



Medical Laboratory Science Council Of Nigeria
(National Medical Laboratory Accreditation Agency)

Federal Statutory Body Established Act 11 2003



MLSCN Headquarters,
Plot 1166 Mohammed N. Umar Lane,
Durumi Phase II Garki, Abuja.
Tel: 08058150005, 07026100004

Website: www.mlscn.gov.ng E-mail: info@mlscn.gov.ng

Registrar/CEO: Dr. Tosan Erhabor

MLSCN/IVD/ VOL.3/172/2022

18TH JULY, 2022

The Managing Director

Codix Pharma Ltd.

14 Michael Adekoya Street,

Off Ilupeju Bye-Pass Ilupeju

Lagos State.

Dear Sir/Madam,

**REPORT OF PRE-MARKET VALIDATION OF STANDARD M10
LAMP+QPCR - POINT-OF-CARE MDX SYSTEM (IVD/21/060)**

Preamble:

The Medical Laboratory Science Council of Nigeria (MLSCN) Act 2003 (CAP M25 LFN 2004), Section 4, Sub-section (e), mandates MLSCN to regulate the production, importation, sales and stocking of diagnostic reagents, equipment and chemicals in Nigeria.

It is in the exercise of this responsibility that MLSCN received your Covid-19 test kit (**Standard M10 Point-of-Care MDx system**) for validation at the MLSCN-IVD Laboratory, Yaba, Lagos, Nigeria.

Laboratory Result Summary:

- 1) At the end of the validation exercise the basic laboratory performance characteristics for the qualitative detection of RNA in SARS CoV-2 is as follows.

Test Kit	Characteristic	Observed Performance (%)	Manufacturer's Claim (%)	MLSCN Acceptable Minimum
Standard M10 LAMP+Qpcr	Sensitivity	92	Not provided	≥ 90%
	Specificity	92	Not provided	≥ 90%
	Accuracy	92	Not provided	≥ 90%

- 2) **Technical Recommendation:** The Medical Laboratory Science Council of Nigeria IVD Technical Committee (MITC) reviewed the **Standard M10 (POC MDx system)** dossier and the validation data. The MITC is **satisfied** that the **Standard M10 Point-of-Care MDx system, Korea** is a fit and proper system for qualitative detection of RNA in SARS CoV-2 in Nasal swabs and have **recommended** its use in Nigeria.

Based on the recommendation of the MITC, MLSCN hereby **grants approval** for the marketing and use of the **Standard M10 Point-of-Care MDx system**, produced by **SD Biosensor, Inc., Republic of Korea** as presented by **Codix Pharma limited**, to be validated in Nigeria, for the qualitative detection of RNA in SARS CoV-2 in Nasal swabs.

You shall be issued with license of authorization to import and market **Standard M10 Point-of-Care MDx system, Korea** as specified above with the MLSCN-IVD Product Listing Number: **MLSCN – IVD/21/060**. This IVD Product listing number must be included in your next product batch with Nigeria destination.

Please, accept the warm regards.


Dr. Tosan Erhabor
Registrar/CEO