IDEXX Summary 12I

Topic: Alternative Test Procedure for US EPA Wastewater Approval of Enterolert™

Title: Alternative Test Procedure (ATP) Summary for US EPA Wastewater Approval of Enterolert

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Report Highlights:

- Under the US EPA ATP protocol, Enterolert was tested against EPA Method 1600 (mEI: a 24-hour membrane filtration US EPA approved method for the detection of enterococci).

- By requirement, this ATP comparison was coordinated by an outside agency certified by US EPA.

- The overall results of the study indicated no significant difference between the two methods, resulting in the March 26, 2007 US EPA Federal Register approval of Enterolert for the detection of enterococci in wastewater.

Alternative Test Procedure (ATP) Summary for the

US EPA Wastewater Approval for Enterolert™

The United States Environmental Protection Agency (US EPA) is charged by the Safe Drinking Water Act and the Clean Water Act to approve test procedures for determining fecal contamination in water. Subsequently, the US EPA has developed an "Alternative Test Procedure (ATP) Protocol" to facilitate this process.

In the March 26th, 2007 US EPA Federal Register, Enterolert was approved as a method for the detection of enterococci in wastewater. To obtain this approval, Enterolert was required to be tested against an approved method as defined in the 40 CFR136.4-136.6, Alternative Test Procedure. This approved method is known as the EPA 1600 mEI method.

The nationwide US EPA ATP protocol for microbiological procedures requires that manufacturers have the ATP comparisons coordinated and performed by an outside laboratory that is US EPA certified.

The first step in getting the study underway was to submit a study plan to the US EPA for approval. After review and discussions with the US EPA, the protocol was approved.

The intent of the US EPA ATP for nationwide approval is to have the new method evaluated as rigorously as possible against a variety of sample matrices that represent, as closely as possible, the types of samples the test will be used for in actual practice. To meet this intent, wastewater plants from 10 states dispersed across the 48 contiguous United States were chosen. In addition to the geographical diversity, plants were also chosen to represent a variety of operational modes and plant sizes.

Natural wastewater samples were successfully used for the comparison. No spiking of samples with lab cultured organisms was needed. The samples were chlorinated to obtain a 2-3 log reduction, causing injury to the bacteria. Ten geographically and operationally diverse wastewater effluents were successfully submitted and used for the study.

The overall results of the study indicated no significant difference between the two methods.

	Enterolert	EPA 1600 MEI method
Mean log value	5.3	5.5
False positive	0%	7%
False negative	11%	12%