

INSTRUCTIONS FOR USE
MINI-SYSTEM ECOSAF
1 - INTENDED USE

In vitro diagnostic device. The Mini-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 Mini-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 WHO¹.

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 protozoa². 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 the detection of protozoa.

3A – MATERIAL PROVIDED - KIT CONTENT

Product	Type	REF	Pack
Mini-System Ecosaf	Kit	25RPP2000	150 tests
Kit content			
<ul style="list-style-type: none"> ▪ 13 mm collection vials with 4 mL Ecosaf fixative, two filters, glass beads and collection spoon ▪ Sedimentation tubes ▪ Sticks 			150 pcs 150 pcs 150 pcs



Note:

Midi System Ecosaf is also available (REF 25RPP8010), with 98 collection vials with 10 mL fixative

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

Product	Type	REF	Pack
Mini-System Caps	Perforated caps for sedimentation tubes	25RPP01	500 pcs
Mini-System Screw Caps	Screw caps for sedimentation tubes	25RPP04AB	500 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

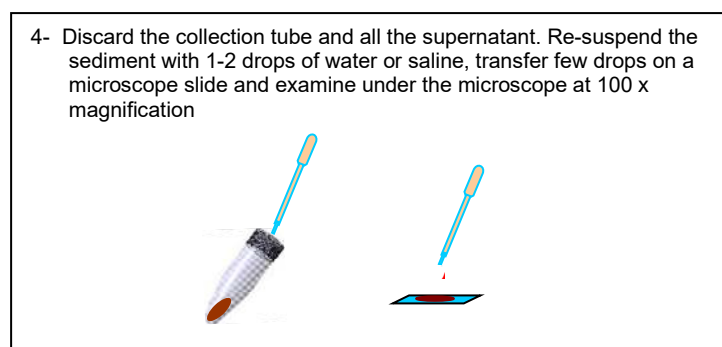
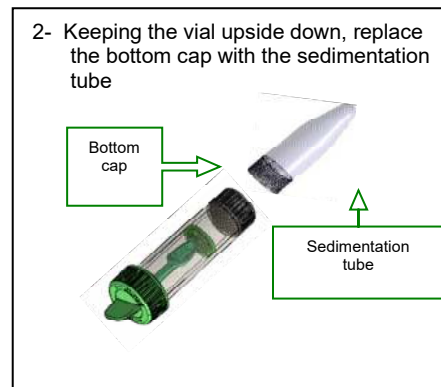
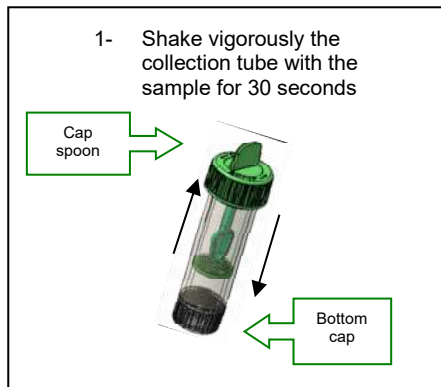
Mini-System Ecosaf is intended for the detection of parasites in faecal specimens.

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 1 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.





6 - TEST PROCEDURE



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. If needed, special caps can be ordered for the sedimentation tubes, useful for closing the tubes after centrifugation, to avoid spills and smell (REF 25RPP01). The cap is perforated so that a Pasteur pipette can be introduced to collect the sediment without the need of removing it. Screw caps are also available for permanent storage of positive samples (REF 25RPP04AB).

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

Mini-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

- Mini-System Ecosaf 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 products 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.

MINI-SYSTEM ECOSAF REF 25RPP2000

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 <i>In vitro</i> 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.

