

Mini Parasep SafEFix™

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

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 SafEFix™ (902500) which fixative solution is environmentally safe. Another kit of Mini Parasep is also available: Mini Parasep Stain Kit (903000) which includes Paraprep 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, 1 reagent is provided: Already filled in the 40 mixing chambers (2.4 mL) is a formalin-free conservation solution.

Parasep Products:

Mini Parasep SafEFix™ Kit
Mini Parasep SafEFix™ solution

PRECAUTIONS

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

1. This is a formalin free conversation solution, classified as non-hazardous. H317 May cause allergic reactions
 P302+P352 If on skin: wash with plenty of soap and water
 P305+P351+P338 If in eyes: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P301+P330+P331 If swallowed: rinse mouth with water. Do not induce vomiting.
 P308+P313 General exposure: seek medical attention..
2. 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 15-35°C.

The liquids must be discarded according to the correct protocol.

SPECIMEN

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

MATERIALS REQUIRED BUT NOT PROVIDED

Centrifuge with 15 mL bucket holder
 Pipette for 3.2 mL
 Microscope
 Slides/coverlips
 Standard saline solution

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



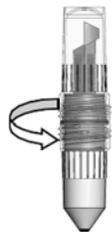
Open the Mini Parasep SafEFix™ mixing tube, take a sample of faeces with the built-in spatula (sample should not exceed 0.5 g or a pea size). Vortex/mix in order to break down the sample.

2. Filtration



Replace lid with the filter and the attached conical tube by screwing the filter into the mixing tube.

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.

4. Sediment recovery and examination



Sediment
to analyze

Carefully unscrew the flat tube and filter, discard the supernatant, add 3.2 mL standard saline solution to the concentrate.

Reclose the flat tube/filter, resuspend and centrifuge again. The resulting concentrate is ready for microscopy. In order to ease the handling of the sample, 3-4 drops of standard saline solution can be added to the concentrate.

USEFUL HINTS

To identify protozoan cysts and to improve the contrast of helminth eggs, it is useful to compare unstained and Lugol-stained samples.

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



= 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



= *In vitro* diagnostic medical device



= Temperature limitation



= Consult instructions for use



= European Authorised Representative

