

MINI-SYSTEM PARAGREEN / MIDI-SYSTEM PARAGREEN

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

INTENDED USE

The Mini-System and Midi-System Paragreen are disposable plastic devices 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 WHO (1). The Paragreen patented fixative is non-hazardous, according to the CE Directive 1907/06, does not contain formalin, alcohol and heavy metals and provides the same preservation activity as Formalin based fixatives (2). Samples diluted in Paragreen have been tested by rapid immune-chromatographic and immunofluorescence commercial assays, without showing any interference (2), allowing a confirmation test from the sediment after centrifugation.

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 (3). 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

MATERIAL PROVIDED - KIT CONTENT

The concentration devices are available in two formats:

Mini-System: 13 mm diameter tubes with 4 mL fixative, kits of 150 tests.

Midi-System: 30 mm diameter tubes with 10 mL fixative, kits of 98 tests.

Kits content: - 150/98 Collection vials with Paragreen fixative, two filters, glass beads and collection spoon.
- 150/98 Sedimentation tubes and Wooden sticks

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

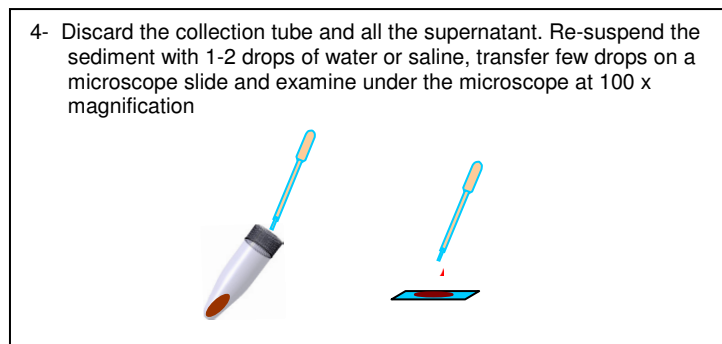
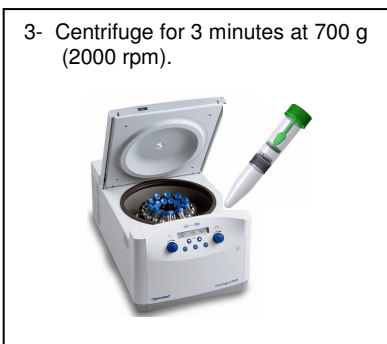
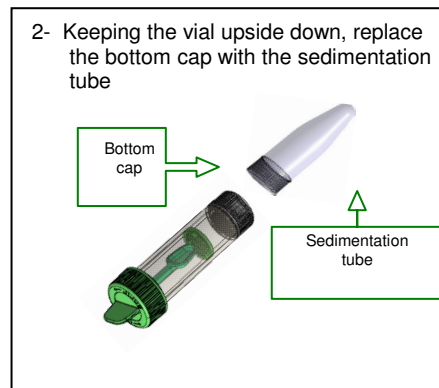
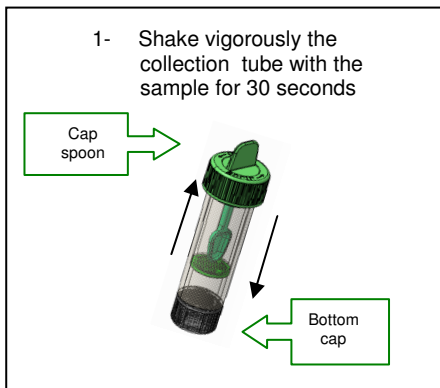
1. For in-vitro diagnostic and professional use only.
2. All patient samples should be treated as infectious material and protective gloves should be used.
3. Do not swallow. Avoid contact with skin and eyes. In case of contact flush with water. Keep out of children.
4. To ensure optimal recovery of 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 anti-diarrheal or laxative medications 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 (Mini-System) or 2-3 mL (Midi-System) 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. Screw caps are also available for permanent storage of positive samples.

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.
3. 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



PRODUCT CODES

CODE	PRODUCT	PACKAGING
25RPP7000	Mini-System Paragreen	150 tests
25RPP8000	Midi-System Paragreen	98 tests
25RPP01	Mini-System Caps	500 pcs
25RPP04AB	Mini-System Screw caps	500 pcs
25RPP05AB	Midi-System Screw caps	250 pcs

Mini-System Ecosaf 25RPP2000 and Midi-System Ecosaf 25RPP8010, containing a Modified Sodium Acetate Formalin fixative, with low formaldehyde content, are also available.



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