



Certified Reference Material Data

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

Batch Number: B285

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: 26 March 2020
Expiration Date: 6 August 2020
Volume: 1.099 ml +/- 24 ul
Suspension media: Buffered saline solution.
Sterilisation method: Gamma Irradiation.

Counts

(Method Ref: CG-014)

Expanded

Mean (i) St.Dev.(ii) Uncertainty(iii)

Cryptosporidium count: 99 1.5 3.8

Giardia count: 100 1.2 3.1

DAPI staining:

Cryptosporidium % +ve 100 %

Giardia % +ve 100 %

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: 26 February 2020
Purification method: Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics\*

Organism: Giardia lamblia
Strain: H3
Source: Gerbil
Shed date: 02 March 2020
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 μ (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, μ(CRM), is calculated as the square root of the sum of squares of the individual contributions (characterization, homogeneity, stability), according to: μ(CRM) = √(μ²\_char + μ²\_homogeneity + μ²\_stability)

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



Accredited for compliance with ISO 17034
Accredited Reference Material Producer
Accreditation No: 20685
Site No: 24813

\* organism identification is not certified

## 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

6 April 2020

## Manufactured by:

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