



### Certified Reference Material Data

This certificate is designed in accordance with ISO Guide 31:2015

Batch Number: **B359**

#### General

**Safety:** This product is non-hazardous.

**Storage:** 2-8°C. Do not freeze.

**Catalogue Number:** CSCG100, CS2CG100, CS4CG100, CSCG500, CS50CG100, JPN-CSCG100, JPN-CS4CG100

**Production Date:** 4 December 2024

**Expiration Date:** 16 April 2025

**Volume:** 1.405 ml +/- 31 ul

**Suspension media:** Buffered saline solution.

**Sterilisation method:** Gamma Irradiation.

Counts	Mean (i)	St.Dev.(ii)	Expanded Uncertainty(iii)
<i>(Method Ref: CG-014)</i>			
<b>Cryptosporidium count:</b>	<b>102</b>	<b>2.2</b>	<b>4.6</b>
<b>Giardia count:</b>	<b>100</b>	<b>2.4</b>	<b>5.1</b>
<b>DAPI staining:</b>			
<b>Cryptosporidium % +ve</b>	<b>100</b>	<b>%</b>	
<b>Giardia % +ve</b>	<b>100</b>	<b>%</b>	

The Mean CFU quantification (i) and associated SD (ii) are traceable to counts using flow cytometry

#### Stock specifics\*

**Organism:** *Cryptosporidium parvum*

**Strain:** Iowa

**Source:** Bovine

**Shed date:** 07 November 2024

**Purification method:** Discontinuous sucrose and cesium chloride centrifugation gradients.

#### Stock specifics\*

**Organism:** *Giardia lamblia*

**Strain:** H3

**Source:** Gerbil

**Shed date:** 11 November 2024

**Purification method:** Sucrose and Percoll density gradient centrifugation

### Certified Values and Uncertainties

#### Enumeration Method

A) CG-014

The count values have been obtained by taking a randomised significant sample of each batch and enumerating cysts and oocysts by flow cytometric analysis.

B) Stability Ref:

Stability testing has been conducted on batch CSCG100-B344 of ColorSeed™ at 4 months.

ColorSeed™ with an assigned property value in terms of its known count value is used as a quality control reference material. This CRM has been produced by flow cytometry and is traceable to natural numbers.

i) The certified value represents the unweighted mean counts from a statistically relevant number of samples covering the entire product batch.

The characterization uncertainty  $\mu$  (characterization) represents the dispersion of measurement values, calculated as standard deviation.

ii) The Standard Deviation is a measure of variability within the batch.

iii) Combined standard uncertainty,  $\mu$ (CRM), is calculated as the square root of the sum of squares of the individual contributions

(characterization, homogeneity, stability), according to:  $\mu(CRM) = \sqrt{\mu^2_{char} + \mu^2_{homogeneity} + \mu^2_{stability}}$

The Expanded Uncertainty, U(CRM) is reported at the 95% Confidence Level with a coverage factor k=2: U(CRM) =  $\mu$ (CRM) \* k.

\* Organism identification is not certified.



Accredited for compliance with ISO 17034  
Accredited Reference Material Producer

NATA is a signatory to the ILAC Mutual Recognition Arrangement  
for the mutual recognition of the equivalence of reference materials certificates

Accreditation No: 20685  
Site No: 24813



**Storage and Handling:**

Store ColorSeed™ at 2-8°C.

**Description:**

ColorSeed™ contains precise known counts of non viable *Cryptosporidium* and *Giardia* labelled with a red fluorescent dye in 1.2ml of clear liquid.

**Intended Use:**

ColorSeed™ is a biological certified reference material containing a precise number of non-viable *Cryptosporidium* and *Giardia*. It is designed for use as an internal quantitative quality control sample.

Instructions for Use (refer to the corresponding Product Insert for more details)

**Seeding the sample (use one tube of ColorSeed™)**

1. Remove and keep the tube cap
2. Add 2 mL of 0.05% (v/v) Tween 20 to the tube
3. Replace cap and vortex for 20 seconds
4. Remove and keep cap and pour tube contents into sample
5. Add 3 mL of reagent grade water to the empty tube
6. Replace cap and vortex for 20 seconds
7. Remove and keep cap and pour tube contents into sample
8. Repeat steps 5, 6 and 7 once more

**Sample Analysis**

9. Analyze the sample as per the laboratory Standard Operating Procedure.
10. Record the number of red fluorescent *Cryptosporidium* and *Giardia* detected.
11. Separately record the number of green-only fluorescent *Cryptosporidium* and *Giardia* detected.
12. Calculate the ColorSeed™ *Cryptosporidium* and *Giardia* recovery using the following formulae:-

$$\text{Cryptosporidium Recovery (\%)} = \frac{\text{red Cryptosporidium detected} \times 100}{\text{number of Cryptosporidium in ColorSeed™ as per C of A}}$$

$$\text{Giardia Recovery (\%)} = \frac{\text{red Giardia detected} \times 100}{\text{number of Giardia in ColorSeed™ as per C of A}}$$

\* Certificate of Analysis

13. Calculate the number of naturally occurring *Cryptosporidium* and *Giardia* in the original sample using the following formulae:-

$$\text{Cryptosporidium} = \frac{\text{green-only Cryptosporidium detected}}{\text{Colorseed™ Cryptosporidium recovery (from step 12)}}$$

$$\text{Giardia} = \frac{\text{green-only Giardia detected}}{\text{Colorseed™ Giardia recovery (from step 12)}}$$

**Safety information:**

ColorSeed™ is not classed as a Dangerous Good or hazardous material. It has been gamma irradiated and the *Cryptosporidium* and *Giardia* are non viable.

Please refer to the Safety Data Sheet (available online [www.biopoint.com.au](http://www.biopoint.com.au))

**References:**

- [1] ISO Guide 30 Reference materials - Selected terms and definitions
- [2] ISO Guide 31 Reference materials - Contents of certificates labels and accompanying documentation
- [3] ISO17034 General requirements for the Competence of Reference material Producers
- [4] ISO Guide 35 Reference materials - Guidance for characterisation and assessment of homogeneity and stability
- [5] AS ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

**Approved Quality Signatory:**

Lucy Millican  
Quality Manager

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