



Instructions for Use

380363-C

IFU on our website / IFU sul nostro sito web / IFU en nuestro sitio web /
IFU sur notre site web / IFU auf unserer Website / IFU no nosso site
<https://www.eiken.co.jp/en/ifu>

SSP available in EUDAMED

English

OC-FIT Calibrator

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

REF V-PH51
REF V-PH52
REF V-PH02

INTENDED USE

OC-FIT Calibrator is intended for use as a calibrator used together with OC-SENSOR FIT reagents on the dedicated automated immunochemical analysers [OC-SENSOR series] to measure faecal haemoglobin. 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. The test is 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	Storage	Compatible analyser
V-PH51	OC-FIT Calibrator	1 x 3 mL	2-8 °C	DIANA
V-PH52	OC-FIT Calibrator	1 x 3 mL	2-8 °C	io, PLEDIA
V-PH02	OC-FIT Calibrator	6 x 1 mL	2-8 °C	Ceres, R70

**MATERIALS REQUIRED BUT NOT PROVIDED

MATERIALS REQUIRED BUT NOT PROVIDED					
Product code	Product name	Contents	Storage	Compatible analyser	
V-PZ01	OC-SENSOR FIT Latex Reagent	5 x 15 mL	2-10 °C	DIANA, PLEDIA	
V-PZ03	OC-SENSOR FIT Buffer	1 x 500 mL	2-10 °C		
V-PZ05	OC-SENSOR FIT Latex Reagent Buffer	4 x 16 mL 4 x 64 mL	2-10 °C	R70	
V-PH18	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	io	
V-PH46	OC-SENSOR FIT Buffer	1 x 200 mL	2-10 °C		
V-PH01	OC-SENSOR FIT Latex Reagent Buffer	2 x 6 mL 2 x 20 mL	2-10 °C	Ceres	
V-PH53	OC-FIT Control LV1	2 x 5 mL	2-8 °C	DIANA, PLEDIA, io, Ceres, R70	
V-PH54	OC-FIT Control LV2	2 x 5 mL	2-8 °C		
V-PH59	OC-FIT Control LV3	2 x 5 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		
VCPZ45 VCPZ47 VCPZ52	OC-Auto Sampling Bottle 4	100 bottles	1-30 °C		
VCPZ54 VCPZ56	OC-Auto Sampling Bottle 4	1000 bottles	1-30 °C		
VCPZ46 VCPZ50 VCPZ51	OC-Auto Sampling Bottle 4 without barcode	100 bottles	1-30 °C		
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	2-8 °C		DIANA, PLEDIA, io
V-PH08		2 x 20 mL			Ceres, R70

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-FIT Calibrator is liquid and ready to use requiring no preparation.

For OC-SENSOR DIANA
OC-FIT Calibrator Hb 2000 ng/mL 1 x 3 mL
OC-FIT Calibrator Diluent 1 x 45 mL

For OC-SENSOR io, PLEDIA
OC-FIT Calibrator Hb 1000 ng/mL 1 x 3 mL
OC-FIT Calibrator Diluent 1 x 45 mL

For OC-SENSOR Ceres, R70
OC-FIT Calibrator Hb 6 levels 6 x 1 mL
CAL1. 0 ng/mL CAL2. 62.5 ng/mL CAL3. 125 ng/mL
CAL4. 250 ng/mL CAL5. 500 ng/mL CAL6. 1000 ng/mL

STORAGE

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

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not freeze this product.
- Do not use expired products.
- Start analysis immediately after setting the calibrators on a rack to avoid evaporation.
- Air bubbles on the surface of the product after being added into sample cups can cause an erroneous measurement. The bubbles should be removed.
- OC-FIT Calibrator uses material derived from human blood. Only blood testing negative for HBs antigens, HIV (HIV-1 and HIV-2) antibodies and HCV antibodies is used, but the presence of pathogens and infection risk cannot be completely ruled out. Therefore, the product should be handled carefully in the same manner as patient samples to ensure safety.
- Use specific calibrator dedicated to a type of analysers and follow instructions in the user manual.
- 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.
- 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.
- Disposal of used reagents and containers should be treated as medical waste in accordance with applicable regulations.

**PROCEDURE

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

[OC-SENSOR PLEDIA, OC-SENSOR DIANA, OC-SENSOR io]

Add 600 µL (12 drops or more) of OC-FIT Calibrator into a sample cup. Add 2 mL (or more) of OC-FIT Calibrator Diluent into another sample cup. 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-FIT Calibrator individually into 6 sample cups. Set these sample cups on a rack according to the user manual and create calibration curve.

[OC-SENSOR R70]

Add 200 µL (4 drops or more) of 6 levels of OC-FIT 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-FIT Calibrator is approximately 50 µL.

New calibration curve should be created;

- When the lot (batch) of latex reagent is changed.
- When the measurement value of OC-FIT Control (LV1/LV2/LV3) is not within the control range.
- When opened latex reagent is used over 2 weeks.
- After maintenance support procedures.

In-Use Stability

OC-FIT 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

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.



Instructions for Use

380363-C

EXPLANATION OF SYMBOLS

LOT	Batch code	Manufacturer	Consult instructions for use
Use by date		IVD	Biological risks
REF	Catalog number	Temperature limitation	Contains sufficient for <n> tests

IVD CE 0123

EC REP **Advena Ltd.**
Tower Business Centre, 2nd Flr., Tower Street,
Swatar, BKR 4013 Malta

EIKEN CHEMICAL CO., LTD.
*4-6 Kanda Surugadal, Chiyoda-ku, Tokyo, 101-0062 JAPAN
<https://www.eiken.co.jp/en/>