INSTRUCTIONS FOR USE

MIDI-SYSTEM ECOSAF

1 - INTENDED USE

In vitro diagnostic device. The Midi-System Ecosaf is a disposable plastic device for the collection, fixation, filtration and concentration by sedimentation of intestinal parasites from faecal specimens.

2 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The collection vials of Midi-System contain a fixative for the morphological preservation of the parasites. The built-in filters eliminate the food debris providing a clean sediment after centrifugation. The parasites are identified by the examination of the concentrated sediment by low magnification microscopy.
The concentration procedure is a modification of the Formalin Ether (Ritchie method), as recommended by WHO[1].
The Ecosaf fixative is a modification of Sodium Acetate Formalin (SAF) fixative, with low formaldehyde content (0.58%).
The filtration is performed by two filters of 400 and 250 microns, the optimal size for obtaining a clean sediment and a good recovery of helminths eggs and protozoa[2]. The filters are included in the collection vial which contains glass beads for facilitating the homogenous suspension of the specimen. After fixation, a sedimentation tube is screwed to the bottom of the collection vial, forming a closed system, which is then centrifuged. The addition of ether or ethyl acetate, normally needed to allow the filtration, is not required as the filtration happens during the centrifugation. After discarding the supernatant, an aliquot of the sediment is examined microscopically. The concentration technique can be combined with a permanent staining to improve de detection of protozoa.

3A – MATERIAL PROVIDED - KIT CONTENT

Product	Type	REF	Pack
Midi-System Ecosaf Kit content ▪ 30 mm collection vials with 10 mL Ecosaf fixative, two filters, glass beads and collection spoon ▪ Sedimentation tubes ▪ Sticks	Kit	25RPP8010	98 tests 98 pcs 98 pcs 98 pcs

Note:
Mini-System Ecosaf is also available (REF 25RPP2000), with 150 collection vials with 4 mL fixative

3B – MATERIAL AVAILABLE – ACCESSORIES NOT INCLUDED IN THE KIT

Product	Type	REF	Pack
Midi-System Screw Caps	Screw caps for sedimentation tubes	25RPP05AB	250 pcs

4 - MATERIALS REQUIRED BUT NOT PROVIDED

1. Transfer Pipettes
2. Microscope Slides and Coverslips
3. Centrifuge
4. Lugol's Iodine
5. Microscope

5 – SPECIMEN COLLECTION

Midi-System Ecosaf is intended for the detection of parasites in faecal specimens.

1. Faeces should be presumably collected before antimicrobial or anti-diarrhoeal therapy where possible and between 10 pm and midnight, or early in the morning, before defecation or bathing.[3]
2. Ideally, collect three stool samples over no more than a 10-day period. It is usually recommended that specimens are collected every other day.[3]
3. Faecal concentrations are carried out on all specimens where examination of parasites is specifically requested and where there are definite clinical indications. All faecal samples from symptomatic individuals should be tested for *Cryptosporidium* oocysts.[3]
4. Avoid the use of antidiarrheal or laxative medications before collecting the sample.
5. Collect the faecal specimen in a clean dry recipient.
6. Avoid contamination of the specimen with urine or water.
7. Mix the specimen thoroughly with the wooden stick and using the spoon under the cap, transfer one spoonful of the specimen into the collection vial. With deep recipients, the wooden stick can be used to fill the spoon. For liquid stool transfer approximately 2-3 mL with a disposable pipette. Do not open the bottom cap of the tube in any moment. Mix to homogenize the diluted specimen.
8. Close the tube tightly and send it to the laboratory for processing.

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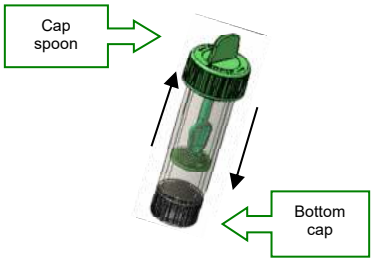
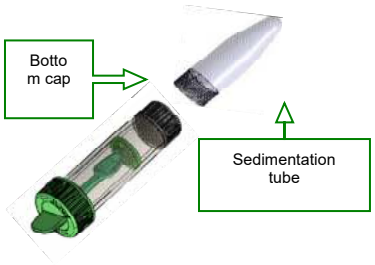
6 - TEST PROCEDURE

1- Shake vigorously the collection tube with the sample for 30 seconds

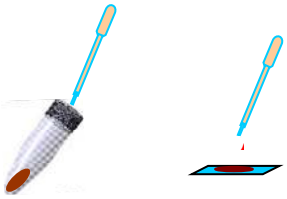


2- Keeping the vial upside down, replace the bottom cap with the sedimentation tube



3- Centrifuge for 3 minutes at 700 g (2000 rpm).

4- Discard the collection tube and all the supernatant. Re-suspend the sediment with 1-2 drops of water or saline, transfer few drops on a microscope slide and examine under the microscope at 100 x magnification



One drop of Lugol's Iodine can be added on the slide to enhance the visibility of parasites. A calibrated ocular micrometer is useful to measure helminths eggs for a correct identification. Examine the entire area of the coverslip in a systematic manner.
Screw caps are available for permanent storage of positive samples (25RPP05AB).

7 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory.

8- PERFORMANCES CHARACTERISTICS

The collection system was evaluated in a study on 100 stool samples for the detection of parasite structures, compared to the reference system consisting of the modified Ritchie technique. The concordance between the two methods was 94.6%, the sensitivity 87%, the specificity 100%, the predictive value of the positive result 96%, the predictive value of the negative result 100%.[4]

9 - LIMITATIONS OF THE METHOD

- Due to the intermittent shedding of the parasites, negative tests should be repeated from new specimens collected in different days.
- Fresh faeces specimens are essential for the examination of trophozoites.[3]
- Midi-System Ecosaf is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

10- PRECAUTIONS AND WARNINGS

- Midi-System Ecosf is a qualitative *in vitro* diagnostic, for professional use only; it must be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- The content of the tube is toxic, do not swallow. Avoid contact with skin and eyes. If accidental ingestion or spillage occurs, consult the Safety Data Sheet.
- All samples must be treated as a potential source of infection. Ensure you follow correct laboratory guidelines at all time. Disposable gloves should be worn for all parasitology investigations.
- Sterilize all biohazard waste before disposal. Dispose the unused vials with the fixative and the sterilized vials inoculated with samples in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- Notify Biolife Italiana Srl (complaint@biolifeitaliana.it) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostics.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

11 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store the product in the original package at 10-30°C. If properly stored, the product may be used up to the expiry date printed on the label; do not use beyond this date. Collection vials with Ecosaf are a "closed system" for single use and must not be opened except when in use.

12 - REFERENCES

1- Bench aids for the diagnosis of intestinal parasites, second edition. Geneve: World Health Organisation; 2019. https://www.who.int/publications/i/item/9789241515344
2- Tritten et al. - Comparison of two commercial Concentration Devices for the Recovery of intestinal Parasites in Stools with the Reference Method (Poster) - Annual Swiss Society for Microbiology Meeting, Basel, 30 Aug – 1 Sep, 2017.
3- Public Health England. (2017). Investigation of specimens other than blood for parasites. UK Standards for Microbiology Investigations. B 31 Issue 5.1. https://www.gov.uk/uk-standards-for-microbiology-investigations-smi-quality-andconsistency-in-clinical-laboratories.
4- Lucrecia Acosta Soto, Luis Navarro Martínez, Fernando Jorge Bornay Llinares. Área de Parasitología, Departamento de Agroquímica y Medio Ambiente. Universidad Miguel Hernández de Elche. 04/08/2011- Unpublished data.

MIDI-SYSTEM ECOSAF REF 25RPP8010

SDS rev 5
Regulation (EU) 2020/878

Substances that contribute to the classification: formaldehyde

Hazard classification and indication:

Carcinogenicity, category 1B	H350 May cause cancer.
Skin sensitization, category 1	H317 May cause an allergic skin reaction.

Labelling
Pictogram

Hazard statements:

H350	May cause cancer.
H317	May cause an allergic skin reaction.
	Restricted to professional users.

Precautionary statements:

P201	Obtain special instructions before use.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P362+P364	Take off contaminated clothing and wash it before reuse.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	This side up	
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	For single use only	Fragile

REVISION HISTORY

Version	Description of changes	Date
Revision 5	Updated layout and content	2023/06

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.