



MINI-SYSTEM PARAGREEN

For the collection, fixation, filtration and concentration of intestinal Parasites with a Safe Fixative

INTENDED USE

The Mini-System is a disposable plastic device for the collection, fixation, filtration and concentration by sedimentation of intestinal Parasites from fecal specimens. The collection vial contains 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.

PRINCIPLE

The concentration procedure is a modification of the Formalin Ether (Ritchie method), as recommended by the WHO (1). The Formalin fixative is replaced by Paragreen, which is non-hazardous and provides the same preservation activity (2). 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. The filters are included in the collection vial which contains 4 ml of fixative and glass beads for facilitating the homogenous suspension of the specimen. After the fixation, a sedimentation tube is screwed to the bottom of the collection vial, forming a closed system, which is then centrifuged in regular 15 ml size tube holders. The addition of Ether or Ethyl Acetate, normally required to allow the filtration, is not required as the filtration happens during the centrifugation.

MATERIAL PROVIDED - KIT CONTENT

- 150 Collection vials containing 4 mL of Paragreen fixative, two filters, glass beads and a collection spoon under the cap.
- 150 Sedimentation tubes
- 150 Wooden sticks

The Paragreen fixative does not contain formalin, alcohol and heavy metals. It is classified as non-hazardous according to the CE Directive 1907/06.

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

The test kit must be stored at room temperature (10-30°C) for the duration of the shelf-life indicated on the label.

WARNING AND PRECAUTIONS

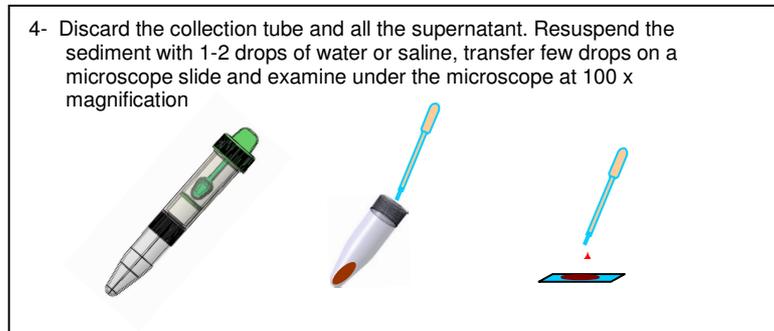
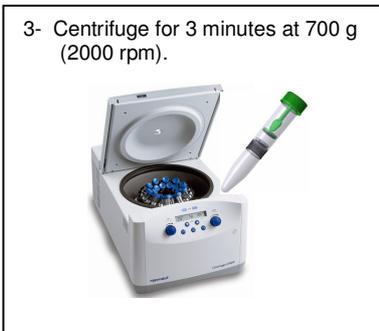
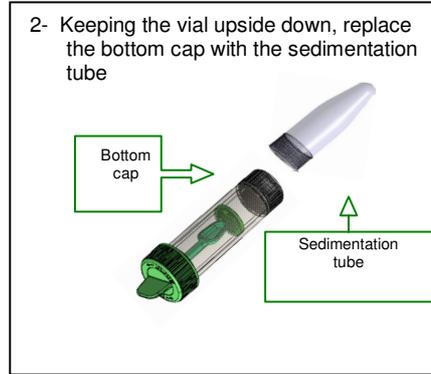
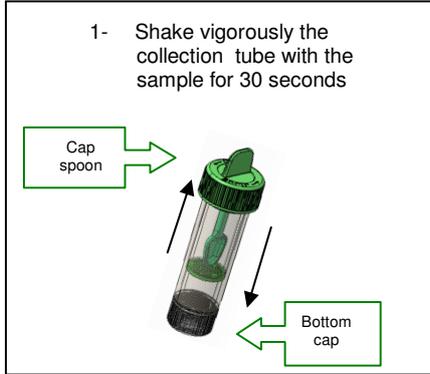
1. For in-vitro diagnostic and professional use only.
2. All patient samples should be treated as infectious material and protective gloves should be used.
3. Do not swallow. Avoid contact with skin and eyes. In case of contact flush with water. Keep out of children.
4. To ensure optimal recovery of parasites it is recommended to take three samples from the patient on successive days.
5. Do not use the test kit beyond expiration date.

SAMPLE COLLECTION

1. Avoid the use of antidiarrheal medication or laxative before collecting the sample.
2. Collect the fecal specimen in a clean dry recipient
3. Avoid contamination of the specimen with urine or water
4. 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 approx. 1 mL with a disposable pipette. Do not open the bottom cap of the tube in any moment. Mix to homogenize the diluted specimen.
5. Close the tube tightly and send it to the laboratory for processing.



PROCEDURE



One drop of Lugol's Iodine can be added on the slide to enhance the visibility of parasites. In this case make sure to eliminate all the supernatant, as the fixative can produce some precipitation in contact with iodine. 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. The cap is perforated so that a Pasteur pipette can be introduced to collect the sediment without the need of removing it.



LIMITATION OF THE PROCEDURE

Due to the intermittent shedding of the parasites, negative tests should be repeated from new specimens collected in different days.

BIBLIOGRAPHY

1. WHO – Bench aids for the diagnosis of intestinal parasites, Geneva 2012. <http://www.who.int/iris/handle/10665/37323>
2. Data on file.

IVD	In Vitro Diagnostic Medical Device	Storage temperature	LOT	Batch number	Manufacturer	Σ	150 units
i	Consult Instructions for use	Use by (month/year)	REF	Catalogue number	Do not reuse	Fragile, handle with care	

PRODUCT CODE

25RPP7000 Mini-System PARAGREEN 150 tests
 25RPP01 Mini-System Cap 500 units
 Also available as:
 25RPP2000 Mini-System ECOSAF 150 tests
 (low Formalin content fixative)

