

# CALiaGold®

## FREQUENT ASKED QUESTIONS

### FOR INTERNAL USE ONLY

#### Sommario

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## 1. What's CALiaGold®?

CALiaGold® is a Sentinel Diagnostics **kit to quantify calprotectin in stool samples**. Calprotectin is a marker of intestinal inflammation, often used to distinguish between IBDs (Inflammatory Bowel Diseases) from IBS (Irritable Bowel Syndrome).

Sentinel Diagnostics developed the first version of latex based immunoturbidimetry for the measurement and quantification of fecal calprotectin, CALiaGold®, in 2018. With a view to continuous improvement of its products, we have developed a new formulation of the assay which will guarantee improved analytical performance and a higher flexibility in the sample management.

The **new formulation of the CALiaGold®** kit is available for promotion and sale and will soon replace the previous version currently “on-market” (REF. 1159000).

## 2. What are the main differences with the previous product?

The new CALiaGold® kit uses a new latex formulation, buffer composition and a new high concentration calibrator (concept similar to FOB Gold® Wide).

As consequence of such modification, the new CALiaGold® shows improved performances and an **increased stability of the sample in the CALiaGold® Tube**. Preliminary data show that the new CALiaGold® tube can be stored at Room Temperature, suggesting the possibility to perform home sampling like for FOB testing. Additionally, the new CALiaGold® kit can be also used on SENTiFOB® analyzer to meet lower throughput requirements (see question N. 18 for additional info on SENTiFOB®).

Specification	CALiaGold Ref. 1159000 (Previous)	New CALiaGold Ref. 1151000	New CALiaGold RV Ref. 1151001
<b>Analytical sensitivity:</b>		<b>SENTiFIT® 270</b>	<b>SENTiFOB®</b>
LOB	12.2 µg/g	3.2 µg/g	7.9 µg/g
LOD	18.3 µg/g	6.1 µg/g	21.5 µg/g
LOQ	21.3 µg/g	18.6 µg/g	38.0 µg/g
<b>Measuring range</b>	22-2200 µg/g	<b>SENTiFIT® 270</b> 20-2200 µg/g	<b>SENTiFOB®</b> 38 - 1800 µg/g
<b>Cut-off value</b>	50 µg/g	50 µg/g	50 µg/g
<b>Open vial stability</b>	60 days (2-8°C)	60 days (2-8°C)	60 days (2-8°C)
<b>Calibration stability</b>	30 days	30 days	30 days
<b>Tube storage conditions</b>	2-8 °C.	2-8°C RT stability under investigation	2-8°C RT stability under investigation
<b>Sample in tube stability</b>	3 days up to 28°C 6 days at 2-8 °C.	3 days up to 37°C 14 days at 2-8 °C.	3 days up to 37°C 14 days at 2-8 °C.
<b>Prozone free</b>	Up to 3000 µg/g	Up to 6000 µg/g	Up to 5000 µg/g
<b>Number of test/kit</b>	<b>100</b>	<b>100</b>	<b>110</b>

### 3. Will the new version have a new name and a new code?

No, to emphasize the idea of continuity, it has been decided that the new kit does not change its name and will always be called CALiaGold® but the product code has changed, in particular we now offer 2 products depending on the instrument used for measurement:

- REF: 1151000 – new CALiaGold® reagent to be used with SENTiFIT® 270
- REF: 1151001 – new CALiaGold® RV reagent to be used with SENTiFOB®

### 4. Does Sentinel Diagnostics provide only the reagent or a complete system?

Sentinel Diagnostics provides a **complete product line** to measure calprotectin which includes:

- CALiaGold® Tube: pierceable collection tube, easy to use
- CALiaGold® reagents, calibrators, controls and diluent developed to be used on Sentinel instruments
- FIT dedicated instruments: SENTiFIT® 270 and SENTiFOB®, automated analyzers.

In the table below, the products needed to run calprotectin test on SENTiFIT® 270 and SENTiFOB® analyzers are listed:

Ref. #	Description	Size	Note	Needed on Instrument	
1151000	CALiaGold®	R1 1x14 mL	100 test/kit	SENTiFIT® 270 Analyzer	
		R2 1x9 mL			
1151001	CALiaGold® RV (Round Vial)	R1 1x19 mL	110 test/kit	SENTiFOB® Analyzer	
		R2 1x12 mL			
1151100	CALiaGold® Calibrator	Cal 1x2 mL	1 high level of Calprotectin to be diluted.	SENTiFIT® 270 Analyzer	SENTiFOB® Analyzer
		Dil 1x15 mL			
1151200	CALiaGold® Control Set	2 x (1 x 1) mL	2 levels: low and high	SENTiFIT® 270 Analyzer	SENTiFOB® Analyzer
1151300	CALiaGold® pierceTube	100 tubes	For dedicated systems	SENTiFIT® 270 Analyzer	SENTiFOB® Analyzer
1151400	CALiaGold® Sample Diluent	1x15 mL	For over range samples	SENTiFIT® 270 Analyzer	SENTiFOB® Analyzer

## 5. What will happen to the previous CALiaGold® kit?

The previous CALiaGold® kit (REF. 1159000) remains available in parallel with the new formulation for a limited period of time. The previous CALiaGold® kit is reserved for Customers who already use it. We recommend to promote the new kit for new installations because it's our intention to move all customers to the new product as soon as possible.

## 6. What's included in the CALiaGold® line?

The CALiaGold® product line is made of the following products:

REF	Name	Kit size	Note
1151000	CALiaGold®	1x14 mL; 1x9 mL (100 tests)	To be used on SENTiFIT® 270
1151001	CALiaGold® RV	1x19 mL; 1x12 mL (110 tests)	To be used on SENTiFOB®
1151100	CALiaGold® Calibrator	1x2 mL; 1x15mL	
1151200	CALiaGold® Control Set	2x(1x1) mL	
1151300	CALiaGold® pierceTube	100 tubes	
1151400	CALiaGold® Sample Diluent	1x15 mL	
1151080	Wash Vials Kit	8 empty vials	

## 7. What's new with the CALiaGold® calibrator?

The new CALiaGold® calibrator uses one single point at high concentration that is automatically diluted by the instrument to create a 6-point calibration curve. To allow the dilution the calibrator kit also includes 15 mL of diluent. The concentration of the high-level point isn't, anyway, fixed and can vary around the concentration of 2200 µg/g (see TcA for the precise value).

## 8. What's new with REF. 1151400 Sample Diluent?

The Sample Diluent REF. 1151400 can be ordered separately. This diluent is a buffer to dilute samples containing calprotectin in concentrations higher than the last calibration point. Diluting the very high samples will allow to have a numerical value of the concentrations for monitoring. This buffer is the same as in the collection devices.

On the contrary, the Sample Diluent is not used for the predilution of every samples because the new CALiaGold® method doesn't require anymore the 1:3 predilution before analysis as it was with previous kit.

## 9. What is the REF. 1151080? What are those vials for?

Using the REF 1151080, 8 empty vials can be ordered. Those vials are used to allow an extra washing step for the reagents needle on the SENTiFIT® 270. The vials must be filled with 70 mL of C1 Washing Solution diluted 1:100 and loaded on board before starting an assay run.

## 10. Is the cut-off value changed with the new version?

No, the cut-off used with the new version is still 50 µg/g, the most used value, chosen by most manufacturers. Moreover, also the other reference values are the same as the previous kit version (50-200 µg/g form low inflammatory response).

Normal value: <50 mg/g	not indicative of inflammation
Elevated value: 50 – 200 mg	low inflammatory response
>200 mg/g	severe inflammation

## 11. Is the new sampling tube different from the previous?

From an external point of view the tube is the same as well as the way to use it. Anyway, the new tube has a longer stability after sampling: 3 days up to 37° C and 14 days at 2-8°C.

## 12. Will it be possible to mix old and new reagents / Cal / QC / tubes (for example old tubes and new reagents)?

No, all the components of the new CALiaGold® kit are optimized to work with tubes and reagents having the new formulation. It will not be possible to mix the tubes and reagents of the previous version with those of the new version.

## 13. Is the CALiaGold® tube the same used for FOB?

No, we use two different tubes, easily recognizable by the color of the caps: green for FOB and yellow for Calprotectin. The composition of the buffer in the tube is different, thus they cannot be exchanged. The way the tubes are designed is the same as FOBGold®: very easy, same way to collect sample and don't require any manipulation. This will encourage the home sampling for calprotectin directly done by the patient and save a lot of time for the Lab.

## 14 Will the new CALiaGold® kit also be available on SENTiFOB®?

Yes, the new CALiaGold® kit is available on SENTiFOB®. See question N. 6 for details of product REFs.

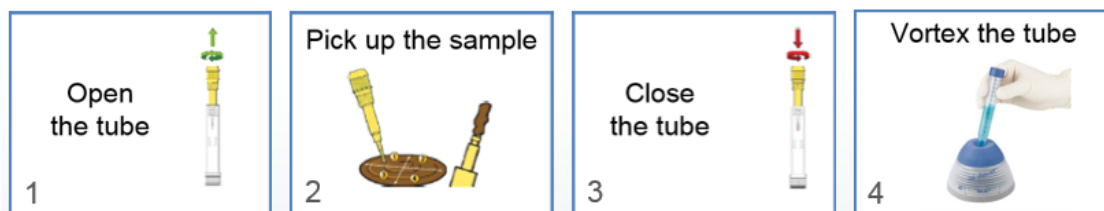
## 15. Is the calibrator referring to an international standard?

No, an international standard or reference material is not available at the moment, therefore we are referring to internal standard material as all the other manufacturers.

## 16. How does the CALiaGold® sampling/extraction phase work?

The CALiaGold® sampling/extraction phase is the easiest among all calprotectin kits and as easy as the FOB sampling. The user should just open the tube, pick up the stools, close the tube. The collection can be done by patient at home or directly by the laboratory collection point.

Once the tube is delivered to the analysis laboratory, the operator should vortex it for 30 seconds and wait 10 minutes. Then the tube can be placed on board for the analysis.



## 17. Additional information on SENTiFIT® 270

SENTiFIT® 270 is a fully automated walk away system, ideal for mid-high volume Fecal Immunochemical Testing (FIT). Using the immunoturbidimetric method, it provides quantitative determination of fCalprotectin and other fecal parameters (like FOB). Below some of the most important features of the instrument:

Throughput	Up to 270 tests/h
Sampling needle	Piercing probe for the use of safe and hygienic piercing tubes
Sample verification	Clot and level detector for correct sampling
Sample management	Continuous loading of samples
Traceability	Automatic barcode reading of samples and reagents
Number of test on board	1250 tests
Reagent on-board stability	Up to 60 days thanks to the refrigerated storage (8-15° C)
fCAL and FOB testing	Performed in the same assay-run in random access mode

## 18. Additional information on SENTiFOB®

SENTiFOB® is a fully automated walk away system, ideal for low-mid volume Fecal Immunochemical Testing (FIT). Using the immunoturbidimetric method, it provides quantitative determination of fCalprotectin and other fecal parameters (like FOB). Below some of the most important features of the instrument:

Throughput	up to 100 tests/h
Sampling needle	Piercing probe for the use of safe and hygienic piercing tubes
Sample verification	Level detector for correct sampling
Sample management	Continuous loading of samples
Traceability	Automatic barcode reading of samples and reagents (option)
Number of test on board	480 tests
fCAL and FOB testing	Performed in the same assay-run in random access mode

## 19. Is it possible to use the same application already used on SENTIFIT® 270 with previous version of CALiaGold®?

No, it will be necessary to use a new application.

The new application is available and can be uploaded on installed SENTIFIT® 270 by trained service engineer.

## 20. Is the new CALiaGold® kit available for sales? What is the delivery time?

Yes, the new CALiaGold® kit can already be ordered. The first kits will be ready for shipment since end of October. In order to better face all the request in due time, it is suggested to contact your Sentinel representative to discuss about quantity needs and timing.

## 21. Where can I found additional information on the products?

Additional technical information is available on our website: [www.sentinel diagnostics.com](http://www.sentinel diagnostics.com)