PRINCIPLE

Many methods have been developed for the concentration of cysts and eggs of parasites found in feces: brine flotation, zinc sulfate flotation, and formalin/ether sedimentation. Price modified the formalin/ether procedure for sedimentation of MIF-fixed fecal specimens. Because of the danger of using ether in the laboratory environment, ethyl acetate was substituted for ether.

The CONSED Concentration Reagent was developed for concentrating the parasites and eggs in fecal specimens by sedimentation. This system was designed especially for use on specimens fixed in Formalin, SAF, and PROTO-FIX®.

In a series of studies, the effectiveness of four different fixatives (10% Formalin, SAF, MIF, and PROTO-FIX) were tested, comparing the formalin-ethyl acetate procedure to the CONSED sedimentation procedure. Juvenile nematodes did not concentrate well using 10% Formalin and SAF, and the procedures using formalin-ethyl acetate with Formalin and SAF unsatisfactorily concentrated protozoan trophozoites (no trophozoites were found). On average, when the CONSED concentration procedure was used, the recovery rate of all stages and all forms of eggs and parasites was higher than the formalin-ethyl acetate method.

SPECIMEN COLLECTION AND PREPARATION

1. Specimens preserved in 5% or 10% Buffered Formalin, SAF, MIF Fixative, PROTO-FIX or fresh samples may be processed with CONSED. The specimen must be fixed for a minimum of 60 minutes to assure adequate fixation of the sample. The specimen should be stored at room temperature.

2. An appropriate clinical patient sample, collected, preserved/fixed, and transported properly is important for the recovery of helminth eggs and larvae (juvenile nematodes) and protozoan trophozoites and cysts. Refer to the Directions For Use supplied with O&P Collection/Transport Sets for collection and transportation methods.

3. Always mix the sample well.

4. The appropriate volume of sample is 2 to 3 grams of fecal matter in 13 to 15 ml of fixative.

FOR IN VITRO DIGNOSTIC USE ONLY

REAGENTS AND MATERIALS

1. Provided
   a. CONSED Concentration Reagent

2. Not Provided
   a. Pasteur pipettes
   b. Centrifuge with a free-swinging head
   c. Microscope/ Microscope slides and coverslips
   d. Cotton-tipped applicators
   e. Reagents and materials for staining and concentration

3. Recommended additional reagents and materials
   a. CELL-BOND™ microscope slides (#0003257)
   b. CONSED, ethyl acetate (#0003344)
   c. PRS™ (#0004044) or PARA-PRO® fc50 (#0004060) Concentration System

4. Storage: Store at room temperature (15º-30º C). Do not heat or expose to direct sunlight.

5. Stability: CONSED is stable to the stated expiration date when stored at the required temperature.

CALIBRATION

N/A

QUALITY CONTROL

Any product showing cloudiness, turbidity, precipitation or coloration should be discarded. The use of a positive parasite control slide for permanent staining procedures is recommended.

PROCEDURE

CONCENTRATION PROCEDURE

1. Place a PRS Concentration Funnel (or other suitable filtration apparatus) into a 15 ml polypropylene centrifuge tube. Remix the specimen thoroughly and pour the sample through the funnel into the tube. NOTE: A filtered specimen volume of 2 ml will be used for this concentration procedure; however, the entire fixed specimen can be filtered through the funnel with the balance of the filtered specimen poured back into the original collection tube. You may filter only 2 ml if desired. Remove and dispose of the funnel.

2. Add 8 ml of CONSED Concentration Reagent and 4 ml of ethyl acetate (or a substitute such as PRO-Clear) to the 2 ml sample in the centrifuge tube. Recap, hold thumb securely over the cap and shake. CAUTION: Pressure may build up in the tube during shaking. Carefully release the pressure by slowly opening the cap on the centrifuge tube away from you.

3. Place tubes in a centrifuge (with a free-swinging head) and spin for 10 minutes at 500 to 600xg. Following centrifugation four layers will develop:
   a. A top layer of mostly ethyl acetate (or substitute)
   b. An interface layer of fatty fecal debris
3. Observe all safety precautions for handling stool specimens.

2. MACROSCOPIC EXAMINATION
   a. The fecal specimen should be examined for consistency.
   b. Record any visible irregularities such as worms, proglottids, mucus and/or blood.

LIMITATIONS
1. The proper fixation of intestinal ova and parasites yields quality microscopic morphology and staining. Specimens not properly fixed [specimens delayed before being fixed, improper ratios of specimen to fixative and improper mixing of the specimen into the fixative] may yield poor microscopic morphology making it difficult or impossible to properly identify the ova or parasite. False negative examinations may occur if too little specimen or if too much specimen is used in the concentration procedures.
2. The xylene substitute AmeriClear® does not yield appropriate stain results and should not be used.

BIBLIOGRAPHY
CONSED™ Concentration Reagent

Manufactured by Alpha-Tec Systems Inc., 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA.

GLOSSARY OF SYMBOLS

LOT Lot number / Número de porción / Número de lote / Partienummer / Numéro de sort / Het Aantal van de partij

REF Catalog number / Número de catálogo / Número de catálogo / Numero di catalogo / Katalogzahl / Numéro de catalogue / Het aantal van de catalogus

IVD For in vitro diagnostic use only / Para el uso diagnóstico in vitro solamente / Para in vitro o uso diagnóstico somente / Solo per uso diagnostico in vitro / Für nur in vitrodiagnosegebrauch / Pour l'usage diagnostique in vitro seulement / Voor kenmerkend slechts gebruik in vitro

Authorized European representative / Representante europeo autorizado / Representante europeu autorizado / Rappresentante europeo autorizzato / Autorisierter europäischer Repräsentant / Represent ant européen autorisé / Gemachtigde Europese vertegenwoordiger

Caution, consult accompanying documents / Precaución, consulte los documentos de acompañamiento / Cuidado, consulte originais acompanhando / Attenzione, consulti i documenti di accompagnamento / Vorsicht, beraten Begleiddokumente / Attention, consultez les documents d'accompagnement / Voorzichtigheid, raadpleeg begeleidende documenten

Store between temperatures indicated / Almacén entre las temperaturas indicadas / Loja entre as temperaturas indicadas / Deposito fra le temperature indicate / Speicher zwischen den Temperaturen angezeigt / Magasin entre les températures indiquées / Opslag tussen vermelde temperature

Consult instructions for use / Consulte las instrucciones para el uso / Consulte instruções para o uso / Consulte le istruzioni per uso / Beraten Sie Anwendungsvorschriften / Consultez les instructions pour l’usage / Raadpleeg instructies voor gebruik

Use by date indicated / Uso por la fecha indicada / Uso pela data indicada / Uso entro la data indicata / Gebrauch bis zum der Dattel angezeigt / Utilisation à la datte indiquée / Gebruik door vermelde datum

Manufacturer / Fabricante / Fabricante / Fornitore / Hersteller / Fabricant / Fabrikant

Contains sufficient for <n> tests / Contiene suficiente para <n> las pruebas / Contem suficiente para <n> testes / Contiene sufficiente per <n> le prove / Enthält genügendes für <n> tests / Contient suffisamment pour <n> des essays / Bevat voldoende voor <n> tests