

MINI-SYSTEM Total-Fix® /MIDI-SYSTEM Total-Fix®

Parasite transport, preservation and concentration system with a Formalin, Mercury and PVA-Free Fixative

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 formalin-free 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 Total-Fix®(1) patented fixative does not contain formalin, alcohol and heavy metals and provides the same preservation activity as Formalin based fixatives.

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

The concentration systems are available in two different formats:

Mini-System: 13mm diameter tubes with 4ml of fixative (150test)

Midi-System: 30mm diameter tubes with 10ml of fixative (98test)

KITS COMPLEMENTS (OPTIONAL)

- Sedimentation cone
- Wooden sticks
- Pipettes
- Cone Tap/Easypick (Fig 1 and 2.)

MATERIAL REQUIRED BUT NOT PROVIDED

- Microscope Slides and Coverslips
- Centrifuge
- Lugol's Iodine
- 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 of toxic substances. If this is not possible, hire an authorized company for it. The container is made of 100% recyclable polypropylen.



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. Correct laboratory guidelines should be followed at all times.
3. Total Fix® is a hazardous solution, do not swallow. If accidental ingestion or spillage occurs, consult the safety data sheet or contact immediately the Toxicology center (contains methanol).
4. Avoid contact with skin and eyes. In case of contact flush with water. If irritation develops, contact a physician immediately.
5. Keep out of children.
6. To ensure optimal recovery of parasites it is recommended to take three samples from the patient on successive days.
7. 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. Transfer one spoonful of sample into the collection vial. (Do not open the bottom cap of the tube in any moment).
5. Mix to homogenize the diluted specimen.
6. Close the tube tightly, the sample is ready for processing.



NOT FOR DOMESTIC USE

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PROCEDURE

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

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

NOTE: If the sample has a very compact appearance, remove the cap from the tube and add 3 drops of surfactant (Tergitol or similar to 20%) to improve its homogenization. One drop of Lugol's Iodine can be added on the slide to enhance the visibility of parasites. Examine the entire area of the coverslip in a systematic manner.

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.

If you want to do some staining: prepare a slide and add a small amount of sediment, spread the sediment on the slide to prepare a fine smear. Allow to dry overnight at room temperature or for several hours (from 30 minutes to 60 minutes if the slide is thicker) in an incubator at 37 ° C. Do not use heaters, these can affect the organisms present in the sample.

NOTE: Since Total-Fix® does not contain PVA (which helps the smear to stick to the slide), albumin may be added to the slide before preparing the fecal smear. However, if the smear is completely dry before staining, it is not necessary to add albumin. Finally, proceed with the staining of choice. Trichrome staining is recommended, although iron hematoxylin may also be used.

LIMITATION OF THE PROCEDURE

- **The sample should remain in the medium at least for 30 minutes**
- Due to the intermittent shedding of the parasites, negative tests should be repeated from new specimens collected in different days.
- **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.

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

(1) Medical Chemical Corporation (MCC)