

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# 34

Preparation: 06/18/08

Expiration: 10/17/08 for *Giardia* & *Cryptosporidium* analysis

Expiration: 11/14/08 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:	71508-12	080721
Date cells collected by source:	7/14/08	7/21/08
Date of initial calibration:	7/23/08	7/23/08
Age of cells (in days):	9	2
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	99.2%	99.7%
Mean of the counts:	99.18	98.77
Standard deviation of the counts:	2.13	1.41
Relative standard deviation:	2.15	1.43

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.