

Certified Reference Material Data

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

Batch Number: B287
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: 7 July 2020
Expiration Date: 17 November 2020
Volume: 0.093 ml +/- 16 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:	98	1.4	3.7
Giardia count:	101	1.9	4.2
DAPI staining:			
Cryptosporidium % +ve	100	%	
Giardia % +ve	100	%	

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

Stock specifics*

Organism: *Cryptosporidium parvum*
Strain: Iowa
Source: Bovine
Shed date: 13 May 2020
Purification method: Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism: *Giardia lamblia*
Strain: H3
Source: Gerbil
Shed date: 13 April 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:

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

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

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:



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15 July 2020

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Page 2 of 2