

MINI-SYSTEM FF / MIDI-SYSTEM FF

Parasite transport, preservation and concentration system with a safe fixative formalin, mercury and PVA-free

The Mini/Midi-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 WHO. The FF 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. Samples diluted in FF have been tested by rapid immune-chromatographic and immunofluorescence commercial assays, without showing any interference, 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. 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 FF fixative, two filters, glass beads and collection spoon.
- 150/98 Sedimentation tubes
- 150/98 Wooden sticks

MATERIAL REQUIRED BUT NOT PROVIDED

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

STORAGE, STABILITY AND DISPOSAL

The test kit must be stored at room temperature for the duration of the shelf-life indicated on the label. Dispose of using specific methods for the destruction of material with biological content. The content of the tube is toxic, consult the legislation on the disposal for toxic substances. If this is not possible, hire an authorized company for it. The container is made of 100% recyclable polypropylen.



WARNINGS 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. 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. 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.

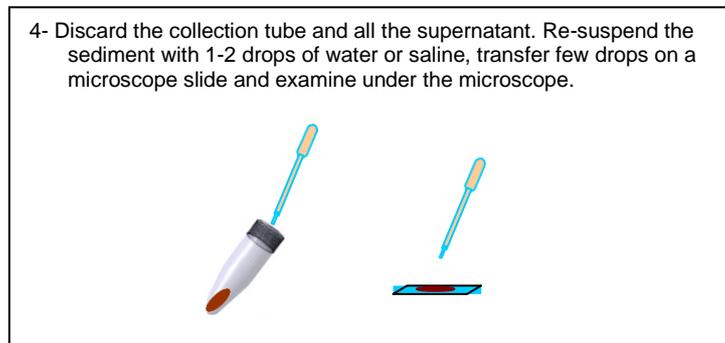
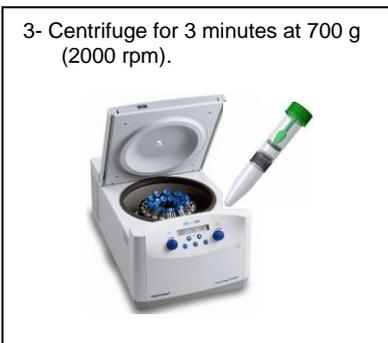
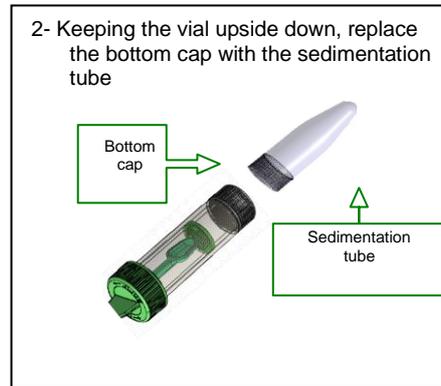
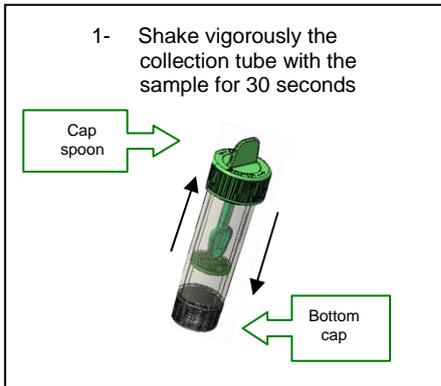
SAMPLE COLLECTION

1. Avoid the use of antidiarrheal 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 1-1,5ml (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 for processing.

NON-DOMESTIC USE

1/2

PROCEDURE



NOTE: 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. Examine the entire area of the coverslip in a systematic manner.

Ethyl acetate can be added if there is a need of a clearer sediment. But if the burden is low this can produce a false negative.

If needed, special caps can be ordered for the sedimentation tubes, useful for closing the tubes after centrifugation, to avoid spills and smell.

LIMITATION OF THE PROCEDURE

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

	Catalogue number		Contains sufficient for n tests
	Consult instructions for use		Manufacturer
	Use-by date		In vitro diagnostic medical device
	Temperature limitation		CE marking of conformity
	Do not use if the package is damaged		Batch code
	Do not re-use		