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Urgent Field Notice

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Commercial name of the affected product: Murex HBsAg Version 3

FCA-identifier: FN-2026-01

Type of action: Field Corrective Action

Date: 19 March 2026

Attention: ////////////////

Details on affected device:
Type of device: Murex HBsAg Version 3
Model name: *9F80-01, 9F80-05*

Batch/serial number / Expiry date

A009510	Exp:30/06/2026
A012410	Exp:30/06/2026
A011310	Exp:30/06/2026
A014310	Exp:31/07/2026
A015810	Exp: 31/10/2026
A017710	Exp: 31/10/2026
A017811	Exp: 31/10/2026
A020211	Exp: 31/12/2026

Description of the problem:
Potential for Invalid Assays and Reduced Sensitivity in Specific Kit Lots.

Recent internal testing has identified that the above listed kit lots may produce positive control results that fall below the acceptance criteria specified in the Instructions for Use (IFU).
As per the product IFU, if the Positive control does not meet IFU criteria, the assay is considered invalid, and test results cannot be interpreted.

Additionally, internal investigations have confirmed that these kits do not meet the sensitivity claim stated in the IFU in terms of analytical sensitivity versus the WHO Third International Standard HBsAg (NIBSC code: 12/226), even though they continue to fulfil the minimum sensitivity requirements of the Common Specifications (CS)[1].

Risk to Health:
There is no risk to patient health associated with Failing positive control as this will invalidate the assay – patient results are uninterpretable. No action is required regarding previously reported patient results.

The risk related to the reduced sensitivity remains low and within an acceptable level. Because the product continues to meet the Common Specification (CS) sensitivity requirements, there is no

[1] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

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reasonable likelihood that use of the device could lead to adverse health effects, medically irreversible harm, or death.

Advise on action to be taken by the user:

Please stop using the affected lots and contact your DiaSorin representative to discuss appropriate next steps or alternative solutions.

Actions taken by Diasorin:
Our investigation confirms that the issue is isolated to the above listed Lots. All other lots currently on the market are not expected to be affected by the same issue.

Transmission of this Field Notice: (if appropriate)

Please forward this communication to all those required individuals within your organisation or to any organisation where the potentially affected devices have been distributed.

Please send a confirmation e-mail that all your customers have been informed.

Contact reference person:

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Organisation: DiaSorin Italia S.p.A UK Branch

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Signature Hkanjee