



Instructions for Use

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OC-SENSOR Sample Diluent

for OC-SENSOR DIANA, PLEDIA, io
for OC-SENSOR Ceres, R70

REF V-PH19
REF V-PH08

INTENDED USE

OC-SENSOR Sample Diluent is intended for use as a high concentration sample diluent used together with OC-SENSOR FIT reagents and OC-FCa Reagent on the automated immunochemical analysers [OC-SENSOR series] to measure faecal haemoglobin and calprotectin.

OC-SENSOR FIT reagents are *in vitro* diagnostic reagents intended for the quantitative measurement of human haemoglobin in faeces. OC-SENSOR FIT reagents aid in the diagnosis of colorectal cancer, neoplasia, dysplasia, polyps, and other disorders associated with gastrointestinal bleeding in conjunction with other clinical findings. The test can be utilized in colorectal cancer screening for asymptomatic population as well as in diagnostic aid and monitoring for symptomatic patients.

OC-FCa Reagent is *in vitro* diagnostic 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 tests are noninvasive, using stool/faeces as test sample. The reagents are used on the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

**MATERIALS PROVIDED

Product code	Product name	Contents	Compatible analyser
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	DIANA, PLEDIA, io
V-PH08	OC-SENSOR Sample Diluent	2 x 20 mL	Ceres, R70

*MATERIALS REQUIRED BUT NOT PROVIDED

For Haemoglobin Measurement
OC-SENSOR FIT Latex Reagent, Buffer
OC-FIT Calibrator
OC-FIT Control
OC-Auto Sampling Bottle 3
OC-Auto Sampling Bottle 4

For Calprotectin Measurement
OC-FCa Reagent
OC-FCa Calibrator
OC-FCa Control
OC-Auto Sampling Bottle 3
OC-Auto Sampling Bottle 4

COMPOSITION

OC-SENSOR Sample Diluent is liquid and ready to use.

It contains buffer solution (HEPES; N-2-hydroxyethyl piperazine-N'-2-ethanesulfonic acid).

The container is made of polyethylene (PE), the cap is made of polypropylene (PP), and the case is made of paper.

STORAGE

This product is stable up to the date printed on the label as long as it remains unopened at a storage temperature of 2-8 °C.

**PROCEDURE

Dilution procedure should be followed in the manner described in the user manual of the automatic analysers.

[OC-SENSOR DIANA, OC-SENSOR PLEDIA]

Set a high concentration sample, an empty sample cup and a sample cup with 2 mL (or more) of the diluent on a dedicated rack. Dilution is performed automatically before measurement on the analyser.

[OC-SENSOR io]

Manually dilute high concentration samples with the diluent, add the diluted sample in a sample cup and measure on the analyser.

[OC-SENSOR Ceres, OC-SENSOR R70]

Set the diluent (REF V-PH08) in the dedicated reagent slot on the analyser with a cap open. Dilution is performed automatically before measurement on the analyser.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use OC-SENSOR Sample Diluent for any purpose other than dilution of high concentration samples.
3. Do not freeze.
4. Do not use OC-SENSOR Sample Diluent after the expiry date.
5. Air bubbles on the surface can cause an erroneous measurement. The bubbles should be removed.
6. The test sample may contain pathogens. Handle with care. After use, all samples and other materials must be considered as medical waste and properly disposed of.
7. Dispose of used reagents and containers as medical waste in accordance with local regulations.

**In-Use stability

for OC-SENSOR DIANA, PLEDIA, io

Stable for 5 months if stored back in a refrigerator after use with cap closed.

for OC-SENSOR Ceres

Stable for 5 months if stored back in a refrigerator after use with cap closed.

Stable for 5 months on-board with cap closed after use on Ceres.

for OC-SENSOR R70

Stable for 5 months if stored back in a refrigerator after use with cap closed.

Stable for 5 months on-board with no recapping required after use on R70.

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.

EXPLANATIONS OF SYMBOLS

LOT	Batch code	Manufacturer	Consult Instructions for use
Use by date		IVD	Biological risks
REF	Catalog number	Temperature limitation	Contains sufficient for $\leq$ tests

IVD CE 0123

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