



Fecal Concentrator Kit II

INTENDED USE

Remel Fecal Concentrator Kit II is a parasite concentration kit recommended for use in qualitative procedures for the concentration of protozoan cysts, oocysts, and helminth eggs and larvae from fecal material.

SUMMARY AND EXPLANATION

The diagnosis of intestinal parasitic infections requires appropriate collection, transport, concentration, staining, and identification of parasites from fecal specimens.^{1,2} A wide variety of sedimentation and flotation concentration methods have been described. The most current sedimentation techniques involve filtering, centrifugation, and defatting steps. The Ritchie formalin-ether sedimentation technique has been modified to avoid safety issues associated with ether.^{3,4,5} The modified procedure replaces ether with other defatting agents, such as ethyl acetate or xylene substitutes.

PRINCIPLE

The Fecal Concentrator Kit II utilizes existing sedimentation methodology along with standardized components to achieve recovery of protozoan cysts, oocysts, and helminth eggs and larvae from preserved fecal specimens. The filtration assembly includes a filter cap screwed to a graduated 50 ml centrifuge tube. Pore diameters in the filter are 600 microns, allowing passage of cysts, eggs, and larvae while retaining microscopic fecal matter and debris on top.⁶ The surfactant, 10% Triton™ X-100, reduces surface tension in order to enhance filtration and frees additional helminth eggs that may be trapped in fecal debris or mucus. Ethyl acetate or xylene substitutes dissolve any fat present in the specimen and aid in the separation of fecal debris from the concentrated sediment containing parasites.

REAGENTS

Triton™ X-100 Reagent, 10% (Alkylaryl Polyether Alcohol)

PRECAUTIONS

This product is for *In Vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and test materials after use. Directions should be read and followed carefully. Refer to Material Safety Data Sheet for additional information.

STORAGE

This product is ready for use and no further preparation is necessary. Store product in its original container at room temperature until used.

PRODUCT DETERIORATION

This product should not be used if (1) the filtration assembly shows evidence of breakage or filter pores appear blocked, (2) the expiration date has passed or contamination is evident with the Triton™ X-100 reagent, or (3) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, AND TRANSPORT

Specimens should be collected and handled following recommended guidelines.^{1,7,8} Specimens should be placed in preservative if examination cannot occur within these time frames: (a) liquid or soft specimens within 30 minutes of passage; (b) semiformed specimens within one hour of passage, and (c) formed specimens within 24 hours of passage. The fixative should be mixed with the specimen using the ratio of three parts fixative to one part stool. Allow the mixture to stand no less than 30 minutes prior to processing. Refer to the instruction sheet provided with the preservative collection system when applicable. Specimens preserved in formalin, SAF, MIF, or other single vial collection systems, are suitable for use with this concentration system.

MATERIALS SUPPLIED

1. Filter Cap/Centrifuge Tube Assembly (50 units)
2. Centrifuge Tube Caps (50)
3. Triton™ X-100 Reagent, 10% (Alkylaryl Polyether Alcohol) (1 x 15 ml)

MATERIALS REQUIRED BUT NOT SUPPLIED

- (1) Fecal specimen preservative/fixative, (2) 0.85% Saline, (3) Centrifuge, (4) Ethyl acetate or Xylene-S (R40133), (5) Applicator sticks, plain and cotton-tipped, (6) Disposable pipettes, (7) 10% Formalin, (8) Glass microscope slides, coverslips (No. 1 thickness), and (9) Microscope with calibrated ocular micrometer.

PROCEDURE⁸

Every fecal specimen represents a potential source of infectious material and should be handled accordingly.

1. If a fresh specimen is received, ½ teaspoon of the specimen should be mixed well with 10 ml of fixative and allowed to fix no less than 30 minutes.
2. Specimens received in preservative or fixative should be thoroughly mixed prior to processing to break up any lumps.
3. Add 5 to 10 drops of 10% Triton™ X-100 to the specimen/preservative mixture, recap the vial, and shake vigorously. This will break down fecal debris and mucus in the specimen.
4. Examine a Filter Cap/Centrifuge Tube Assembly ensuring that the 50 ml centrifuge tube is securely attached to the filter cap.
5. Remove the cap from the specimen/preservative vial and insert the filtration assembly into the open end of the vial. Make sure the filtration assembly has formed a tight seal with the specimen vial.
6. Invert the specimen vial/filtration assembly to allow filtration into the centrifuge tube. The centrifuge tube may be gently shaken or tapped against a counter top in order to encourage filtration.
 - a. Usually, 8 ml of the specimen/fixative mixture prepared in step 1 will provide sufficient sediment for examination.
 - b. If the specimen was received in a preservative or fixative vial, filtering 3-4 ml should be sufficient unless there is very little stool in the vial.
7. Gently unscrew the centrifuge tube from the filter cap/specimen vial. Discard the filter cap/specimen vial.
8. Add 0.85% saline to near the top of the tube and seal with the cap provided in the kit.
9. Centrifuge for 10 minutes at 500 x g. The amount of sediment obtained should be approximately 0.5 to 1.0 ml.
10. Decant the supernatant. Repeat steps 8-10 if the supernatant fluid is cloudy or dark.
11. Resuspend the sediment in the tube with 10% formalin. Fill the tube ⅔ full only.
12. Allow the tube to stand for at least 10 minutes before adding the defatting agent.
13. Add 4-5 ml of a defatting agent (e.g., Xylene-S or ethyl acetate).
14. Cap the tube and shake vigorously for 30 seconds. Direct the capped end of the tube away from your face.
15. Wait 15-30 seconds then carefully loosen the cap to release pressure.
16. Retighten the cap and centrifuge for 10 minutes at 500 x g. Four distinct layers should form from the top down:
 - a. Defatting agent
 - b. Plug of fecal debris and fat
 - c. Formalin
 - d. Fecal sediment

17. Hold the tube vertically and ring the plug of fecal debris with an applicator stick. Decant all of the supernatant fluid. (The supernatant fluid may also be aspirated off with a disposable pipette while holding the tube in an upright position.)
18. Decant the layers of defatting agent, fecal debris and fat, and discolored formalin.
19. Continue to hold the tube in the decanting position. Using a cotton-tipped swab remove all excess fluid from the inside wall of the tube.
20. Add one to two drops of saline to the sediment and mix.
21. Proceed with examination according to established laboratory procedures.

INTERPRETATION OF THE TEST

Consult appropriate references for proper examination of sediment and identification of parasites.^{1,8}

QUALITY CONTROL

All lot numbers of Fecal Concentrator Kit II have been tested and have been found to be acceptable. Quality control should be performed in accordance with established laboratory procedures. Consult appropriate references for recommended guidelines.^{1,8} If aberrant quality control results are noted, patient results should not be reported.

LIMITATIONS

1. The Fecal Concentrator Kit II is compatible with most fecal transport vials. Evaluate appropriately and with caution prior to implementation of procedure.
2. Ideally, 0.5-1 ml of fecal sediment should remain for adequate recovery and examination of parasites. Ineffective concentration may result from too much or too little sediment being obtained.^{1,8}
3. Specimens preserved in PVA may be used, however precipitates may form during the defatting step and certain organisms may not concentrate well. Morphology may also be distorted, especially with protozoa.^{1,8} Consult appropriate references for proper concentration technique when necessary.
4. Substances and medications, such as barium, mineral oil, bismuth, antibiotics, antimalarials, and nonabsorbable anti-diarrheal preparations, interfere with the detection of intestinal protozoa. Parasites may be undetectable for one to several weeks after administration of any of these substances. Barium and antibiotics that alter intestinal flora are the most common of these substances. Specimen collection should be delayed for seven days after administration.^{1,8}
5. Some microbiologists prefer to substitute 10% formalin for 0.85% saline throughout the procedure. Tap water may also be substituted. However, if tap water is added to fresh stool specimens, the cyst form of *Blastocystis hominis* may rupture and free-living contaminants may be introduced.^{1,8}

6. Excess defatting agent in the fecal sediment will cause bubbles to form in the smear prepared for examination, which may obscure objects of interest.^{1,8}
7. Recommended centrifugation time and speed must be adhered to for adequate recovery of parasites. *Cryptosporidium* oocysts and microsporidial spores may be missed if proper centrifugation is not performed.¹




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PACKAGING

REF R21911, Fecal Concentrator Kit II50 Units/Kit

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

Manufactured for Remel Inc.
Triton™ X-100 is a trademark of Union Carbide.

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