

AccuSpike-IR Product Specification and Analysis Report

Product: 1.5 mL polypropylene vial containing 100 each, counted by flow-cytometry cell sorting, of *Giardia lamblia*, H3 isolate, cysts and *Cryptosporidium parvum*, Iowa isolate, oocysts suspended in 0.75 mL of a de-ionized water/0.01% Tween 20 solution. AccuSpike-IR is designed for percent recovery determination with matrix (environmental) and reagent water samples by US EPA Methods 1622 and 1623.

Species/genus identification method: Direct immunofluorescence microscopy with genus-specific monoclonal antibodies; also phase microscopy.

Purification method: Cysts and oocysts are purified from feces by sucrose and Percoll density gradient centrifugation.

Quantitation method: Cells enumerated using flow cytometry.

Storage Conditions: 4 C. DO NOT FREEZE.

Inactivation/Sterilization: Gamma irradiation.

Lot# 37

Preparation: 10/28/08

Expiration: 01/20/09 for *Giardia* & *Cryptosporidium* analysis

Expiration: 02/17/09 for *Cryptosporidium* analysis ONLY

Calibration Data

| Test: | Spike Preparation | Spike Preparation |
|-----------------------------------|---------------------------------|----------------------------------|
| Organism: | <i>Cryptosporidium</i> | <i>Giardia</i> |
| Source of Organism: | Experimentally infected mice. | Experimentally infected gerbils. |
| Organism strain: | CpAZ | H3 |
| Stock suspension lot number: | 100108-15 | 081015 |
| Date cells collected by source: | 10/1/08 | 10/15/08 |
| Date of initial calibration: | 10/22/08 | 10/22/08 |
| Age of cells (in days): | 21 | 7 |
| Storage media: | De-ionized Water/0.01% Tween 20 | De-ionized Water/0.01% Tween 20 |
| Storage temperature: | 4 C | 4 C |
| Viability (PI) before Irradiation | 99.7% | 99.7% |
| Mean of the counts: | 99.70 | 99.76 |
| Standard deviation of the counts: | 0.88 | 2.07 |
| Relative standard deviation: | 0.88 | 2.07 |

Notes from Sorting Facility:

- (1) Mean, standard deviation and relative standard deviation are calculated from a minimum of 12 calibration verification samples per set of 10 standards.
- (2) Parasites are evaluated for general quality and intactness under DIC microscopy prior to use.