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All correspondence should be addressed to the Director General

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 28th August 2026

To: Distributors, Public and Private Hospital Pharmacies, Healthcare Professionals

URGENT FIELD SAFETY NOTICE:

VOLUNTARY FIELD SAFETY CORRECTIVE ACTION OF APTIMA HIV-1 QUANT DX ASSAY MANUFACTURED BY HOLOGIC BV, BELGIUM

(DRIED BLOOD SPOT FACTOR NOT CALCULATED ON RESULTS REPORT ON PANTHER SYSTEM)

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to ensure the quality, safety and efficacy including performance of medicines and allied substances, respectively, for human and animal health protection.

On this background, the Authority wishes to notify all distributors, public and private hospital pharmacies and healthcare professionals on the voluntary Field Safety Corrective Action (FSCA) of the above-mentioned product. This follows the discovery that rapid completion of the Dried Blood Spot (DBS) testing workflow and/or missing steps in the process may prevent the DBS Conversion Factor from being applied in the Panther Results Report and subsequently lead to quantification that is lower than the actual HIV-1 viral load.

Product details:

s/n	Item Number	Description	Manufacturer	UDI Impacted
1.	ASY-12006	Dried Blood Spot (DBS) Supplement For Aptima HIV-1 Quant DX Assay, IVD	Hologic BV, Belgium	15420045511811

RISK ASSESSEMENT

The Aptima HIV-1 Quant Dx Assay is designed to first amplify any HIV-1 RNA present in the sample. If no assay signal is generated, the assay will report HIV-1 as 'not detected' and not quantify the level of HIV-1 present in the sample. If HIV-1 RNA is detected, the assay will subsequently use the assay signal and DBS Conversion Factor (if assigned as a DBS sample) to calculate the concentration level of HIV-1 RNA present in the sample. When an assay signal is detected, the assay will report HIV-1 as 'detected' and/or provide the concentration level of HIV-1 RNA detected.

Based on the assay design, when the DBS Conversion Factor is not applied to a DBS specimen, the Aptima HIV-1 Quant Dx Assay will continue to amplify HIV-1 RNA if present in the sample and

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Website: www.zamra.co.zm

correctly detect the presence (or absence) of the HIV-1 virus. Since the assay correctly detects HIV-1, there is no impact on diagnosis of HIV-1 infection, including Early Infant Diagnosis.

While the assay detects the presence or absence of HIV-1, a missing DBS Conversion Factor for a DBS specimen will cause the assay to miscalculate the level of HIV-1 RNA present. Because the assay signal is determined from a diluted sample, the absence of the Conversion Factor leads to the assay software under-quantifying HIV-1 viral load. This under-quantification may affect the clinical management and prognosis of patients infected with HIV-1.

REQUIRED ACTION

All users of this device are required to follow instructions provided in the Dried Blood Spot (DBS) Supplement to the Aptima HIV-1 Quant Dx Assay Package Insert (AW-29377) and ensure Aptima HIV-1 Quant Dx Assay test orders are assigned to the samples before applying the DBS Conversion Factor.

The Panther System Test Procedure for System Preparation for DBS Specimens states the following:

1. Set up the system according to the instructions provided in the Panther System Operator's Manual.
2. Load the specimen rack.
3. Apply the Dried Blood Spot Conversion Factor to assay test orders for DBS specimens.
4. Confirm that all specimens have been assigned the DBS Conversion Factor on the Panther GUI prior to assay processing of that specific specimen rack.

All distributors of this product are required to inform their customers of this notification. Further, all users of the product are required to read this notification and share it with appropriate staff within the Diagnostics Molecular Laboratory. In addition, they are required to post a copy of this notice in a visible location for awareness and retain a copy for record purposes.

All users of this device who may notice a missing DBS Conversion Factor or need assistance with testing DBS specimens are encouraged to contact the local Hologic support representative or the Hologic Technical Support department on +254 796 269327 or email at Africa.service@hologic.com.

Further, users can notify the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL