EPA "GUIDE STANDARD"

The "Guide Standard and Protocol for Testing Microbiological Water Purifiers" (The Standard) was developed by a task force, beginning in 1984, to be a general guide for determining the microbial removal/inactivation effectiveness of certain types of water treatment units on waters of unknown quality.

The purpose of The Standard is to provide *at least* the minimum features and framework for testing a treatment unit. It utilizes a performance based format and is intended to provide a realistic worst case use of the unit under study.

MICROBIOLOGICAL WATER PURIFIER

A microbiological water purifier is intended to be used to treat water of unknown microbiological quality. So in order for a manufacturer to make a removal/inactivation claim for *any organism* by their treatment unit, the unit must remove/inactivate all types of pathogenic organisms. The Standard has selected 3 types of challenge organisms to represent the various waterborne organisms of public health concern: Bacteria (*Klebsiella terrigena*), Viruses (Polio and Rota) and Protozoan Cysts (*Giardia*).

TYPES OF TREATMENT UNITS

There are several basic types of units or processes described in The Standard which cover a wide range of treatment possibilities. Ceramic Candle filters, with and without silver; Ultraviolet Units; units that utilize iodine, silver or halogens; Batch systems; and in-line systems. All these help to guide the manufacturer in designing a protocol for their particular treatment product.

VIROLOGY

A polio and rota virus cocktail challenge is required by The Standard. Demonstration of a 4 $\log_{10}$ (99.99%) reduction is required on the combined polio/rota virus challenge matrix. BioVir is an established leader in environmental virus testing and is an EPA approved Virus testing laboratory under the Information Collection Rule requirements.

BACTERIOLOGY

Klebsiella terrigena is the bacterial challenge organism for The Standard. Demonstration of a 6 $\log_{10}$ (99.9999%) reduction is required. A full array of bacteriological challenge testing is available at BioVir including *Klebsiella terrigena*. We routinely analyze samples from HPC to special water treatment and disinfection device challenge studies using salmonella, bacillus and other bacteria.

PROTOCOL DEVELOPMENT / GOOD LABORATORY PRACTICES

Since treatment products come in a host of configurations, The Standard allows for alteration and addition to The Standard so long as the level of testing and it's intent is not compromised. BioVir will tailor any protocol to the individual manufacturer's needs while maintaining the spirit of The Standard.

Regulator involvement early in the protocol development process is an important recommendation by BioVir. Regulator involvement will serve to streamline and expedite the challenge study process and will help to ensure that data derived from the project will be accepted. BioVir is available to act on the manufacturer's behalf if requested to do so.

BioVir will perform work under Good Laboratory Practices (GLP) documentation. Our data package will be comprehensive and presented in a understandable format.

CRYPTOSPORIDIUM ANIMAL INFECTIVITY STUDIES

The Standard was last updated in 1987 when *Giardia lamblia* was the major waterborne protozoan of concern. Since that time *Cryptosporidium* has supplanted *Giardia* because of it's small size and ability to survive traditional treatment methods. Therefore, BioVir would recommend performing any challenge study to demonstrate a 99.9% reduction using Cryptosporidium rather than Giardia.

The Standard as described for Giardia *infectivity* allows for excystation methods of analysis. However, the excystation method for determining Cryptosporidium infectivity has been shown to be questionable. Generation of infectivity data, which is crucial to demonstrating disinfection effectiveness of non-filtering microbiological water purifiers, can be attempted by a number of methods with varying degrees of certainty.

Cell culture for cryptosporidium infectivity is now the method of choice for determining Cryptosporidium viability. Much comparative research has been performed over the last few years comparing the cell culture technique with the animal infectivity model for detection of viable cryptosporidium. Cell culture has been shown to be just as effective as the animal model and at a significant cost savings over the course of a study. Other testing methods available at BioVir include the animal model, vital dyes such as DAPI/PI and Excystation.

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