

**Certified Reference Material Data**

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

**General**

<b>Safety:</b>	This product is non-hazardous.
<b>Storage:</b>	2-8°C. Do not freeze.
<b>Catalogue Number:</b>	CSCG100, CS2CG100, CS4CG100, CS50CG100, W-CSCG100, W-CS4CG100
<b>Production Date:</b>	30 July 2020
<b>Expiration Date:</b>	10 December 2020
<b>Volume:</b>	1.088 ml +/- 22 ul
<b>Suspension media:</b>	Buffered saline solution.
<b>Sterilisation method:</b>	Gamma Irradiation.

<b>Counts</b> <i>(Method Ref: CG-014)</i>	Expanded		
	Mean (i)	St.Dev.(ii)	Uncertainty(iii)
<b>Cryptosporidium count:</b>	<b>98</b>	<b>2.3</b>	<b>5.2</b>
<b>Giardia count:</b>	<b>99</b>	<b>2.1</b>	<b>4.6</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 natural number counts using flow cytometry*

**Stock specifics\***

<b>Organism:</b>	<i>Cryptosporidium parvum</i>
<b>Strain:</b>	Iowa
<b>Source:</b>	Bovine
<b>Shed date:</b>	08 July 2020
<b>Purification method:</b>	Discontinuous sucrose and cesium chloride centrifugation gradients.

**Stock specifics\***

<b>Organism:</b>	<i>Giardia lamblia</i>
<b>Strain:</b>	H3
<b>Source:</b>	Gerbil
<b>Shed date:</b>	03 July 2020
<b>Purification method:</b>	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: Exp # 1421

Stability testing has been conducted on batch CS-CG100-38 of ColorSeed™ at 5 months and 5 days.

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:

$$\mu(\text{CRM}) = \sqrt{\mu^2_{\text{char}} + \mu^2_{\text{homogeneity}} + \mu^2_{\text{stability}}}$$

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

## 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:-

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

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

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

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

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

## 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  
10 August 2020

## Manufactured by:

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