ColorSeed™

Certificate of Analysis

Certified Reference Material Data

Batch Number: B322

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

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:	21 September 2022
Expiration Date:	1 February 2023
Volume:	1.364 ml +/- 2 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:**	492	4.5	9.3
***Giardia* count:**	489	3.1	6.4

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:	*Cryptosporidium parvum*
Strain:	Iowa
Source:	Bovine
Shed date:	11 August 2022
Purification method:	Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism:	*Giardia lamblia*
Strain:	H3
Source:	Gerbil
Shed date:	30 August 2022
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: $\mu(CRM) = \sqrt{\mu^2_{char} + \mu^2_{homogeneity} + \mu^2_{stability}}$

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

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 *Cryptopsporidium* 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 (%) =
red *Cryptosporidium* detected x 100
number of *Cryptosporidium* in ColorSeed™ as per C of A

Giardia Recovery (%) =
red *Giardia* detected x 100

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:-

Cryptosporidium =
green-only *Cryptosporidium* detected
Colorseed™ *Cryptosporidium* recovery (from step 12)

Giardia =
green-only *Giardia* detected

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 *Cryptospordium* 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

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