OC-Auto Sampling Bottle 3

(For OC-SENSOR series)

REF V-PZ25

REF V-PZ26

INTENDED USE

OC-Auto Sampling Bottle 3 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 disorders. The sampling and test are noninvasive, using stool/faeces as test sample. Sampling with OC-Auto Sampling Bottle 3 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
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

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 3 contains buffer (HEPES; N-2-hydroxyethylpiperazine-N'-2-ethane- sulfonic acid, 2 mL).

OC-Auto Sampling Bottle 3 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 3 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 tighten 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 3 demonstrated that samples stored at 2-10 °C for 28 days had 95±14.7%, at 25 °C for 7 days had 96±20.4%, for 14 days had 93±23.5%, and at 30 °C for 7 days had 89±20.5%, for 14 days had 84±23.6% of haemoglobin recovery (in-house data, recovery rate shown as mean±2SD). However, haemoglobin in some samples may undergo rapid denaturation or degradation, resulting in false negatives. Therefore, samples should be stored at 2-10 °C and analysed as soon as possible.

Calprotectin

Performance testing with OC-Auto Sampling Bottle 3 demonstrated that samples stored at 2 °C for 31 days had 88±23.4%, at 25 °C for 3 days had 80±33.4%, and at 30 °C for 3 days had 66±42.4% of calprotectin recovery (in-house data, recovery rate shown as mean±2SD). Perform measurement at least 1 hour after collection in OC-Auto Sampling Bottle 3. Calprotectin in some samples may undergo rapid denaturation or degradation, resulting in false negatives. Therefore, samples should be stored at 2-10 °C and analysed as soon as possible.

WARNINGS AND PRECAUTIONS

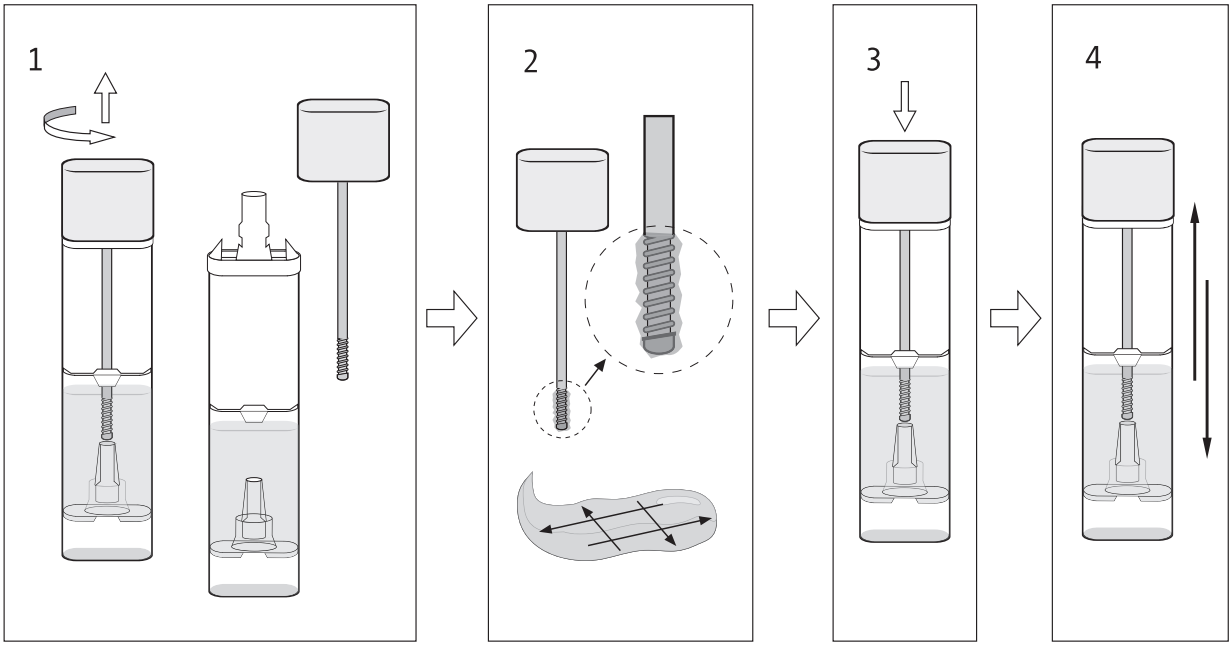
1. For *in vitro* diagnostic use only.
2. Do not pour out the liquid in OC-Auto Sampling Bottle 3 or add water to it.
3. Do not break the aluminium seal.
4. Do not collect faecal samples during menstruation.
5. Do not use OC-Auto Sampling Bottle 3 directly on a human body.
6. Do not use OC-Auto Sampling Bottle 3 for any purpose other than collecting faecal samples.
7. Keep OC-Auto Sampling Bottle 3 out of reach of children.
8. Perform measurement soon after sampled OC-Auto Sampling Bottle 3 has been received. If analysis is not immediately possible, store OC-Auto Sampling Bottle 3 in the refrigerator at 2-10 °C and analyse as soon as possible.
9. For calprotectin, perform measurement at least 1 hour after collection in OC-Auto Sampling Bottle 3.
10. After OC-Auto Sampling Bottle 3 is taken out of the refrigerator, be sure to bring it to room temperature before measurement.
11. Do not use OC-Auto Sampling Bottle 3 after the expiry date.
12. 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.
13. Dispose of used OC-Auto Sampling Bottle 3 as medical waste in accordance with local regulations.
14. The buffer in OC-Auto Sampling Bottle 3 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.
15. 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.

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.
3. Hiraoka S, Takashima S, Inokuchi T, et al. The novel latex agglutination turbidimetric immunoassay system for simultaneous measurements of calprotectin and hemoglobin in feces. Intest Res. 2019;17(2):202-209.

PROCEDURE FOR SPECIMEN COLLECTION

Illustration



Notice

In case of occurrence of any serious incident 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 *In vitro* diagnostic medical device	Biological risks
REF Catalog number	Temperature limitation	Contains sufficient for <n> tests

IVD CE

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

EIKEN CHEMICAL CO., LTD.
4-19-9 Taito, Taito-ku, Tokyo, 110-8408 JAPAN
https://www.eiken.co.jp/en/

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