

Topic: US EPA Approval of Invitrogen's™ MX-7 Mixer
Title: Invitrogen's™ MX-7 Mixer Approval for use with EPA Method 1623 – Alternative Test Procedure (ATP) Summary
Author(s): Brian Strohecker, Invitrogen Senior Associate Scientist
Source: Invitrogen Federal Systems
Date: November 2007

Report Highlights:

- Under the US EPA ATP protocol, the Invitrogen MX-7 Mixer was tested against EPA Method 1623 (taken from EPA Method 815-R-05-002: Cryptosporidium and Giardia in Water by Filtration/IMS/FA).
- By requirement, this ATP comparison was coordinated by independent labs in the United Kingdom.
- The proposed modification to EPA Method 1623 consists of replacing the manual rocking steps with a specialized mixing apparatus to improve results and to minimize the risk of operator injury.
- The overall results of the study indicated no significant difference at the 95% confidence level in the percentage recovery of oocysts or the variance between the Dynal IMS Rotator method and the existing manual IMS method, resulting in the November 5, 2007 US EPA Federal Register approval of Invitrogen's MX-7 Mixer for the detection of Cryptosporidium and Giardia in water.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CINCINNATI, OHIO 45268

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

November 5, 2007

REF: BD 06-0002

James Meegan
Senior Director of Research and Development
Invitrogen Federal Systems
7335 Executive Way
Frederic, MD 21704

Dear Mr. Meegan:

We have completed our processing of your ATP application for approval of Invitrogen's MX-7 Mixer for use with EPA Method 1623. Based on our review of your Tier 2 Study Report, test method, and other supporting information use of Invitrogen's MX-7 Mixer with EPA method 1623 provides data meeting the quality control acceptance criteria for *Giardia* and *Cryptosporidium* specified in Method 1623. Accordingly, in our opinion the MX-7 Mixer would be acceptable for use in the Agency's Long Term 2 Enhanced Surface Water Treatment Rule monitoring program.

We appreciate your interest and important contributions to the Agency's parasite monitoring programs. Please feel free to contact me at miller.carrie@epa.gov if you have any questions or comments.

Sincerely,

A handwritten signature in blue ink that reads "Carrie Miller".

Carrie Miller, Manager

Cryptosporidium Lab QA Evaluation Program
Technical Support Center

cc: Terry C. Covert, Lakeshore Engineering Services, Inc.
Steve Wendleken, Technical Support Center, USEPA