



Instructions for Use

341843-A

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English

OC-Auto Sampling Bottle 4

(For OC-SENSOR series)

REF VCPZ45 **REF** VCPZ46

REF VCPZ47 **REF** VCPZ50

REF VCPZ51 **REF** VCPZ52

REF VCPZ54 **REF** VCPZ56

INTENDED USE

OC-Auto Sampling Bottle 4 is designed as a sampling device and a container for a faecal specimen. It is used together with the dedicated immunochemical analysers, OC-SENSOR series and their reagents intended for the measurement of human haemoglobin and calprotectin as *in vitro* diagnostics. The testing population includes asymptomatic participants in screening programs and patients with symptoms suspected of intestinal disorders¹⁻². The sampling and test are noninvasive, using stool/faeces as test sample. Sample collection with OC-Auto Sampling Bottle 4 is done manually, and the measurement is processed using the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.

MATERIALS PROVIDED

Product code	Product name	Contents	Storage
VCPZ45	OC-Auto Sampling Bottle 4	100 bottles	1-30 °C
VCPZ52			
VCPZ46	OC-Auto Sampling Bottle 4 without barcode		
VCPZ47	OC-Auto Sampling Bottle 4 RED		
VCPZ50	OC-Auto Sampling Bottle 4 without barcode RED		
VCPZ51	OC-Auto Sampling Bottle 4 without barcode BROWN		
VCPZ54	OC-Auto Sampling Bottle 4	1000 bottles	
VCPZ56			

MATERIALS REQUIRED BUT NOT PROVIDED

For Haemoglobin Measurement

OC-SENSOR FIT Latex Reagent, Buffer

OC-FIT Calibrator

OC-FIT Control

OC-SENSOR Sample Diluent

For Calprotectin Measurement

OC-FCa Reagent

OC-FCa Calibrator

OC-FCa Control

OC-SENSOR Sample Diluent

COMPOSITION

OC-Auto Sampling Bottle 4 contains buffer (HEPES; N-2-hydroxyethylpiperazine-N'-2-ethane- sulfonic acid, 2 mL).

OC-Auto Sampling Bottle 4 is made of polypropylene (PP) and their bottoms sealed with two layers of aluminium. Sampling probes are made of acrylonitrile butadiene styrene (ABS) resin. Integrated filters and collection bags are made of polyethylene (PE).

STORAGE

OC-Auto Sampling Bottle 4 is stable until the date printed on the label assuming the bottle remains unopened at a storage temperature of 1-30 °C.

PROCEDURE FOR SPECIMEN COLLECTION

Refer to the illustration on the next page.

1. Remove the green cap by turning to the left and pulling upwards.
2. Collect the faecal sample with the sampling probe by scraping from different areas of the surface of the faeces. Collect the amount enough to cover the groove of the probe.
3. Insert the sampling probe to the collection device and tightly close the cap. Do not repeat more than once.
4. Shake the bottle up and down several times.

Note: If the faeces are hard, moisten it with water before collecting the sample using the sampling probe.

STABILITY AFTER SAMPLING

Haemoglobin

Performance testing with OC-Auto Sampling Bottle 4 demonstrated the stability of haemoglobin recovery (in-house data, recovery rate shown as mean $\pm$ 2SD). Examples of measurement of faecal samples are shown below. However, the haemoglobin in some samples may undergo rapid denaturation or degradation, resulting in false negatives. Therefore, samples should be stored at 2-10 °C upon receipt in the laboratory and analysed as soon as possible.

Temperature	Recovery rate	
2-10 °C	103 $\pm$ 4.5 % for 28 days	98 $\pm$ 5.3 % for 55 days
25 °C	89 $\pm$ 2.8 % for 28 days	83 $\pm$ 6.9 % for 55 days
30 °C	88 $\pm$ 3.6 % for 28 days	86 $\pm$ 4.0 % for 42 days
40 °C	91 $\pm$ 4.2 % for 14 days	84 $\pm$ 11.5 % for 28 days
50 °C	95 $\pm$ 4.5 % for 3 days	82 $\pm$ 10.1 % for 7 days

Calprotectin

Performance testing with OC-Auto Sampling Bottle 4 demonstrated the stability of calprotectin recovery (in-house data, recovery rate shown as mean $\pm$ 2SD). Perform measurement at least 1 hour after collection in the sample collection device. Examples of measurement of faecal samples are shown below. However, the calprotectin in some samples may undergo rapid denaturation or degradation, resulting in false negatives. Therefore, samples should be stored at 2-10 °C upon receipt in the laboratory and analysed as soon as possible.

Temperature	Recovery rate	
2-10 °C	98 $\pm$ 12.3 % for 14 days	91 $\pm$ 24.8 % for 31 days
25 °C	92 $\pm$ 33.2 % for 14 days	81 $\pm$ 37.3 % for 31 days
30 °C	93 $\pm$ 16.9 % for 7 days	82 $\pm$ 41.4 % for 14 days
35 °C	96 $\pm$ 18.2 % for 3 days	85 $\pm$ 35.4 % for 7 days
40 °C	92 $\pm$ 26.8 % for 3 days	79 $\pm$ 38.9 % for 7 days

Note: The values shown in the tables are provided as reference, and the stability may vary depending on the specimen.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For single use only.
3. Do not pour out the liquid in OC-Auto Sampling Bottle 4 or add water to it.
4. Do not break the aluminium seal.
5. Do not collect faecal samples during menstruation.
6. Do not use OC-Auto Sampling Bottle 4 directly on a human body.
7. Do not use OC-Auto Sampling Bottle 4 for any purpose other than collecting faecal samples.
8. Keep OC-Auto Sampling Bottle 4 out of reach of children.
9. Perform measurement promptly after completed OC-Auto Sampling Bottle 4 has been received. If analysis is not immediately possible, store OC-Auto Sampling Bottle 4 in the refrigerator at 2-10 °C and analyse as soon as possible.
10. For calprotectin, perform measurement at least 1 hour after collection in OC-Auto Sampling Bottle 4.
11. After OC-Auto Sampling Bottle 4 is taken out of the refrigerator, be sure to bring it to room temperature before measurement.
12. Do not use OC-Auto Sampling Bottle 4 after the expiry date.
13. 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.
14. Dispose of used OC-Auto Sampling Bottle 4 as medical waste in accordance with local regulations.



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15. The buffer in OC-Auto Sampling Bottle 4 contains sodium azide (NaN_3 <0.1 %). In case of contact with the buffer to eye, mouth, or skin, wash thoroughly with plenty of water and see a doctor for proper treatment if necessary.
16. Because neither haemoglobin nor calprotectin are distributed uniformly in faeces, it is recommended to collect specimen with the sampling probe by scraping from different areas of the surface of the faeces.
17. The performance data presented in this IFU is for reference only. It may vary depending on the specimen used and measurement conditions.

NOTICE

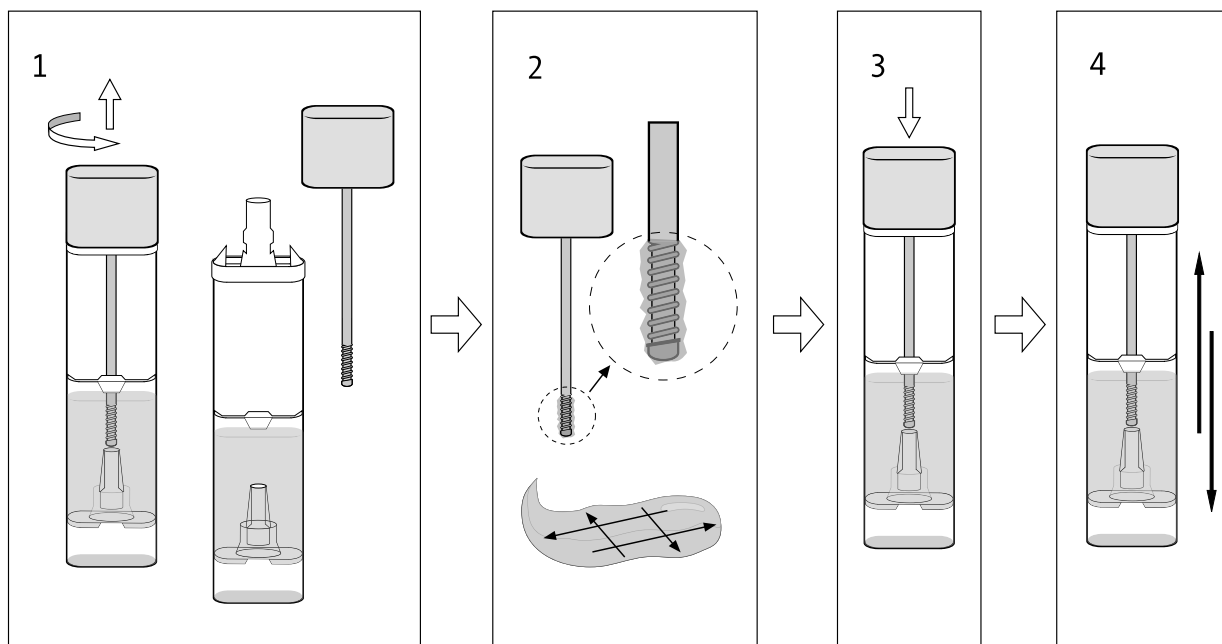
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

REFERENCE

1. Halloran SP, Launoy G, Zappa M; International Agency for Research on Cancer. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First Edition-- Faecal occult blood testing. *Endoscopy*. 2012;44 Suppl 3:SE65-SE87.
2. Levi Z, Rozen P, Hazazi R, et al. A quantitative immunochemical fecal occult blood test for colorectal neoplasia. *Ann Intern Med*. 2007 Feb 20;146(4):244-55.

PROCEDURE FOR SPECIMEN COLLECTION

Illustration



EXPLANATION OF SYMBOLS

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



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