

**Certified Reference Material Data**

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

**Batch Number: B284**
**General**

**Safety:** This product is non-hazardous.  
**Storage:** 2-8°C. Do not freeze.  
**Catalogue Number:** CSCG100, CS2CG100, CS4CG100, CS50CG100, W-CSCG100, W-CS4CG100  
**Production Date:** 13 February 2020  
**Expiration Date:** 25 June 2020  
**Volume:** 1.092 ml +/- 11 ul  
**Suspension media:** Buffered saline solution.  
**Sterilisation method:** Gamma Irradiation.

Counts (Method Ref: CG-014)	Expanded		
	Mean (i)	St.Dev.(ii)	Uncertainty(iii)
<b>Cryptosporidium count:</b>	<b>99</b>	<b>2.3</b>	<b>5.0</b>
<b>Giardia count:</b>	<b>101</b>	<b>2.0</b>	<b>4.4</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

**Stock specifics\***

**Organism:** *Cryptosporidium parvum*  
**Strain:** Iowa  
**Source:** Bovine  
**Shed date:** 15 January 2020  
**Purification method:** Discontinuous sucrose and cesium chloride centrifugation gradients.

**Stock specifics\***

**Organism:** *Giardia lamblia*  
**Strain:** H3  
**Source:** Gerbil  
**Shed date:** 31 December 2019  
**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: 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,  $\mu(\text{CRM})$ , is calculated as the square root of the sum of squares of the individual contributions (characterization, homogeneity, stability), according to:

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

The Expanded Uncertainty,  $U(\text{CRM})$  is reported at the 95% Confidence Level with a coverage factor  $k=1.96$ :  $U(\text{CRM}) = \mu(\text{CRM}) * k$ .

## 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

21 February 2020

## Manufactured by:

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