THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR ON CALL® PLUS CODE FREE BLOOD GLUCOSE MONITORING SYSTEM

Version number 2.0, 18.05.2026

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1. Introduction

ON CALL® PLUS CODE FREE is a class C In Vitro diagnostic devices belonging to the clinical laboratory specialty category. It is approved in Tanzania as a system for use in adults, children and elderly by healthcare professionals and general public.

1.1. Administrative Information

Registration number	TAN 24 MDR 0192
Brand Name (if relevant)	On Call plus Code Free
Common name	Blood Glucose Monitoring System
Class of the device and rule applied	Class C as per Rule 4 for classification of In Vitro Diagnostic Devices
GMDN code and term	63087, Blood glucose/blood pressure monitoring system, home-use
Name and complete address of the Market Authorization Holder	Vasco Pharmaceutical Company Ltd P.O BOX 13176, Arusha, Tanzania. Telephone: +255 748 100 030
Name and address(es) of local responsible person (LRP).	Vasco Pharmaceutical Company Ltd P.O BOX 13176, Arusha, Tanzania. Telephone: +255 748 100 030

1.2. Assessment Procedure

The application for registration of ON CALL® PLUS CODE FREE was submitted on 25/03/2024. The product underwent full assessment. Assessment was completed in 03 rounds of evaluation. ON CALL® PLUS CODE FREE was registered on 07/11/2024.

2. Technical information

2.1. Intended use

The intended use of ON CALL® PLUS CODE FREE as declared by the manufacturer and approved by TMDA is indicated for monitoring glucose in fresh capillary whole blood samples. ON CALL® PLUS CODE FREE is approved for use in healthcare settings and at home by both trained personnel or laypersons.

2.2. Device details and features

ON CALL® PLUS CODE FREE is a system with accessories. ON CALL® PLUS CODE FREE has been registered as a system which consists of blood glucose meter, 100 lancets, one (1) lancet device and a control solution. It is a closed system.

ON CALL® PLUS CODE FREE is an automated device. It is used for monitoring of diabetes mellitus. ON CALL® PLUS CODE FREE operates by an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood. The test out-put is quantitative.

The type of specimen used is fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm and is collected by capillary finger prick.

A portable, electrically-powered instrument used with other devices (e.g., reagent, test strips, a blood pressure cuff, and accessories) intended used for the quantitative measurement of glucose levels in whole blood in a short period, typically several minutes, and to noninvasively measure pressure; it is designed to be used for self-testing by a layperson in the home, and some types may in addition be used at the point-of-core. The measured glucose values are used to manage blood glucose levels, primarily by persons with diabetes mellitus. This analysis is typically included blood glucose monitoring system.

2.3. Commercial presentation

There is one (01) approved commercial presentation: One (01) ON CALL PLUS CodeFree™ Meter in Transparent plastic bag. One (01) ON CALL PLUS CodeFree™ Meter and accessories are placed in a box.

Additional contents include
• ON CALL PLUS CodeFree™ Test strips
• ON CALL PLUS Check strip
• 3V battery type CR2032 • User Instruction Guide
• Quick Guide
• Self-test Diary
• Test Strip Package Insert
• Carrying Case
• Lancing device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)
• Lancets.

2.4. Items required but not submitted

ON CALL PLUS Control Solution
• Control solution package insert.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life in months.
1. STANDARD™ Glucose Control Solution can be used for 3 months after opening the container
2. ON CALL PLUS Code Free™ blood glucose test strips 6 months after first opening from the container
3.1.2. Storage conditions

The recommended storage conditions is 2°C – 32°C (36°F – 90°F).

3.1.3. Shipping conditions

The recommended shipping conditions is Transport Condition -20°C – 50 °C (-4°F – 122°F)

4. Manufacturing site audit

The manufacturer of the device is ACON LABORATORIES, Inc.,10125 Mesa Rim Road San Diego, CA 92121, USA. Post Code: 10125 Mesa Rim Road San Diego, CA 92121, USA, Telephone: + 1(858) 875-800, E-mail: info@aconlabs.com.

Quality audit of the manufacturing facility was conducted through site visit on 05th- 6th March 2023. 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: accuracy (trueness), precision (repeatability and reproducibility).

5.2. Clinical Performance

Clinical performance was conducted at manufacturing site. The following parameters were tested; Trueness and precision.

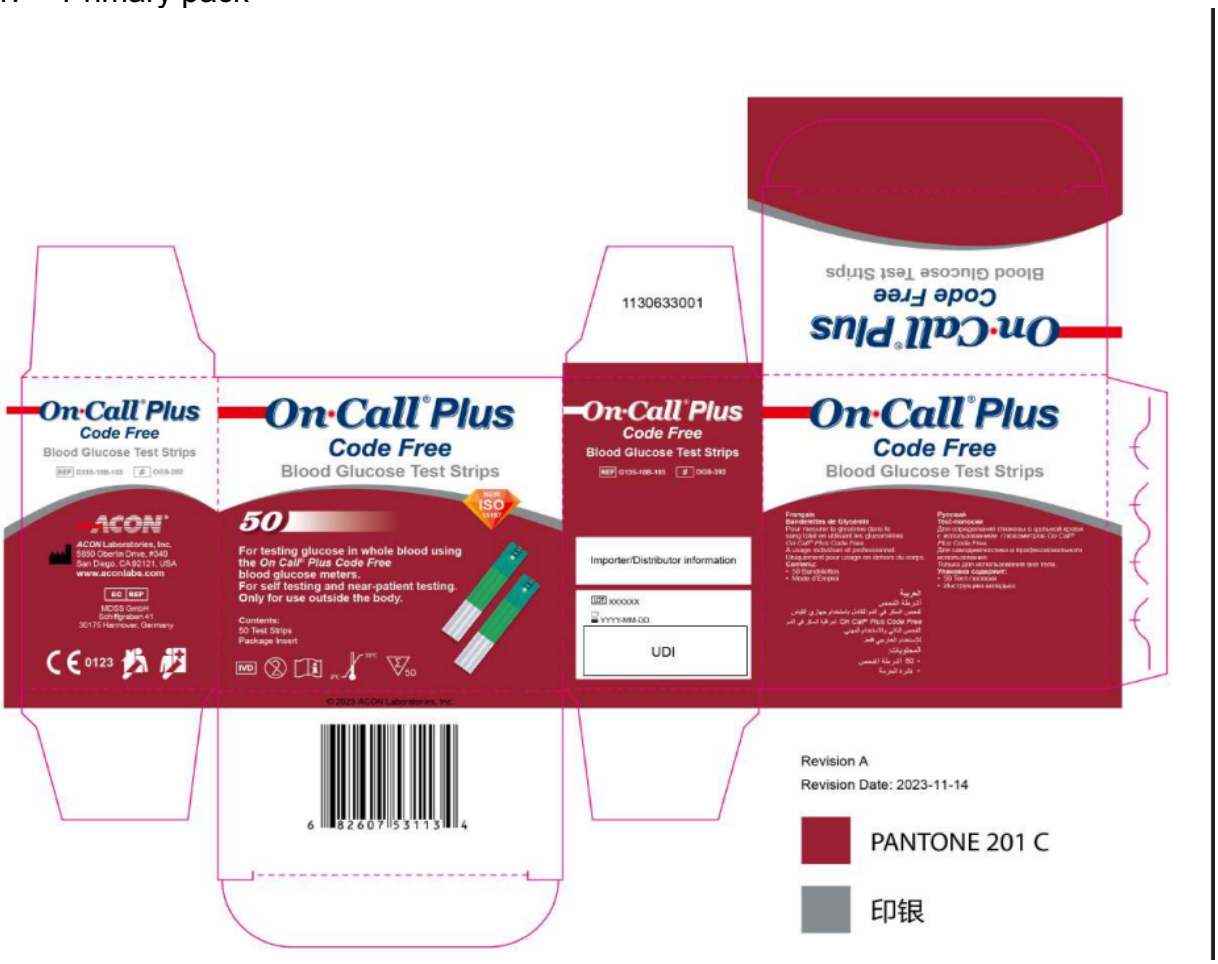
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 99.8% and 99.5% respectively. The studies further concluded that ON CALL® PLUS CODE FREE is capable of consistently producing accurate and reliable test output.

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 user manual, package insert, instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack

N/A

6.3 Instructions for use/Package insert

Click here for IFU or see the last page


Package Insert-Test Strips.pdf

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 instruction. ON CALL® PLUS CODE FREE is 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 any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

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

On·Call® Plus Code Free

Blood Glucose Test Strips Package Insert

REF G135-10B-102 REF G135-10B-103 REF G135-10B-104 REF G135-10B-105 REF G135-10B-106	# OGS-393	English

PRINCIPLE AND INTENDED USE

The *On Call® Plus Code Free* Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the *On Call® Plus Code Free* Blood Glucose Meters to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip, then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is shown on the meter display. The meters are calibrated to display plasma-like concentration results.

For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes. For self-testing and professional use. *On Call® Plus Code Free* Blood Glucose Test Strips are used by people with diabetes at home and by healthcare professionals for the quantitative measurement of glucose in capillary whole blood from the fingertip, palm and forearm.

COMPOSITION

Each test strip contains the following reactive chemicals: Glucose oxidase < 25 IU, Mediator < 300 µg. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored in their protective vial. The vial's cap must be tightly closed. This is to keep the test strips in good working condition.
- Store test strips in a cool, dry place at room temperature, 2-35°C (36-95°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- To ensure accurate results, use the test strips at room temperature.
- Do not store the test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date may produce incorrect test results.
  Note: All expiration dates are printed in Year-Month-Date format.
- Use a new vial of test strips for only 6 months after opening. The opened vial expiration date is 6 months after the vial was first opened. Write the opened vial expiration date on the vial label after you open it.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Do not use test strips after the expiration date shown on the vial. Expired test strips may give incorrect blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- The sample must only be applied to the tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

MATERIALS PROVIDED

- Test Strips
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

INSTRUCTIONS FOR USE

See your User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial only to remove a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
2. Run the blood glucose test following the instructions contained in your User's Manual.
3. The blood glucose test result will be shown on the meter display window. This result should fall within the target range recommended by your healthcare professional. If your blood glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: *On Call® Plus Code Free* Blood Glucose Monitoring Systems allow alternative site testing for palm and forearm testing in additional to fingertip testing. There are important differences among fingertip, palm and forearm samples that you should know. Important information about palm and forearm glucose testing:

- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes:[1]

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Your blood glucose meter must be handled carefully. See your User's Manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your User's Manual to run a quality control test. Three ranges CTRL 0, CTRL 1 and CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a Level 0 or level 2 test. Contact your dealer for information on purchasing control solution. For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range, and Control Solution 2 tests should fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, **DO NOT** use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your dealer for help.

LIMITATIONS

- The *On Call® Plus Code Free* meters, test strips and other components of the *On Call® Plus Code Free* Blood Glucose Monitoring Systems have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- Use only with whole blood. Do not use with serum or plasma samples.
- Do not use for testing neonates.
- Very high (above 60%) and very low (below 25%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of vitamin C and other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 1.1-33.3 mmol/L (20 - 600 mg/dL).
- Fatty substances (triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The *On Call® Plus Code Free* Blood Glucose Monitoring Systems have been tested and shown to work properly up to 10,000ft (3,048 meters).
- Severely ill persons should not run the glucose test with the *On Call® Plus Code Free* Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with *On Call® Plus Code Free* Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of materials.

PERFORMANCE CHARACTERISTICS

The *On Call® Plus Code Free* blood glucose monitoring system complies with the requirements of EN ISO 15197:2015 / ISO 15197:2013 (*in vitro* diagnostic test systems - requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus). The *On Call® Plus Code Free* Blood Glucose Meters are calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Reproducibility, Precision

Ten replicate assays were each run on ten *On Call® Plus Code Free* Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following reproducibility, precision estimates.

MEAN	2.32 mmol/L (41.7 mg/dL)	4.16 mmol/L (74.9 mg/dL)	7.18 mmol/L (129.3 mg/dL)	10.84 mmol/L (195.2 mg/dL)	16.81 mmol/L (302.6 mg/dL)
Standard Deviation mmol/L (mg/dL) or Coefficient of Variation (CV)	0.07 mmol/L (1.32 mg/dL) (SD)	0.14 mmol/L (2.43 mg/dL) (SD)	3.4%	3.3%	3.1%

Intermediate Precision

Ten replicate assays drawn from 3 strip lots were run on ten *On Call® Plus Code Free* Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following intermediate precision estimates.

Control Solution Level	MEAN	Standard Deviation mg/dL (mg/dL)or Coefficient of Variation (CV)
Low (CTRL 0)	2.34 mmol/L (42.2 mg/dL)	0.08 mmol/L (1.41 mg/dL) (SD)
Normal (CTRL 1)	6.86 mmol/L (123.4 mg/dL)	3.0%
High (CTRL 2)	20.61 mmol/L (370.9 mg/dL)	2.6%

System Accuracy

The capillary blood glucose measurements were taken by a trained technician using the

On Call® Plus Code Free Blood Glucose Meter (y). Capillary blood samples were obtained from the fingertip sampling sites of 112 participants and from the palm and forearm sampling sites of 102 participants for the *On Call® Plus Code Free* Blood Glucose Meter testing. All samples were analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: *On Call® Plus Code Free* (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mmol/L)/(mg/dL)	R	N
Fingertip	1.02	-0.14/-2.57	0.99	600
Palm	1.03	-0.32/-5.74	0.99	200
Forearm	1.03	-0.30/-5.34	0.99	200

The sample range was 2.32 to 27.89 mmol/L (41.7 to 502 mg/dL) for *On Call® Plus Code Free* Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 2.10 to 26.61mmol/L(37.8 to 479 mg/dL) for *On Call® Plus Code Free* Blood Glucose Meter testing with blood sampled from palm and forearm sites.

System Accuracy Results for Glucose Concentration < 5.55 mmol/L (100 mg/dL)		
Within±0.28mmol/L(5mg/dL)	Within±0.56mmol/L(10mg/dL)	Within±0.83mmol/L(15mg/dL)
136/162 (84.0%)	161/162 (99.4%)	162/162 (100.0%)

System Accuracy Results for Glucose Concentration ≥ 5.55 mmol/L (100 mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
332/438 (75.8%)	426/438 (97.3%)	435/438 (99.3%)

System Accuracy Results for both Glucose Concentration between 37.8 mg/dL and 502mg/dL		
Within ± 0.83mmol/L (15 mg/dL) or ± 15 %		
Fingertip Site	Palm Site	Forearm Site
597/600 (99.5%)	199/200 (99.5%)	199/200 (99.5%)

System accuracy according to EN ISO 15197:2015 / ISO 15197:2013, >99% of measured glucose values fall within the minimum acceptable performance criteria.

User Study

Participants used the *On Call® Plus Code Free* Blood Glucose Monitoring System. This study showed that the patient can run the test properly.

Linear Regression Results: *On Call® Plus Code Free* (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mmol/L)/(mg/dL)	R	N
Fingertip	1.00	0.06/1.00	0.99	105

A study evaluating glucose values from fingertip capillary blood samples obtained by 105 lay persons showed the following results:

99.0 % of the subjects' measurement results are within ± 0.83 mmol/L (± 15 mg/dL) or ± 15 % of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL) or above 5.55 mmol/L (100 mg/dL).

REFERENCES

1. ADA, Standards of Care in Diabetes-2023

INDEX OF SYMBOLS

CTRL	Control Range		Use-by date		Consult instructions for use
REF	Catalogue number	LOT	Batch code	IVD	*In vitro* diagnostic medical device
#	Model Number		Manufacturer		Temperature limit
	Do not reuse	Σ	Contains sufficient for <*n*> tests		

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