

**Field Safety Notice
N. 01/2022**

Product Name	List Number (LN)	Lot Number	Expiration Date
CALiaGold® Control Set	1151200	10948 11025 11165	02/2023

UDI	SRN - Manufacturer
08058056682734	IT-MF-000012556

Date: March 02, 2022

Details on affected devices:

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

Description of the problem:

An accuracy issue using Sentinel CALiaGold® Control Set REF 1151200 has been encountered, when testing the control material, values obtained were within the reference range listed in the Assigned Concentration Table (TcA) but all results were constantly above 1 Standard Deviation.

Patient Impact:

The accuracy of patient results is not affected. However, the use of affected CALiaGold® Control Set lots may cause 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 order to use the product properly, please follow the instructions described here below,
2. Fill in all the required fields of the "Receipt of the Safety Notice" and return it to Your local representative,
3. Review the content of this communication with your Medical Director and retain this letter for any future reference.

SENTINEL DIAGNOSTICS

If the following lots of CALiaGold® Control Set REF 1151200 have been distributed inside or outside your company, please consider the new following values:

CALiaGold® Control Level 1			
Lot Number	Expiration Date	New Target Values µg/g	Old Target Values µg/g
10948	02/2023	96.0 ± 19.2	84.8 ± 17.0
11025			
11165			

CALiaGold® Control Level 2			
Lot Number	Expiration Date	New Target Values µg/g	Old Target Values µg/g
10948	02/2023	352.1 ± 70.4	327.9 ± 65.6
11025			
11165			

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,

Marco Buonaguidi

Head of Marketing and Sales

Patricia Dupé

Head of Quality System

Distributor

Please, send this document to customerservice@sentinel.it or via fax to no. + 39 02 3455146.

Field Safety Notice Receipt

Field Safety Notice N.: 01/2022 Date: March 02, 2022	Product(s): CALiaGold® Control Set Code(s): 1151200 Lot(s): 10948, 11025, 11165
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☐ I acknowledge that I have read and understood the Field Safety Notice.

Code	Lot	Number of received kits

Name	
Title	
Company/Institute	
Address	
Phone	
Fax n	
E-mail	

Notes/Comments:

Date, signature and company stamp

User

Please, send this document by mail or fax to your local representative

Field Safety Notice Receipt

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