

Mini Parasep Stain Kit

Faecal Parasite Concentrator

For *in vitro* diagnostic use

INTENDED USE

Mini Parasep is a closed system for a clean and efficient concentration of intestinal parasites from human faecal probes. The simple 4 step kit provides a fast and simple method to concentrate helminth ova as well as protozoan cysts/oocysts.

SUMMARY AND EXPLANATION

The microscopic examination of stool specimen enables a diagnosis of intestinal parasitic infection. Faecal concentration has become a routine procedure as it allows the detection of small numbers of organisms that may be missed using other methods. Sedimentation is designed to separate protozoan organisms and helminth eggs and larvae from faecal debris by centrifugation.

PRINCIPLE OF THE TEST

The faecal sample is taken with the spoon on the filter and mixed into the tube with the solutions. After a short mixing and centrifugation step, Mini Parasep is reopened and the sediment is ready for microscopy.

It is a single use, disposable device offering significant time saving as well as prevention against cross-contamination. The unique tangential hexagonal filter provides a fast and reliable filtration of the sample, leading to a clean background.

REAGENTS

The Mini Parasep Stain Kit which includes Mini Parasep Formalin and Iodine stain solution. The kit provides all material and solutions needed for 40 tests. 3 other kits of Mini Parasep are also available: Mini Parasep Formalin (900000), Mini Parasep SAF (901000) or Mini Parasep SafeFix™ (902500) which fixative solution is environmentally safe.

Materials are supplied ready to use.

Composition

Mini Parasep consists of 2 parts: the solution tube (mixing chamber) and the filter with attached conical tube.

In each kit, 3 reagents are provided:

A 10% formalin solution with Triton X already filled in the 40 mixing chambers (1.9 mL).

One bottle containing 40 mL of ethyl acetate for emulsification of the sample.

One bottle containing 20 mL of Iodine Potassium Iodide (Lugol solution) and Eosin for stain.

Parasep products:

Mini Parasep Stain Kit

Mini Parasep Formalin solution

Mini Parasep Ethyl Acetate

Mini Parasep Iodine solution

PRECAUTIONS

For professional use only. For *in vitro* diagnostic use only

- Formalin

H302 Harmful if swallowed

H317 May cause an allergic skin reaction.

H332 Harmful if inhaled.

H341 Suspected of causing genetic defects.

H350 May cause cancer

P280 Wear protective gloves/protective clothing/eye protection/ face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P308+P313 IF exposed or concerned: Get medical advice/ attention.
- Ethyl acetate

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P261 Avoid breathing vapour/spray.

P303+361+353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Iodine Potassium Iodide and Eosin.

No hazard data established. May cause mild irritation and brown staining when exposed to skin, may cause nose and throat irritation when exposed for a longer time. Use protective gloves and eye protection. Store in a cool, dry, well ventilated area. Keep out of bright light.
- All patient samples should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.

STABILITY AND STORAGE

The kits are stable until the expiry date stated on the packing. The kits should be stored at 15-25°C.

The liquids must be discarded according to the correct protocol.

SPECIMEN

Use fresh or preserved stool. Stool specimens could be preserved in formalin for up to one year.

MATERIALS REQUIRED BUT NOT PROVIDED

Centrifuge with 15 mL bucket holder

Pipette for 0.8 mL

Microscope

Slides/coverslips

TEST PROTOCOL

Please adhere to the following guidelines when handling Mini Parasep. To avoid cross contamination, the Mini Parasep device should remain closed at all times except when introducing the sample or when retrieving the final concentrated sample for examination.

1. Sample Preparation

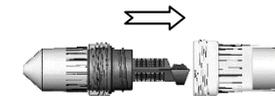
Unscrew lid.

Add 0.8 mL of ethyl acetate and 0.5 mL of the stain solution to the mixing chamber.



2. Emulsification and Filtration

Introduce in the mixing chamber a pea sized (0.5 g) faecal sample using the spoon in the end of the Mini Parasep filter thimble. More is not necessary, it only leads to a darker background.



Seal Mini Parasep by screwing in the filter thimble / sedimentation cone unit.

Vortex to emulsify the sample with the sedimentation cone pointing upwards.



3. Centrifugation



Invert Mini Parasep and centrifuge at 1,000 g for one minute or 500 g for five minutes. Mini Parasep fits all 15 mL centrifuge buckets.

To calculate the required rpm for any centrifuge:

$$\text{RPM} = \sqrt{\frac{g}{1.12r}} \times 1000$$

rpm: rotor speed in revs/min.

g: centrifugal force (for Mini Parasep : 1.000 x g or 500

x g) r: radius, horizontal distance between

sedimentation cone tip and spindle centre, measured

in mm.

The sediment should be extracted within 1 hour after centrifugation or it could revert to a mixture.

4. Sediment recovery and examination

Open very slowly to avoid aerosol release.



Sediment
to analyze

Unscrew and discard the mixing chamber and filter thimble. Loosen the fatty plug, and pour off all the liquid above the sediment. Transfer the sediment for examination.

REFERENCES

1. Garcia, LS., Bruckner, DA., Diagnostic Medical Parasitology, Elsevier, N.Y. 1988
2. Perry, JL, *et al.*, *Parasite detection efficiencies of five stool concentration systems*, J.Clin. Micro., 28:1094, 1990

	= CE marking (European directive 98/79/CE on in vitro diagnostic medical devices)
	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Contains sufficient for <n> tests
	= <i>In vitro</i> diagnostic medical device
	= Temperature limitation
	= Consult instructions for use
	= European Authorised Representative

USEFUL HINTS

Sometimes, the addition of 3 drops of NaCl solution could be useful, especially when the sediment is very dark. That would simplify microscopy.

PERFORMANCE DATA

A comparative study was performed between the Paraprep system and the modified Ridley-Allen concentration method which is an open technique.

One hundred faecal samples, both fresh and preserved, were examined in duplicate by both techniques. They were containing a wide range of ova, larvae, cysts and oocysts as follows:

- 26 faecal samples were contaminated with ova; 21 of which contained only 1 species of helminth and 5 contained 2 or 3 species of helminths.
- 24 faecal samples were protozoan cysts or oocysts positive; 15 of which contained only one species of protozoa and 9 contained 2 or more protozoa.
- 50 faecal samples were negative from ova, cysts or larvae.

A comparable recovery of parasites was noted in both methods.

