



MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

(Federal statutory Body Established by Act 11, 2003)

Public Health In-Vitro Diagnostics Control Laboratory (IVD Lab)

(NINAS ISO 17025:2017 ACCREDITED LABORATORY)

8 Harvey Road, Yaba Lagos Nigeria

Email: ivds@mlscn.gov.ng; info@mlscn.gov.ng , Website: www.mlscn.gov.ng



7.8 FORM A VI

Lab ID No: IVD/23/04

TEST REPORT		(please tick here if report is amended) <input type="checkbox"/>	
Company Name	Codix Pharma Limited		
Contact Address	14 Michael Adekoya Street, Off Ilupeju Bye-pass, Ilupeju, Lagos State.		
E-mail Address	info@codixpharma.com , info@codixgroup.com		
Phone Number	09087194346, 07098819739		
1. PRODUCT INFORMATION			
Product Name (Under evaluation)/Brand	OnPoint GH82 Blood Glucose Monitoring System and Strips	Product Condition <input checked="" type="checkbox"/> GOOD <input type="checkbox"/> FAIR	
Country of Origin	Nigeria	If fair Comment	
Date of Manufacture	February 2023 and March 2023	Date Received	20/10/23
Batch number	Not provided	Date of Evaluation	(Batch 9)
Lot No.	H82X0 (Glucometer) HXB24H1D1 HXB25Y1D1 HXB27H1D1 HXB28Y1D1 HXC01H1D1 HXC02Y1D1		November 6 th to December 18 th 2023
Serial No.	H82X000195 H82X000243 H82X000400 H82X000212 H82X000181 H82X000201		
Test Method:	Comparative Method (CLSI EP12-A2)	Time	10.00am-4.00pm
Date of Expiration: February 2025 and March 2025	Result from an External provider: NO	Temperature Humidity	20 °C to 25 °C 20% to 60%



2. PERFORMANCE CHARACTERISTICS

IVD Kit: IVD/23/04	Characteristic	Observed Performance (%)	Manufacturer's Claim (%)	MLSCN Acceptable Minimum
OnPoint GH82 Blood Glucose Monitoring System and Strips	Precision (Repeatability CV)	5.0626	5.0000	Excellent CV $\leq 10\%$ Good CV $>10\% \leq 20\%$ Fair CV $>20\% \leq 30\%$ Poor CV $>30\%$
	Accuracy	0.9012	0.9747	CC ≥ 1

Key: CV= Coefficient of variation
CC= Correlation coefficient

3. TECHNICAL RECOMMENDATION

The Medical Laboratory Science Council of Nigeria IVD Technical Committee (MITC) reviewed the **OnPoint GH82 Blood Glucose Monitoring System and Strips** dossier and the validation laboratory data. The glucose results obtained by the device correlates well (**0.9012**) with standard laboratory glucose oxidase assay. The validation has found that the **OnPoint GH82 Blood Glucose Monitoring System and Strips** satisfactorily performed glucose estimation in capillary blood by finger pricking. The MITC therefore **recommended** its use in Nigeria.

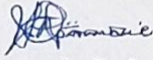
Based on the recommendation of the MITC, MLSCN hereby **grants' approval** for the marketing and use of **OnPoint GH82 Blood Glucose Monitoring System and Strips**, produced by **COLEXA BIOSENSOR LTD, Nigeria** as presented by Codix Pharma Limited to be validated, in Nigeria, for self-testing for glucose estimation in capillary blood by finger pricking.

You are hereby issued with a certificate of authorization to market **OnPoint GH82 Blood Glucose Monitoring System and Strips, Nigeria** as specified above with the MLSCN-IVD product listing number: **MLSCN-IVD/23/04**. This IVD Product listing number must be included in your next product batch with Nigeria destination.

4. AUTHORIZATION

Verified by:

Signature:



Name: **Oparanozie Jude**

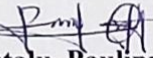
Position: Quality Assurance Manager

Comment: OK.

Date: 18th December, 2023

Report Authorized by:

Signature:



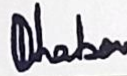
Name: **Offutalu, Paulinus N.**

Position: Laboratory Manager/ Principal Investigator

Comment: OK.

Date of Issue: 18th December, 2023

Approved by:
Signature/ Date



Name **Dr. Tosan Erhabor**

Position Registrar/CEO, MLSCN