ColorSeed™

Certificate of Analysis

Certified Reference Material Data

Batch Number: B283

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, CS50CG100, W-CSCG100, W-CS4CG100

Production Date: 16 January 2020

Expiration Date: 28 May 2020

Volume: 1.076 ml +/- 10 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:**	**99**	**2.2**	**4.8**
***Giardia* count:**	**100**	**2.4**	**5.1**

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: 30 November 2019

Purification method: Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism: *Giardia lamblia*

Strain: H3

Source: Gerbil

Shed date: 21 October 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 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=1.96: U(CRM) = μ(CRM) * k.

NATA ACCREDITED FOR TECHNICAL COMPETENCE

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 *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
24 January 2020

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