Epitope Diagnostics, Inc.

Fecal Ova/Parasite Concentration Kit

An Advanced & Clean Method for Processing Fecal Sample for the Aid of Ova/Parasite Detection

REF **FPC200** Σ 50 2–30°C EU: IVD CE

INTENDED USE
This device is produced for the processing of fecal sample in the aid of concentrating fecal Ova/parasite for microscopic examination. Each kit contains 50 sets of the device for processing 50 fecal samples.

BACKGROUND
Fecal sample Ova/parasite concentration is a routine procedure for improving the detection rate or reducing the false negative results. Traditionally, the concentration procedure used in laboratories requires the use of either an ether or an ethyl acetate as a lipid removing agent and formalin as a fixative. The process involves the use of either expensive brass sieves or the use of tea strainers as the filter element. Wherein, tea strainers have a very open pore structure of at least 600 micron and due to the shape of the strainer, it is a non-linear pore size. The fecal matter is filtered directly through these meshes in a dead stop manner, and hence, there is the tendency for occlusion of the filter. There is also a formation of a secondary filter layer, which retains eggs and allows the extrusion of particles (particularly fibers) into the sediment. The net result is a reduction in egg yield and in sample clarity.

This device is produced for easy, effective and clean processing fecal samples with concentration of Ova/parasite for microscopic examination.

DEVICES & REAGENTS:
All devices and reagents in this kit can be stored at room temperature.

1. **Sample Collection Lid (GFC-110):** 50 units/kit
2. **Sample Mixing Tube (GFC-120):** 50 units/kit
3. **Filter (GFC-130):** 50 units/kit
4. **Sedimentation Tube (GFC-140):** 50 units/kit
5. **Buffer A (PS-010):** This buffer is pre-added into each Sample Mixing Tube**.** It contains less than 3% formalin.
6. **Buffer B (PS-020):** 2 bottles of 25 mL of this reagent are provided in this kit. This reagent contains ethyl acetate.

SAFETY PRECAUTIONS
The reagents must be used in professional laboratory and is for in vitro diagnostic use only. Wear gloves while performing this assay and handle these reagents as if they are hazardous. Both buffers may cause severe irritation on contact with skin. Repeated exposure may cause skin dryness or cracking. Vapor may cause drowsiness and dizziness. Do not get in eyes, on skin, or on clothing. Never transfer any reagents with mouth. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED
1. Precision single channel pipettes capable of delivering 50 µL, 200 µL, and 1000 µL, etc.
2. Repeating dispenser suitable for delivering 1 mL.
3. Disposable pipette tips suitable for above volume dispensing.
4. Disposable glass slides.
5. Lugol solution (Sigma, Cat# L-6146)

SPECIMEN COLLECTION
Using sample Collection Lid (GFC-110) collect a full lid of stool sample. No special preparation of individual is necessary prior to specimen collection. Collected stool sample should be immediately put into the Sample Mixing Tube with Buffer A. This sample is stable at room temperature up to 5 days for fecal Ova/parasite detection.

SAMPLE PROCESS PROCEDURE

1. Patient Sample Preparation
(1) Patient sample need to be mixed well using a vortex mixer or just hand mix.

2. Ova/Parasite Concentration Procedure
(1) Add 1 mL of Buffer B into each Sample Mixing Tube and mixing 10 seconds with a Vortex mixer
(2) Unscrew and discharge the Sample Collection Lid from the top of Sample Mixing Tube.
(3) Screw the Filter/Sedimentation Tube onto the top of Sample Mixing Tube.
(4) Flip over the position of Sample Mixing Tube vs. the Sedimentation Tube and vortex mixing the sample for 10 seconds until the buffer in Sample Mixing Tube gets into the Sedimentation Tube.
(5) Centrifuge the tubes at 300 – 350 g for 5 – 10 minutes.
(6) Remove and discharge the Filter/Sample Mixing Tube from the top of Sedimentation Tube.
(7) Carefully discharge the supernatant without disturbing the pellet on the bottom of the Sedimentation Tube.
(8) Gently mix the pellet and transfer a drop onto a glass slide for microscopic detection of Ova/parasite.
(9) As an alternative to step (8), add 50 µL of Lugol solution to the pellet for color development before being checked under a microscope.

PROCEDURAL NOTES
1. Careful technique is necessary to ensure reproducibility and maximum detective sensitivity.
2. All reagents should be mix gently and thoroughly prior use. Avoid foaming.

WARRANTY
This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Diagnostics, Inc. DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Diagnostics, Inc. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state.

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