



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CINCINNATI, OHIO 45268

Office of Ground Water and Drinking Water
Standards and Risk Management Division

November 03, 2004

Drs. Saul Tzipori and Udi Zuckerman
Tufts University, School of Veterinary
Medicine Division of Infectious Diseases
200 Westboro Road
North Grafton, MA 01536

Dear Drs. Tzipori and Zuckerman,

We are pleased to inform you that, in the judgment of the U.S. EPA Office of Ground Water and Drinking Water's Technical Support Center, the June 2003 version of EPA Method 1623, as modified by the use of a Haemonetics portable continuous-flow centrifuge and 50-L source water samples, meets the acceptability criteria for *Cryptosporidium* in EPA Method 1623. This determination is based on the Tier 2 validation study demonstrating that this modified method met the acceptance criteria for EPA Method 1623 for *Cryptosporidium* in source water for three of the four laboratories participating in the study using 50-L samples. Please note that the study did not demonstrate that three laboratories could achieve acceptable recoveries for *Giardia* in source water.

EPA also considers this to be an acceptable modification of the June 2003 version of EPA Method 1622. This determination is based on the acceptable *Cryptosporidium* results of the Tier 2 validation study and the previously performed comparison of *Cryptosporidium* results from EPA's original Method 1622 and Method 1623 interlaboratory validation studies, in which no significant differences were observed between the two methods for *Cryptosporidium* recovery and variance. _

Although acceptable performance was not demonstrated for *Giardia* during this Tier 2 study, laboratories that wish to apply the modification to EPA Method 1623 for both *Cryptosporidium* and *Giardia* can do so by spiking samples with both organisms when conducting initial and ongoing performance demonstration tests. These tests are required for any laboratory wishing to adopt a modified method, and are described in Section 9.0 of EPA Methods 1622 and 1623. A modified version of Method 1623 is acceptable for use for both organisms if the laboratory demonstrates acceptable performance for both *Cryptosporidium* and *Giardia*.

_ *Results of the Interlaboratory Validation Study of EPA Method 1623*. U.S. Environmental Protection Agency, Office of Water. 2001. EPA-821-R-OI-028.

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Please note also that EPA may develop minimum detectable value (MDV) criteria for EPA Method 1623. Laboratories using Method 1623, or modified versions of the method, will be required to demonstrate that these MDV criteria are met if such criteria are established by EPA.

We appreciate your efforts in developing and demonstrating the equivalence of alternate components to those validated in EPA Methods 1622 and 1623. If you have any questions, please email me at moulton.carrie@epa.gov.

Sincerely,

A handwritten signature in dark ink, reading "Carrie Moulton". The signature is written in a cursive style with a large initial "C".

Carrie Moulton
Cryptosporidium Laboratory Quality Assurance
Evaluation Program Manager

cc: Greg Carroll, EPA OGWDW SRMD TSC
Herb Brass, EPA OGWDW SRMD TSC
Dan Schmelling, EPA OGWDW SRMD SRRB
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