

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# 43

Preparation: 07/09/09

Expiration: 10/01/09 for *Giardia* & *Cryptosporidium* analysis

Expiration: 10/29/09 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:	63009-23	090706
Date cells collected by source:	6/30/09	7/6/09
Date of initial calibration:	7/7/09	7/7/09
Age of cells (in days):	7	1
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	97.4%	99.3%
Mean of the counts:	99.04	99.26
Standard deviation of the counts:	1.46	1.63
Relative standard deviation:	1.48	1.64

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.