



LT2ESWTR - METHOD 1622/23 FAQs

Introduction

The *Long Term 2 Enhanced Surface Water Treatment Rule* (LT2ESWTR or LT2) rule was promulgated in the Federal Register on January 5th, 2006 after many years in development. The effective date of the rule is March 6, 2006 and staggered-start (based on population served) testing for *Cryptosporidium* will begin in September 2006.

BioVir has received many questions regarding the requirements for cryptosporidium sampling and analysis associated with LT2-mandated testing. We hope that you find the information below informative.

1. **What are some of the potential costs associated with 1622/1623 analysis?**
 - a. Basic Analysis including filter (client supplies 10 Liter grab sample and BioVir filters in the lab. BioVir can also provide one filter for field filtration); or
 - b. Basic Analysis without filter (utility supplies their own filter and filters in-the-field).
 - c. Additional filters required as a result of matrix (i.e., Turbid sample which clogs filter element prior to filtering 10 liter volume. 2 Filters max required).
 - d. Additional slides (sub-samples) for examination required as a result of matrix (i.e., Packed pellet volume in excess of ½ mL. 1 slide per ½ mL of packed pellet. Examination of 2 mL of packed pellet or 10 Liters required.)
 - e. Matrix spike samples at every site and every 20 samples thereafter.
 - f. All freight costs.

2. **Which is the better Method, 1622 or 1623?**
 - a. Neither. The methods are virtually identical except that Method 1622 detects only cryptosporidium while Method 1623 detects cryptosporidium and giardia.
 - b. Reportable protozoan data to the EPA for LT2 is for cryptosporidium only. Data generated regarding giardia if Method 1623 is chosen, will be reported only to the Utility and will be for Utility use only.

3. **What volume of sample do I take?**
 - a. At least 10 Liters.
 - b. More volume can be taken but the EPA encourages that a similar volume be taken consistently throughout the study.
 - c. Gelman HV capsule filters are approved for up to a 50 Liter sample volume.
 - d. Link to EPA LT2 web site and Proposed LT2 Rule can be found on under "LT2 Information" on our web-site home page at www.biovir.com.

4. **If the detection limit for a 10 liter sample is <0.1/Liter, how can I achieve a <0.075/Liter concentration for my utility to land in Bin 1?**
 - a. According to the Rule the calculation for determining bin classification is to be based on averaging the oocyst concentrations measured for individual samples.
 - b. The individual sample concentrations are to be determined by dividing the total oocyst count by the total volume assayed.
 - c. It is important to note the amount *assayed* may not be equal to the amount *sampled*.

The amount assayed will be affected by the individual sample quality and by your choices in limiting the examination of additional slides.

- d. The method that systems will use to average individual sample concentrations depends on the number of samples collected and the length of the sampling period. For Large Systems (>10,000) collecting 24 to 47 samples they will calculate the highest twelve month running annual average during the 24 month collection period. For Large Systems collecting at least twice monthly samples during the 24 month collection period the arithmetic mean of all samples will be calculated.

5. How can I affect the average number per liter?

- a. Take more samples (consistently throughout the program).
- b. Take larger volume samples (consistently throughout the program).

6. How should I collect the sample?

- a. By Grab sample (for example a 10 L cubitainer); or
- b. In-the-field filtration.

7. What are some of the advantages to filtering in the field?

- a. If you supply your own filter, you save effort by obtaining all your filters at one time;
- b. Filtering at your Utility makes taking a larger sample more practical.
- c. The larger volume increases the denominator for calculating which "Bin" you will belong.
- d. The cost of shipping 10 L of water + ice is pretty expensive (the water alone will be over 20 lbs).
- e. The filter element is easier to chill and keep cold.
 - i. Samples need to be chilled (<20° C) as quickly as possible. Target 10° C.
 - ii. Samples must be chilled (<20° C) prior to shipment. Target 10° C.
 - iii. Samples must arrive at BioVir unfrozen and at <20° C or they must be rejected according to the rule.

8. What are some of the disadvantages to filtering in the field?

- a. Sampling is more cumbersome.
- b. Sampling requires a filtration apparatus.
- c. Creates a greater possibility of freezing the samples (filter cartridge /v/ bulk water) during shipment (would invalidate sample).
- d. MATRIX SPIKE: EPA stipulates that the matrix spikes (with Crypto) have to be done using the planned sampling volume (e.g., 10L or 50L), must be within 10% of the regular sample volume and should be collected using a split-stream technique. The split-stream technique allows for collection of the regular and matrix spike samples simultaneously.
- e. MATRIX SPIKE: Matrix spike samples will always have at least a 10 Liter grab sample associated with them. If 10 Liters equals the regular sample volume, then the grab is simply sent to the lab with the regular sample. If the regular sample is of greater volume (e.g. 50 Liters) then the Utility may filter 40L liters in the field and ship the capsule filter and the remaining 10 Liters as a grab sample to BioVir ; BioVir will add the spike to the additional 10 L here at the lab and process the final 10L plus spike through the same filter. **Note:** a matrix spike will always entail two samples, one is the regular sample and the other is the one to be spiked. You need to obtain and maintain

a sampling apparatus.

9. **Does BioVir supply the carboys? If you do, is there an additional cost?**
 - a. BioVir supplies one 2.5 gal (10L) cubitainer at no additional cost (except for shipping).

10. **When do I submit a matrix spike sample?**
 - a. EPA recommends submission of a Matrix Spike sample with the initial sample. 5% of samples must have an associated matrix spike.

11. **Does the matrix spike cover all of my sources, or do I have to conduct a matrix spike for each one?**
 - a. The matrix spike is site specific, each site will require at least 2 matrix spike samples during the course of the LT2.

12. **Does BioVir provide filters for filtering in the field?**
 - a. We will provide filters if requested. We can provide a quotation based on Analysis with or without cartridge filters.
 - b. A utility may buy their own filters (BioVir plans to use Gelman HV filters almost exclusively).
 - c. In addition, if we supply the filters, then we will be sending them to you prior to your pre-scheduled sample date(s).

13. **If I filter in-the-field, where do I get a sampling apparatus?**
 - a. BioVir will have a limited number of field sampling kits (all the hoses, flow restrictor, pressure regulator, etc.) that, if you use BioVir exclusively for LT2 testing, will be yours to keep and maintain for the duration of LT2.
 - b. If you assemble your own apparatus, BioVir can supply you with a basic schematic and parts list.

14. **Will you provide the 10L vessel for the Matrix Spike Sample?**
 - a. We can if requested.
 - b. We will send you a 10L cubitainer.

15. **Do you send us the ice packs, any container we may need and/or a container to send filter or cubitainer back?**
 - a. You will need to provide wet ice in order to chill samples prior to packaging and shipment. BioVir has performed a number of experiments regarding this issue. Call us for additional details.
 - b. We can provide a 48 qt. cooler for use in shipping your bulk samples (you would be responsible for the shipping charges).
 - c. In the case of shipping a pre-chilled filter, we provide reusable ice bricks and a insulated shipping container.
 - d. In any case, if we supply the containers, you only pay for the shipping, not the containers themselves.

- 16. What kind of advance notice do you need for setting us up with accounts payable information, filtering apparatus, and all the information for "set-up" we will need?**
- a. We can set the administrative details up after receiving a purchase order (e-mail, FAX or phone).
 - b. Payment arrangements are made through our office manager, Nancy Rice (nlr@biovir.com, same phone/fax numbers listed above).
 - c. Scheduling is completed by contacting any of our customer service personnel.
 - d. The filtering apparatus can be sent to you soon after you call.
 - e. Right now sample shipment is on a "first come" basis. We expect that as the mandated start date nears and many Utilities are gearing up to begin sampling, that sampling dates will be determined by "space available".
- 17. I want to use this data as "Grandfathered Data". Can I?**
- a. If you intend to submit the Cryptosporidium results to the EPA as "Grandfathered Data" you must first let us know of your intent. The requirements of Method 1623 for LT2 differ from the method as published.
 - b. You must adhere to the requirements of the LT2ESWTR Rule. Some of the requirements for data submitted as "grandfathered" are:
 - i. The data must be generated using the validated versions of EPA Method 1622/1623.
 - ii. Be fully compliant with the QA/QC criteria specified in the version of Method 1622/23 used to generate the data.
 - iii. Be representative of a plant's source water(s) and the source water(s) must not change.
 - iv. Samples must be collected at least each calendar month and on a regular basis. Currently 2 days before or after a set date each month. Please see final rule Section IV,1,g. Grandfathered Data Quality Requirements.
 - v. Data should be collected in equal intervals of time over the entire collection period (e.g. Daily, weekly or monthly). Deviations in the sampling frequency of previously collected data are allowed under certain conditions. Please see final rule Section IV,1,g. Grandfathered Data Quality Requirements.
 - vi. Data collected prior to January 1999 is not valid.
 - vii. All source water Cryptosporidium data collected during the period must be submitted.
 - viii. Sample volumes of at least 10L must be analyzed or, in cases where 10L are not analyzed, at least 2 mL of packed pellet volume or the volume filtered by 2 capsule filters must be analyzed.
 - ix. Matrix spike samples must be analyzed at a frequency of at least 5% (1 per 20 monitoring samples).
 - x. Sample temperature at receipt must be unfrozen and <20°C or sample will be rejected.
 - c. Schedule for Submission of Grandfathered Data
 - i. Utilities submit their intent to grandfather data within 3 months prior to their mandated monitoring start date.
 - ii. Utilities must report previously collected monitoring results for grandfathering, along with required documentation listed in Section IV.1.g of the Final Rule no later than 2 months after their required monitoring start date.
- 18. I have other questions. How can I get them answered?**
- a. Call 1-800-GIARDIA (442-7342), we'll be happy to help you.
 - b. E-mail us at csj@biovir.com, ejb@biovir.com, or red@biovir.com
 - c. Go to www.biovir.com and click on the LT2 Information button where you will find more information and links to the EPA LT2 web-site.