Date: 28 April 2025

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (FSN)
Merlin Assay

Dear esteemed Distributor and Customer,

This letter is to inform you that SkylineDx is conducting a Field Safety Corrective Action (FSCA) regarding the software of the device (Merlin Assay Analysis Software, MAAS).

The devices that are affected:

Device type	**CE IVD**
Commercial name	**Merlin Assay**
Device Model	**DM010334EUN00**
Software version	**DMAS1.0134EUN**
Basic UDI-DI	**N/A**
Primary clinical purpose of device(s)*	**For professional use only**
Affected Lot Number	**AG23062101 / R23062101**

A. Reason for Field Safety Corrective Action (FSCA)

Description of the problem and Hazard giving rise to the FSCA:

Merlin Assay (an IVD medical device) consists of 3 items: Merlin Assay Reagent Kit Box 1, Merlin Assay Reagent Kit Box 2, and Merlin Assay Analysis Software, MAAS. An internal complaint discovered a bug in the software. The test may display a Merlin result instead of an 'Invalid' result. At the moment, there are still devices available on the market which might be used before the expiration date. Although the probability of the bug impacting the result is expected to be very low (further investigation ongoing), to reduce any risk, the manufacturer would like to ask the distributor and their customers to implement a manual verification until the bug fixing is implemented.

In the worst case and very unlikely scenario, the results generated may lead to the delayed treatment of the patient. However, due to the technical possibility to retrospectively verify the

data and the fact that Merlin Assay should not be used as a standalone tool, we expect the risk to be negligible.

B. Type of Action to Mitigate Risk

Actions by SkylineDx (Manufacturer):

Actions Completed:

1) Retrospective assessment and manual check of all generated Merlin Assay results at SkylineDx Diagnostic Lab.
2) Notified the distributor of the issue.
3) Provide support to the customers for continued use of the Merlin Assay through manual verification check of their generated data.
4) We confirm that we have informed the respective Competent (Regulatory) Authorities.

Actions in progress:

5) If results have been used for clinical decision making (both in and outside trial setting), retrospective assessment of the results generated for all users.
6) Implement permanent solutions at the customer sites by the release of the updated MAAS.

Target Completion Date: Q2 2025

Actions to be taken by Distributor and Customer:

1) Before the new version of the software can be available, Merlin Assay can still be performed. However, a manual step on the verification of the instrument data must be conducted before importing it into the MAAS.
2) Customers are required to update their MAAS once the new version is available.

We would like to kindly request the recipients hereof confirm their receipt of this notification via the email below.

We sincerely apologize for the inconvenience this will cause. If you have any questions, please feel free to contact customersupport@skylinedx.com.

Sincerely,