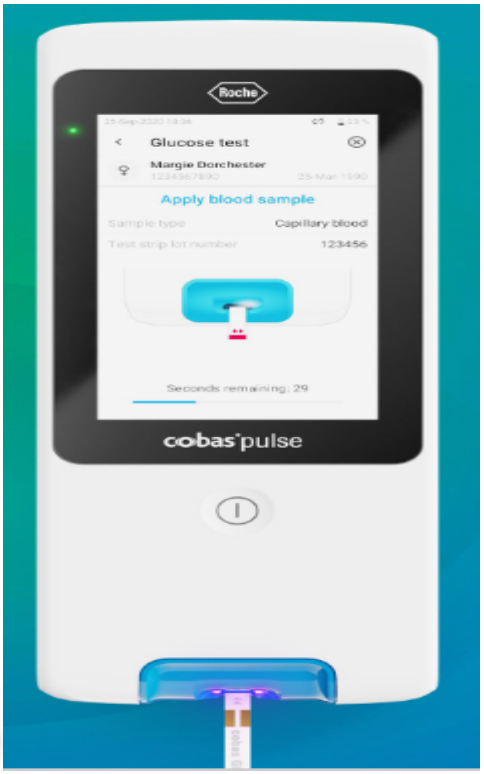
cobas® pulse is a semi-automated device. It is used for diagnosis and monitoring of blood glucose. cobas® pulse operates by FAD-dependent glucose dehydrogenase enzyme oxidizing the glucose. During the reaction, electrons are transferred by the enzyme to an electrochemical mediator, which then conveys these electrons to the surface of an electrode. The current generated by the reaction is proportional to the concentration of glucose present in the blood sample. Interfering effects of sample properties and environmental conditions are compensated using AC and DC signals. The test output is quantitative.

The type of specimen used is venous whole blood, arterial whole blood, capillary whole blood, and neonatal heel stick and is collected by venipuncture, Capillary, arterial, or heel stick.

Device description:

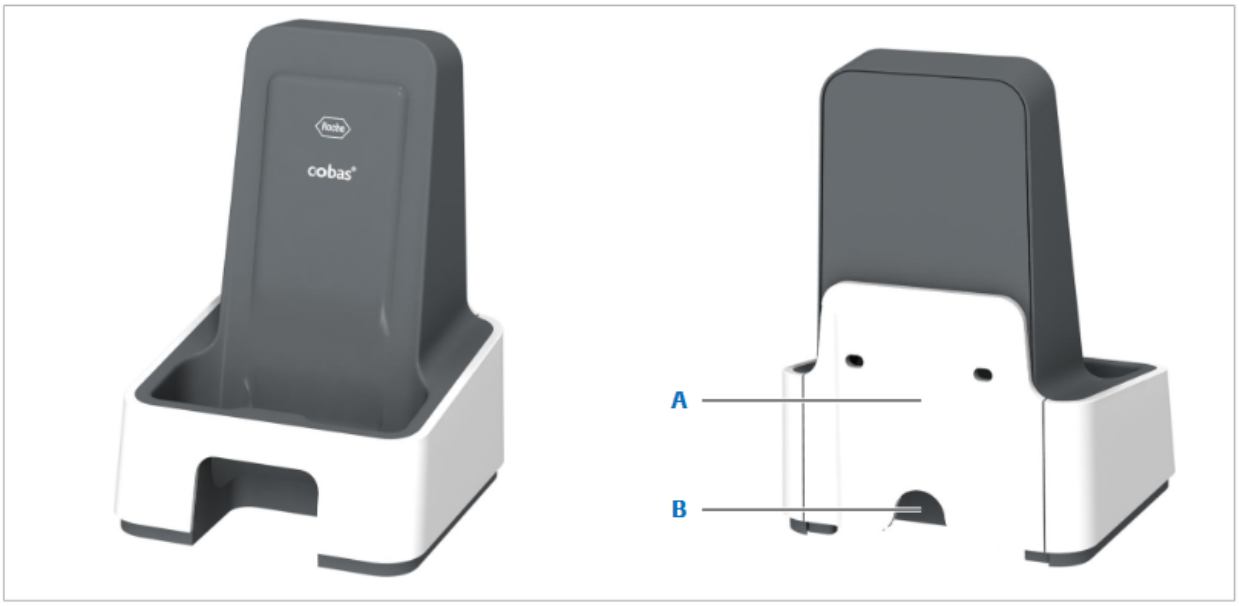
According to the claim of assay description from manufacturer, the cobas® pulse is an in vitro diagnostic instrument intended for the quantitative determination of glucose in whole blood using the Cobas® GLU test strips. The cobas® pulse is intended for near-patient testing. Not for self-testing.







A Instrument
B Charging station
C Carry case



A Rear panel / wall mount

B Access to power inlet

Charging station



cobas® GLU linearity kit



cobas® GLU QC kit



cobas® GLU test strips

2.3. Commercial presentation

There is a single meter approved commercial presentation as follows: one (1) unit in the primary pack.

Additional contents include: Pack of cobas® pulse Meter, Blood Lancets, Cobas 2x2.5 ml QC solution, cobas GLU linearity kit, cobas GLU test strips and user manual.

2.4. Items required but not submitted

Specimen collection containers, Sample dropper, timer or watch, tourniquets, cotton swabs (alcohol swabs).

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life for cobas GLU test strips is 24 months.

3.1.2. Storage conditions

The recommended storage conditions for cobas GLU test strips are:

- Store at temperatures between 2-30 °C. Do not freeze.
- Store away from extreme temperatures and moisture levels.
- Tightly recap the container immediately after removing a test strip to protect the test strips from humidity.
- Store unused test strips in their original test strip container with the cap closed.
- The test strips are stable up to the expiration date specified on the container, when stored in the original container under the recommended storage conditions.
- If the container is open or damaged before using the test strips for the first time, do not use the test strips.

3.1.3. Shipping conditions

Cobas GLU test strips can withstand shipping temperatures ranging from -20°C for up to 21 days to 45°C for up to 120 hours. These values represent the allowable extremes the product may encounter during transit.

4. Manufacturing site audit

The manufacturer of the device is Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany.

Quality audit of the manufacturing facility was conducted through desk review on 30/06/2020. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters*: Method comparison between cobas pulse to cobas 6000 reference.*

ISO 15197:2013 Criteria

Criterion A: *95 % of the measured glucose values shall fall within either ± 0.83 mmol/L (±15 mg/dL) of the average measured values of the reference measurement procedure at glucose concentrations <5.55 mmol/L (<100 mg/dL) or within ± 15 % at glucose concentrations ≥ 5.55 mmol/L (≥100 mg/dL).*

Criterion B: *99 % of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes.*

Study Performance Results:

Cobas Pulse:

Criterion A: [<100 mg/dL], 100.0% (all lots), 100.0% (lot 322), 100.0% (lot 325), 100.0% (lot 326).

FDA acceptance criteria

- ≥95% of results shall be within ±12 mg/dL of the reference test at <75 mg/dL, or ±12% of the reference test result at ≥75 mg/dL.
- ≥98% of the results shall be within ±15 mg/dL of the reference test at <75 mg/dL, or ±15% of the reference test result at ≥75 mg/dL.

Study Performance Results:

- Within 12 mg/dL or 12%: 99.4%.
- Within 15 mg/dL or 15%: 99.6%.

5.2. Clinical Performance

Clinical performance was conducted at *NB Research, Inc. 6505 E. 82nd St. Suite 107, Indianapolis, IN 46250*. The following parameters were tested accuracy, repeatability, reproducibility, and precision.

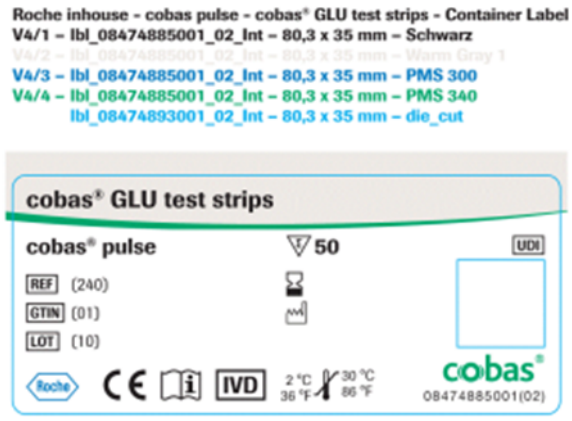
Based on results of the performance studies, it was concluded that; Combined Accuracy according to ISO Criteria, depicted per FDA guidance was 99.4%. The studies further concluded that cobas® pulse is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

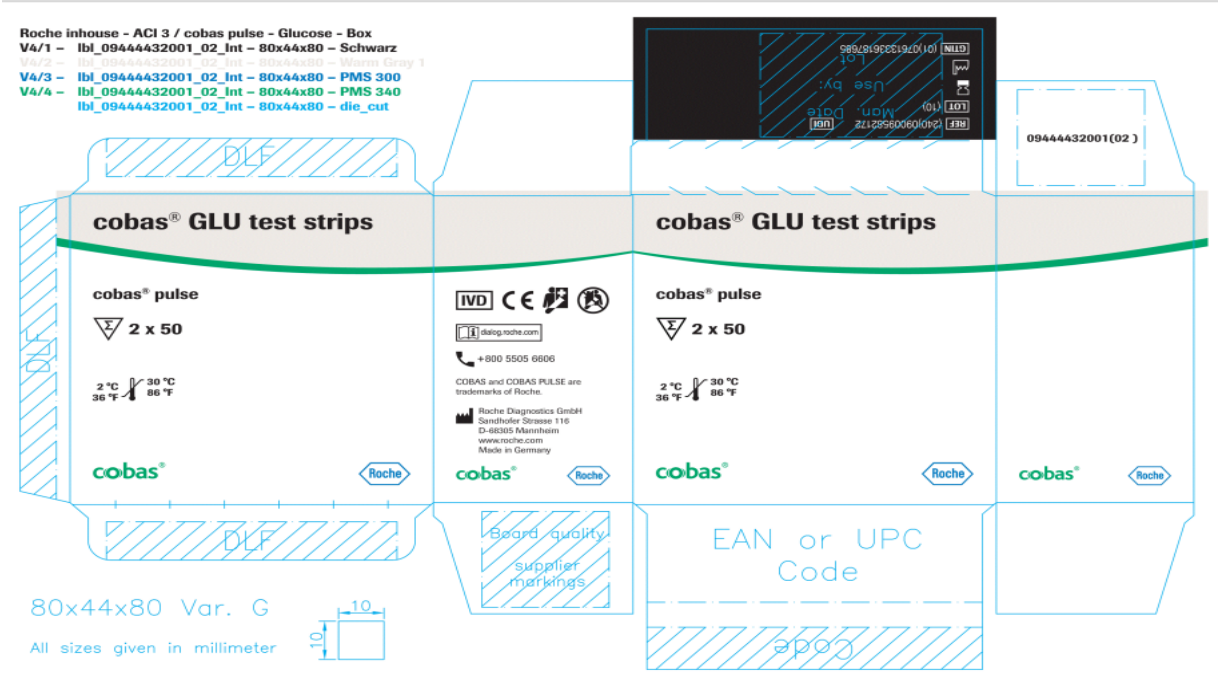
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The *package insert/ instructions for use* include all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack for the cobas GLU test strips



6.2. Secondary pack for the cobas GLU test strips



6.3 Insert Instructions for use/Package insert

Instructions for use can be accessed by clicking here

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instructions. Hence, *cobas® pulse* was recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Tap into the future of care

cobas® pulse system



Introducing cobas® pulse

Point-of-care reimagined



Always at the forefront of innovation

Roche had an ambitious vision...

To not only engineer a professional connected glucose system, but provide and run a POC platform for healthcare professionals and institutions.

A platform to be the gateway to the future of digital health; improving workflows and changing healthcare in favour of cost efficiency and better patient care.

The benefit technological innovation brings to improving care

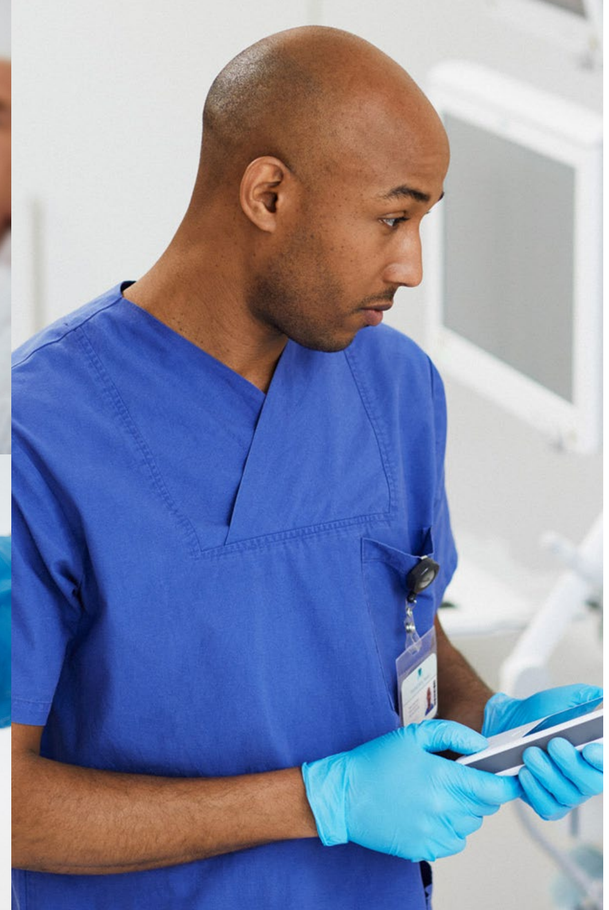
We promise you:

1. A glucose meter that can easily help with your most challenging patients
2. A device so simple to use, it can make your day-to-day working life easier
3. A system with versatile uses and functions to improve patient care

Designed with healthcare professionals in mind, **cobas® pulse** is a multipurpose glucose management system in the next generation of hospital point of care (POC).







The three pillars of innovation behind cobas® pulse

cobas® pulse incorporates three pillars of innovation:

Advanced safety and performance

Simplicity

Enhanced digital power

Tap into
Advanced safety and performance

1. **Advanced accuracy**
   Reliable and safe to use in all hospital settings
2. **No interferences**
   Tested against all relevant potential interferents
3. **Reduced risk of contamination**
   Easy-to-clean and robust design

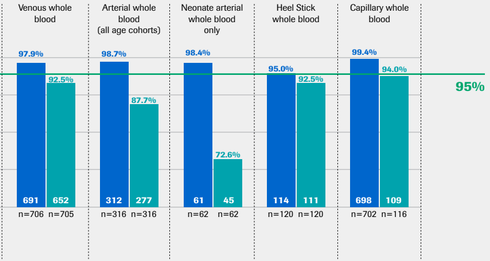


Enhanced analytical performance

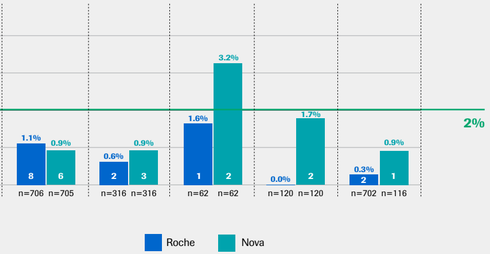
- Trust every result, every time, with the clinically reliable **cobas® pulse** system.
- Measuring glucose levels in hospital POC has improved accuracy and precision, thanks to the new technology we've embedded.
- The polarity change in the excitation signal allows for the elimination of interfering effects by electrochemically active interferents
- Lab like results, no need for repetition or uncertainty gives piece of mind for nurses, clinicians, and laboratory personnel.

Every 50 milliseconds, 9 values are recorded from the current response, capturing 1600 data points (~60 times more than with Accu-Chek® Inform II).[1]

Performance according to CLSI criteria
Glucose concentration breakpoint at 100mg/dL (5.55 mmol/L)



Performance according to CLSI criteria
Glucose concentration breakpoint at 75mg/dL (4.2 mmol/L)



1st

cobas® pulse will be the only system tested according to the latest FDA[2] and CLSI POCT12-A3[3] guidelines which demand the highest analytical standard.

No interferences[1]

During verification and clinical evaluation no drug or endogenous substance showed interference.

Evaluation of:
- Hematocrit
- Skin Disinfectants
- 142 endogenous and exogenous interferents tested (many more assessed)
- High ascorbic acid concentration
- Oxygen

Guidelines adopted:
- FDA Guidance for Industry: Blood Glucose Monitoring Test Systems for Prescription Point-of Care Use (2020)
- CLSI EP07-A3/EP37
- ISO 15197:2013

Benefits:

Peace of mind

Device can be used on all patient populations



Reduced risk of contamination

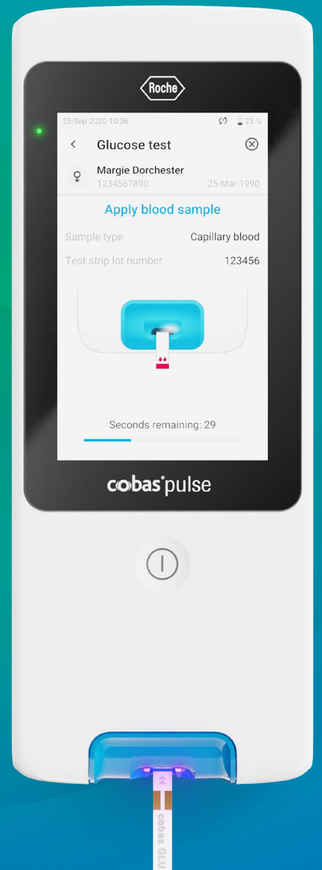
- Tested against 12k cycles of cleaning and disinfections[4]
- Compatible with aggressive cleaning and disinfection agents
- Reduced pathogen transmission – elimination of Hepatitis B[4] following disinfection of the product

Hospitals can be intense environments – drops, spills and accidents happen every day.

But you don't have to worry about **cobas® pulse** system, it's easy to clean, robust design is ready for anything.

Tap into
Simplicity

1. **Simple to learn**
   Intuitive interface for seamless roll out
2. **Simple to use**
   Features that save time and improve safety
3. **Simple to take care of**
   Robust design and highly portable



As simple to use as your mobile phone

cobas® pulse system contains features to simplify you daily life.

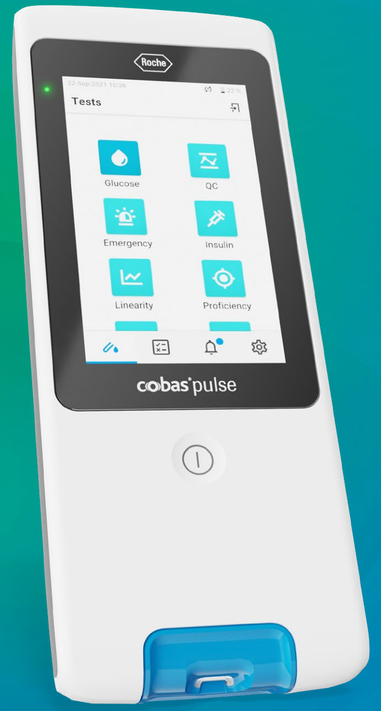
- Strip port multicolour light to guide during glucose testing
- A flash light for use on dimly lit wards
- Automatic strip ejection to reduce contamination risk
- Flexible login with RFID badge, barcode scan and keyboard entry for total compliance and tracking
- Wireless charging
- Camera with autofocus for improved barcode reading

cobas® pulse uses an intuitive Android™ based interface for ease of everyday use



Tap into
Enhanced digital power

1. **Healthcare apps for your every need**
   Choose from a variety of selected apps
2. **Keeps you connected**
   Full interoperability and connection options
3. **Configured for you**
   cobas® infinity edge offers easy set up



Apps designed to help improve patient care

cobas® pulse system enables you to benefit from a truly versatile range of operations, letting your team switch between tasks seamlessly. And keep up to date with patient trends and health insights at the tap of a screen by downloading Roche-selected third-party apps.

Glucose

OTE app*

Vital signs

Urinalysis

Documentation

Digital Biomarkers

Insulin dosing

More coming soon...

For explanatory reasons only.

The use of any third-party app is subject to a separate license agreement with the respective third-party app developer. Roche gives no warranties (express or implied) with regard to any third-party app. Third-party apps might not be available in your country.

diagnostics.roche.com/appexchange

* Other Test Entry

Tap into smart connectivity

cobas® infinity edge smart delivers enhanced services and benefits



Ever-increasing services for your subscription

Enable remote service from Roche for POC devices

Software & App Distribution

Lot Distribution

Installation and Registration

Service Data Extraction

Tap into

Your team's highest potential

The benefits of **cobas® pulse** system – from saving time to best-in-class support – extend to everyone in your facility.

All of which enables everyone to give your patients the very best care

- Point-of-care Coordinator
- Nurse
- Physician
- Executive
- IT Manager
- App Developer

diagnostics.roche.com/cobas-pulse



References

1. *Roche Diagnostics International Ltd. cobas GLU test strips Method Sheet 2021.*
2. *FDA Guidance Document: Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use (2020), document number 1755.*
3. *CLSI, POCT12-A3 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities -Approved Guideline- Third Edition. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania 19087 USA, 2013*
4. *Roche data on file.*

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