



# Instructions for Use

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English

## OC-FCa Control LV1

## OC-FCa Control LV2

## OC-FCa Control LV3

**REF** V-PH13

**REF** V-PH14

**REF** V-PH15

### INTENDED USE

OC-FCa Controls LV1/LV2/LV3 are intended for use as an internal quality control in immunochemical faecal calprotectin tests. They are especially compatible with OC-FCa Reagent on the 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 | Compatible analyser |
|--------------|--------------------|----------|---------|---------------------|
| V-PH13       | OC-FCa Control LV1 | 2 x 5 mL | 2-8 °C  | PLEDIA, Ceres, R70  |
| V-PH14       | OC-FCa Control LV2 | 2 x 5 mL | 2-8 °C  |                     |
| V-PH15       | OC-FCa Control LV3 | 2 x 5 mL | 2-8 °C  |                     |

### \*\*MATERIALS REQUIRED BUT NOT PROVIDED

| Product code               | Product name                              | Contents              | Storage | Compatible analyser |
|----------------------------|-------------------------------------------|-----------------------|---------|---------------------|
| V-PH11                     | OC-FCa Reagent                            | 2 x 8 mL<br>2 x 15 mL | 2-10 °C | PLEDIA              |
| V-PH09                     | OC-FCa Reagent                            | 2 x 8 mL<br>2 x 15 mL | 2-10 °C | Ceres, R70          |
| V-PH12                     | OC-FCa Calibrator                         | 6 x 1 mL              | 2-8 °C  | PLEDIA, Ceres, R70  |
| V-PH19                     | OC-SENSOR Sample Diluent                  | 3 x 45 mL             | 2-8 °C  | PLEDIA              |
| V-PH08                     |                                           | 2 x 20 mL             | 2-8 °C  | Ceres, R70          |
| V-PZ25                     | OC-Auto Sampling Bottle 3                 | 100 bottles           | 1-30 °C | PLEDIA, Ceres, R70  |
| V-PZ26                     | OC-Auto Sampling Bottle 3 without barcode | 100 bottles           | 1-30 °C |                     |
| VCPZ45<br>VCPZ47<br>VCPZ52 | OC-Auto Sampling Bottle 4                 | 100 bottles           | 1-30 °C |                     |
| VCPZ54<br>VCPZ56           | OC-Auto Sampling Bottle 4                 | 1000 bottles          | 1-30 °C |                     |
| VCPZ46<br>VCPZ50<br>VCPZ51 | OC-Auto Sampling Bottle 4 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 Control is liquid and ready to use requiring no preparation. For OC-SENSOR PLEDIA, Ceres and R70

|                             |          |
|-----------------------------|----------|
| OC-FCa Control LV1 (Middle) | 2 x 5 mL |
| OC-FCa Control LV2 (High)   | 2 x 5 mL |
| OC-FCa Control LV3 (Low)    | 2 x 5 mL |

### STORAGE

OC-FCa Control 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 analyses immediately after setting the controls 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 control 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.
10. The calprotectin concentration is printed on the label of each bottle.

### PROCEDURE

Minimum requirement is to analyse the OC-FCa Control LV1 and LV2 before sample analysis on a daily basis. Analyse OC-FCa Control LV3 as required. Follow the detailed measurement procedure in the user manual of the automatic analysers.

Add an appropriate amount of OC-FCa Control into a sample cup and then operate the automatic analyser according to its instructions. For a single measurement, it uses 150 µL (3 drops) of OC-FCa Control, including a dead volume of 100 µL of a sample cup. For a duplicated measurement, it uses 200 µL (4 drops).

When the measurement value of OC-FCa Control (LV1/LV2/LV3) is not within the control range set by each laboratory, new calibration curve should be created.

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

### In-use Stability

OC-FCa Control is stable for 2 months 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

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### EXPLANATION OF SYMBOLS

|             |                |                                    |              |                                   |
|-------------|----------------|------------------------------------|--------------|-----------------------------------|
| LOT         | Batch code     | IVD                                | Manufacturer | Consult instructions for use      |
| Use by date |                | In vitro diagnostic medical device |              | Biological risks                  |
| REF         | Catalog number | Temperature limitation             |              | Contains sufficient for <n> tests |

**IVD** **CE 0123**

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