

Field Safety Notice
CALiaGold® pierceTube

Product Name	Reference number <u>REF</u>	Lot Number	Expiration Date	UDI
CALiaGold® pierceTube	1151300	31390	04/2025	(01)8058056682741(17)240430 (10)31390(240)1151300
		40037	05/2025	(01)8058056682741(17)250531 (10)40037(240)1151300
		40045	05/2025	(01)8058056682741(17)250531 (10)40045(240)1151300

SRN - Manufacturer
IT-MF-000012556

Date: June 13, 2024

Details on affected devices:

This letter contains important information regarding CALiaGold® pierceTube REF 1151300, for the lots referenced above.

Please review the below information carefully and follow the necessary actions.

Description of the problem:

Following a customer complaint, Sentinel detected a defect in some collection tubes of the lots referenced above.

The defect is an inner plastic crack that connects the two chambers of the collection tube, causing a reduction of the buffer volume needed for the measurement.

It cannot be excluded that a significant volume decrease may lead to the impossibility to perform the test.

Patient Impact:

CALiaGold® pierceTube is intended to be used to collect and store the human feces. The product is intended to be used in conjunction with CALiaGold® Reagent for the measurement of human calprotectin in feces.

Significantly reduced buffer volume, in the defective tubes, may cause a delay in patient results.

Calprotectin is not an urgent test, therefore, the impact of the delay can be considered not significant for patient management.

Actions to be taken:

1. In case of remaining stock of the affected lots of CALiaGold® pierceTube REF 1151300, 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 September 30, 2024.
4. Review the content of this communication with your Medical 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.

Marco Buonaguidi
Head of Marketing and Sales

Patricia Dupé
Head of Quality System