

Certified Reference Material Data

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

Batch Number: **B357**

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:	30 October 2024
Expiration Date:	12 March 2025
Volume:	1.445 ml +/- 7 ul
Suspension media:	Buffered saline solution.
Sterilisation method:	Gamma Irradiation.

Counts

(Method Ref: CG-014)

	Mean (i)	St.Dev.(ii)	Expanded Uncertainty(iii)
Cryptosporidium count:	102	1.8	4.0
Giardia count:	100	2.4	5.2
DAPI staining:			
Cryptosporidium % +ve	100	%	
Giardia % +ve	100	%	

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

Stock specifics*

Organism:	<i>Cryptosporidium parvum</i>
Strain:	Iowa
Source:	Bovine
Shed date:	10 October 2024
Purification method:	Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism:	<i>Giardia lamblia</i>
Strain:	H3
Source:	Gerbil
Shed date:	08 October 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 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: $\mu(CRM) = \sqrt{\mu^2_{char} + \mu^2_{homogeneity} + \mu^2_{stability}}$

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

Issue: 8
Date: 9/10/2024
Page 1 of 2



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)

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

6 November 2024



Manufactured by:
BioPoint Pty Ltd
Suite 16, 13A Narabang Way, Belrose, Sydney, NSW 2085
Tel: +61 2 8316 7939
www.biopoint.com.au

Issue: 8
Date: 9/10/2024
Page 2 of 2