



Instructions for Use

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OC-FIT Control

LV1	REF V-PH53
LV2	REF V-PH54
LV3	REF V-PH59

INTENDED USE

OC-FIT Control LV1/LV2/LV3 are intended for use as an internal quality control in faecal immunochemical tests for haemoglobin. They are especially compatible with OC-SENSOR FIT reagents on the 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-PH53	OC-FIT Control LV1	2 x 5 mL	2-8 °C	All
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	

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-PH18	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	io
V-PH33	OC-SENSOR FIT Latex Reagent	2 x 7 mL	2-10 °C	MICRO
V-PH46	OC-SENSOR FIT Buffer	1 x 200 mL	2-10 °C	MICRO, io
V-PH01	OC-SENSOR FIT Latex Reagent Buffer	2 x 6 mL 2 x 20 mL	2-10 °C	Ceres
V-PH51	OC-FIT Calibrator	1 x 3 mL	2-8 °C	MICRO, 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
V-PZ25	OC-Auto Sampling Bottle 3	100 bottles	1-30 °C	All
V-PZ26	OC-Auto Sampling Bottle 3 without barcode	100 bottles	1-30 °C	
V-PH19	OC-SENSOR Sample Diluent	3 x 45 mL	2-8 °C	DIANA, PLEDIA, MICRO, io
V-PH08		2 x 20 mL		

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 Control is liquid and ready to use requiring no preparation.

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

The haemoglobin concentration range is printed on the labels of a bottle.

STORAGE

OC-FIT Control 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.
- Air bubbles on the surface of the product after being added into sample cups can result in erroneous measurement. The bubbles should be removed.
- OC-FIT Control 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.
- When used on the OC-SENSOR series analysers, OC-FIT Control must be used with OC-FIT Calibrator (**REF** V-PH51, V-PH52, V-PH02) dedicated to each analyser.
- 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.

PROCEDURE

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

Add an appropriate amount of OC-FIT 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-FIT 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-FIT 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-FIT Control is approximately 50 µL.

In-use stability

OC-FIT 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

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

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

IVD **CE** 0123

EC **REP** **Advena Ltd.**
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