OC-FCa Calibrator REF V-PH12

INTENDED USE

OC-FCa Calibrator is intended for use as a calibrator used together with OC-FCa Reagent on the dedicated automated immunochemical analysers [OC-SENSOR series] to measure faecal calprotectin.
OC-FCa Reagent is *in vitro* diagnostic assay reagent intended for the quantitative measurement of calprotectin, inflammatory protein, in faeces. The OC-FCa Reagent aids in diagnostic and monitoring of inflammatory bowel diseases (IBD; e.g. ulcerative colitis, and Crohn's disease) in conjunction with other clinical findings. The test can be utilized in diagnostic aid and in monitoring for symptomatic patients. The test is noninvasive, using stool/faeces as test sample. The reagent is used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

MATERIALS PROVIDED

Product code	*Product name*	*Contents*	*Storage*
V-PH12	OC-FCa Calibrator	6 × 1 mL	2-8 °C

MATERIALS REQUIRED BUT NOT PROVIDED

Product code	*Product name*	*Contents*	*Storage*
V-PH11	OC-FCa Reagent (OC-SENSOR PLEDIA)	2 × 8 mL 2 × 15 mL	2-10 °C
V-PH09	OC-FCa Reagent (OC-SENSOR Ceres)	2 × 8 mL 2 × 15 mL	2-10 °C
V-PH13	OC-FCa Control LV1	2 × 5 mL	2-8 °C
V-PH14	OC-FCa Control LV2	2 × 5 mL	2-8 °C
V-PH15	OC-FCa Control LV3	2 × 5 mL	2-8 °C
V-PH19	OC-SENSOR Sample Diluent	3 × 45 mL	2-8 °C
V-PH08		2 × 20 mL	2-8 °C
V-PZ25	OC-Auto Sampling Bottle 3	100 bottles	1-30 °C
V-PZ26	OC-Auto Sampling Bottle 3 without barcode	100 bottles	1-30 °C

REQUIRED MATERIALS NOT PROVIDED BY THE MANUFACTURER

Prepare these materials before measurement

- Wash solution: Sodium hypochlorite 0.15% (0.10%–0.30% is acceptable)
- Purified water for wash: Distilled or de-ionized water (1.0-10.0 MΩcm is acceptable)
- Sample cups
- Printer paper: Thermal printer paper which fits the analyser

REAGENTS

OC-FCa Calibrator is liquid and ready to use requiring no preparation.
For OC-SENSOR PLEDIA, and Ceres
OC-FCa Calibrator 6 × 1 mL

CAL1.	0 µg/g	CAL2.	85 µg/g	CAL3.	340 µg/g
CAL4.	850 µg/g	CAL5.	1700 µg/g	CAL6.	2720 µg/g

STORAGE

OC-FCa Calibrator is stable until the date printed on the label when stored at 2-8 °C.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not freeze this product.
3. Do not use expired products.
4. Start analysis immediately after setting the calibrators on a rack to avoid evaporation.
5. Air bubbles on the surface of the product after being added into sample cups can cause an erroneous measurement. The bubbles should be removed.
6. No human-derived materials are contained in this product; however, the risk of infection and the possible existence of other pathogens cannot be ruled out completely. The product should be handled carefully in the same manner as patient samples to ensure safety.
7. If reagents get into eye or mouth, rinse it out with large volume of running water, and perform other first aid required. If necessary, seek medical attention.
8. Avoid contamination and evaporation by sealing the bottle properly with a cap and put it back in the refrigerator after use. It is advised to minimize the time left in room temperature and keep the calibrator refrigerated when not in use. In-use stability can be altered if the instruction is not followed.
9. Disposal of used reagents and containers should be treated as medical waste in accordance with applicable regulations.

PROCEDURE

Create the calibration curve in the manner described in the user manual of the automatic analysers.

[OC-SENSOR PLEDIA]
Add 200 µL (4 drops or more) of 6 levels of OC-FCa Calibrator individually into 6 sample cups. Set these sample cups on a rack according to the user manual and create calibration curve.

[OC-SENSOR Ceres]
Add 150 µL (3 drops or more) of 6 levels of OC-FCa Calibrator individually into 6 sample cups. Set these sample cups on a rack according to the user manual and create calibration curve.

Note: Volume of 1 drop from the vial of OC-FCa Calibrator is approximately 50 µL.

New calibration should be created:
-When the lot of OC-FCa Reagent is changed.
-When the measurement value of OC-FCa Control (LV1/LV2/LV3) is not within the indicated range or the control range set by each laboratory.
-When opened OC-FCa Reagent bottles are re-used after over 2 weeks of storage at 2-10 °C.
-When opened OC-FCa Reagent bottles are left onboard for more than 2 weeks.
-After maintenance support procedures.

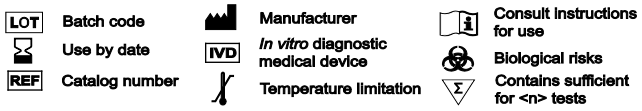
In-Use Stability

OC-FCa Calibrator is stable for 2.5 months (10 weeks) after opening. The stability for this period is kept if it is capped properly and put back in the refrigerator when not in use. In-use stability can be altered in case of contamination, evaporation and/or storage at improper temperatures.

NOTICE

In case of occurrence of any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer, and the competent authority of the Member State in which the user and/or the patient is established.

EXPLANATION OF SYMBOLS



IVD CE 0123

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