Mini Parasep

Faecal Parasite Concentrator

For *in vitro* diagnostic use

CE

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

Mini Parasep is available in 3 different kits providing all material and solutions needed for 40 tests: Mini Parasep Formalin (900000), Mini Parasep SAF (901000) or Mini Parasep Gold PLUS (902500) which fixative solution is environmentally safe. Another kit of Mini Parasep is also available: Mini Parasep Stain Kit (903000) which includes Mini Parasep Formalin and Iodine stain solution. 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, 2 reagents are provided:

Already filled in the 40 mixing chambers (2.4 mL). In Mini Parasep SAF, it is a SAF (Sodium acetate-Acetic acid-Formalin) solution with Triton X.

One bottle containing 40mL of Ethyl Acetate for emulsification of the sample.

Parasep Products:

Mini Parasep SAF Kit

Mini Parasep SAF solution
Mini Parasep Ethyl Acetate

PRECAUTIONS

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

1. SAF
   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.

2. 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.

3. 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

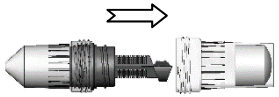
Please adhere to the following guidelines when handling Mini Parasep. To avoid cross contamination, the Mini Parasep device should remain closed at all times except when introducing the sample or when retrieving the final concentrated sample for examination.

1. Sample Preparation

Unscrew lid.

Add 0.8 mL of ethyl acetate 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.

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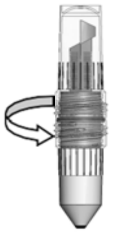
3. Centrifugation



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:

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

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.

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.

One drop of Lugol can be added to identify protozoans when necessary.

Sediment
to analyze

USEFUL HINTS

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

To identify protozoan cysts and to improve the contrast of helminth eggs, it is useful to compare unstained and Lugol-stained samples. For this purpose, Mini Parasep Stain Kit (reference 903000) and Mini Parasep SAF Kit (reference 901000) can be used on the same stool sample.

If desirable, ethyl acetate can be added after the introduction of the faecal sample. For this purpose, reopen the filled ƎĜlĜ ǹ"ǐ"ȡ±Å (remove conus). Then, add the amount of ethyl acetate through the filter and close the system again.

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.

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

CALCULATION OF NECESSARY RPM

The RPM of the used centrifuge can be obtained from the following table, simply by measuring the distance between spindle centre of the rotor and the sedimentation conus end of the Paraprep device. All data are for 1,000 x g, the numbers in the right column represent the rpm for the centrifuge used:

DISTANCE IN MM	RPM
140	2.500
150	2.400
160	2.400
170	2.300
180	2.200
190	2.200
200	2.100
210	2.100
220	2.000
230	2.000
240	1.900
250	1.900

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