

## Package insert MIF-Method

### Enrichment system for the Parasitology

For „In Vitro“ Diagnostic Use Only

Instructions for use 

#### **Name and purpose of use of the enrichment system**

Optimised system for the concentration of parasitic elements in stool samples

The described system is based on the *MIFC- or Bailenger-Method* (sedimentation principle). The concept meets the highest standards in diagnostics and is recommended by scientists and clinical laboratories.

#### **Warnings and Precautions**

Before the usage of the enrichment system, please read carefully and completely these instructions.

The enrichment system is designed for the mechanical enrichment of parasites from stool samples. Stool samples have always to be handled as infectious material. (Protecting wears , gloves).

The provided MIF-solution contains Formaldehyde and Thimerosal. The delituted Formaldehyde solution is irritant. Formaldehyde is suspected to create cancer. In case of contact with skin immediately flush vigorously with water. Thimerosal is a mercury containing organic compound. Thimerosal is very toxic and may not get into the environment.

#### **Storage and expiry date**

Filled and empty vials are to be kept at room temperature until the expiry date on the packaging. Do not the use the kit the after the expiry date printed on the packaging of the kit.

#### **Compounds of the enrichment system:**

1. filled sample vials MIF-solution (Thimerosal 0.02%, Formaldehyde 2.3%, Glycerol 1.0% ), cap with spoon.
2. Filter vials for centrifugation with inserted filter

## Samples

Stool samples fresh and untreated. Stool samples are usually delivered to the laboratory in a commercial available sample vial (plastic) and are taken from these vials into the sample tube of the enrichment system.

## Sample preparation

For optimal results give one level spoon full into the sample tube filled with 3.3 ml MIF-solution. See figure 1, page 4.

Procedure of the concentration process

(parallel tests for one sample enhance the exactness of the results)

- Loading of the sample tube (containing 3.3 ml of Liquid A)
- The closed sample tube has to be shaken to remove the sample from the sample collector (spoon) (using a shaker, *Vortex*)
- The sample collector and the screw cap are removed from the sample tube
- Addition of Liquid B (1.25 ml ethyl acetate) to the sample tube, **Pic.3** (0.2 ml of Liquid C, *Lugol*, may be added for staining, see below)
- The filter tube is connected to the sample tube and the whole system is turned upside down
- The sample is mixed thoroughly (10-30 seconds with a shaker, *Vortex*, depending on the sample), **Pic.4** (finely the sample has to be well suspended in the liquid phase)
- Active filtration by hand until the liquid phase is transferred into the sample tube), **Pic.5**
- Short pause of 1-2 minutes (a break of several hours leads to phase separation)
- The filtered suspension is centrifuged for 5-10 minutes at 1500-2000 g, **Pic.6**
- After removal of the sample tube and the filter the liquid phase is poured out. The sediment contains the parasitic elements (protozoa, helminths, i.e. eggs and larvae), **Pic.7**
- Possible staining of the sediment with a few drops of Liquid C, *Lugol*, for better recovering of the parasitic elements (Liquid C may also be added directly to the prepared slide)
- If Liquid C is not used, it can be useful to add a few drops of Liquid A or physiologic saline solution and mix it with the concentrate to make the transformation to the slide easier
- A part of the sediment is transferred to the slide, **Pic.7**, the sample has to be examined several times to enhance the exactness of the results, at least two times!
- Recommended magnification: x100 for helminths (eggs and larvae)  
x400-1000 for protozoa  
(fungi, i.e. yeast, are an indicator for a good concentration process)

Literatur:

Allan L. Truant,\* Stephen H. Elliott, Michael T. Kelly, and Jerome H Smith. 1981. Comparison of Formalin-Ethyl Ether Sedimentation, Formalin-Ethyl Acetate Sedimentation, and Zinc Sulfate Flotation Techniques for Detection of Intestinal Parasites. J. Clin. Microbiol. Vol. 13, No. 5: 882-884

Janitschke, K. et al. 1986. Empfehlungen zur Laboratoriumsdiagnostik der Amöbiasis, Giardiasis, Kryptosporidiose und weiterer Kokzidiosen (herausgegeben von der

Kommission des Bundesgesundheitsamtes "Laboratoriumsdiagnostik Intestinaler und Pulmonaler Parasitosen"). Lab. med. 10: 118-123

Mehlhorn, H., Düwel, D., Raether, W. 1986. Diagnose und Therapie der Parasiten von Haus-, Nutz- und Heimtieren. Gustav Fischer Verlag, Stuttgart, New York, 1.1 Methoden

Melvin, D. and M. M. Brooke. 1974. Laboratory procedures for the diagnosis of intestinal parasites. U.S. Department of Health, Education and Welfare, publication no. (CDC) 75-8282. Center for Disease Control, Atlanta, GA.

### **Quality control**

Each lab should define its own quality control system. The application of an enrichment system is recommended in ring-trials.

### **Note for device combination:**

In the centrifuging step fitting accessories for the centrifuge have to be present. For the enrichment both fixed angles rotors and swinging rotors are suitable. In case of swinging rotors free swinging should be possible.

### **Notes for secure disposing:**

For disposing the enrichment system the regulations of the lab for disposing polluted waste should be observed.

### **Procedure for decontamination**

In case of unintended flow out of reagents the liquid should be wiped up and flushed vigorously with water.

### **General notes**

- This diagnostic tool and all its containing compound may only be used for scientific purposes or if notified only for in vitro diagnostic.
- The supplied MIF-solution contains formaldehyde and thimerosal. Please observe appropriate safety measures. Avoid contact with skin!
- Never pipette with your mouth.
- During the test procedure wear protecting clothes, ey-protection and disposable gloves.
- Do not eat, drink or smoke in the laboratory.
- All samples should be handled as infectious material.
- Do not use or mix reagents from different lots.
- For the quality control the guidelines for medical laboratories have to be observed.
- The characteristic data of the kit as incubation times, incubation temperature and pipetting volumes have been defined internally by the manufacturer. Changes not confirmed by the manufacturer may influence the results. The manufacturer can therefore not be held reliable for any resulting damage from this.
- In case of claims to guaranty the rejected product has to be resend to the manufacturer together with a written explanation within 14 days.
- Do not the use the kit the after the expiry date printed on the packaging of the kit.

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# Instructions for MIFC or Bailenger Method

## Optimized faecal parasite concentration system

### security

- sterile sample after loading, no cooling is required
- small amounts of organic solvents

### comfort

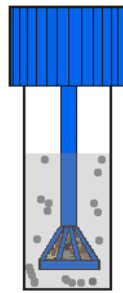
- easy to handle
- no annoyance due to the closed system

### quality

- standardization (defined pore size) and possible quality control
- optimized concentration of the parasitic elements



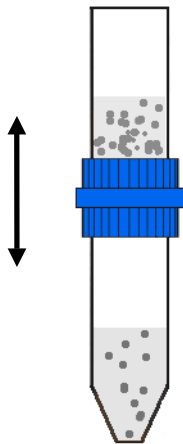
Pic.1 Sampling



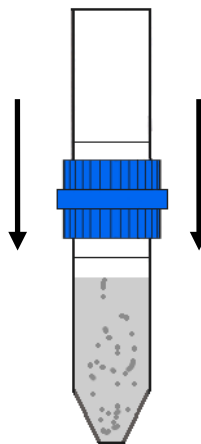
Pic.2 Loading the sample tube



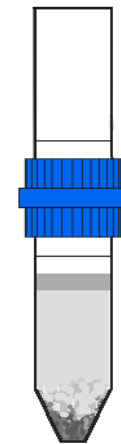
Pic.3 Addition of Liquid B



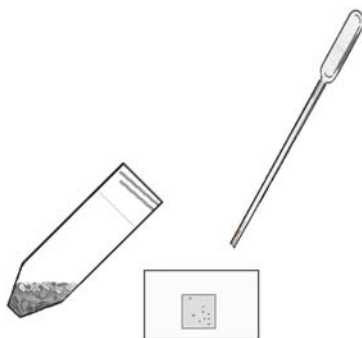
Pic.4 Mixing



Pic.5 Filtration



Pic.6 Phase separation



Pic.7 Microscopic diagnostics

**Liquid A:** Conservation medium !  
**Attention irritant !** Do not breath vapours, wash contaminations vigorously with water.

**Liquid B:** Ethyl acetate!  
**Attention inflammable!** (Keep away from open flames !)

**Liquid C:** Lugol

