SENTINEL DIAGNOSTICS

Field Safety Notice
N.01/2023

Product Name	Reference number REF	Lot Number	Expiration Date
CALiaGold® Calibrator	1151100	20282 20361 20626 21024	05/2023 08/2023 10/2023 02/2024
CALiaGold® Control Set	1151200	20360 20363 20462 20853 30590	06/2023 08/2023 08/2023 02/2024 06/2024
CALiaGold® Sample Diluent	1151400	20137 20362 20627 30591	05/2023 08/2023 10/2023 06/2024

UDI	SRN - Manufacturer
08058056682734	IT-MF-000012556

Date: May 17, 2023

Details on affected devices:

This letter contains important information regarding CALiaGold® Calibrator REF 1151100, CALiaGold® Control Set REF 1151200 and CALiaGold® Sample Diluent REF1151400, for the lots referenced above.
Please review the below information carefully and follow the necessary actions.

Description of the problem:

Based on the data collected from some customer sites, a high recovery of CALiaGold® Control Set REF 1151200 may be found.
Internal studies confirmed that the issue is due to an instability of the materials caused by some detergent lots used in the manufacturing of CALiaGold® Control Set REF1151200 and also of CALiaGold® Calibrator REF 1151100, and CALiaGold® Sample Diluent REF 1151400.

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Patient Impact:

No significant impact on patient management is expected since, according to Good Laboratory Practices, the analysis should not be executed when Quality Control values exceed the specific ranges.
In this case, the use of affected CALiaGold® Control Set lots may have caused a delay in patient result reporting.
Calprotectin is not an urgent test, therefore, the impact of the delay is not significant in patient management.

Actions to be taken:

1. In case of rema1n1ng stock of the affected lots of CALiaGold® Calibrator IREEj 1151100, CALiaGold® Control Set IREEj 1151200 and CALiaGold® Sample Diluent IREEj 1151400, stop using the products.
2. Dispose the affected lots in accordance with your national and local safety and environmental regulations.
3. Fill in the "Field Safety Notice Receipt" and return it to Your local representative by June 20, 2023.
4. Review the content of this communication with your Medica! Director and retain this letter for any future reference.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

Reference person:

If you or any of your customers have any questions regarding this information, please contact your local area Customer Service.

We apologize for any inconvenience this may cause and thank you for your collaboration.

Best Regards.

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