

AccuSpike-IR Product Specification and Analysis Report

Product: 2.0 mL, self-standing, polypropylene microtube 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, 1623, and 1623.1.

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# 126

Preparation: 04/29/2021

Expiration: 07/22/2021 for *Giardia* & *Cryptosporidium* analysis

Expiration: 08/19/2021 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: | 21413-102 | 210415 |
| Date cells collected by source: | 4/13/21 | 4/15/21 |
| Date of initial calibration: | 4/20/21 | 4/20/21 |
| Age of cells (in days): | 7 | 5 |
| 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% | 99.3% |
| Mean of the counts: | 99.80 | 100.00 |
| Standard deviation of the counts: | 1.30 | 1.20 |
| Relative standard deviation: | 1.30 | 1.20 |

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.