



bio point

World's first Certified Reference Material for *Cryptosporidium* and *Giardia* Accreditation to ISO 17034

BioPoint's new CRM Certificate of Analysis for EasySeed and ColorSeed explained below

The BioPoint manufacture site is now accredited as a Certified Reference Material Producer under ISO 17034 by the National Association of Testing Authorities, Australia (NATA).

BioPoint is proud to announce

that EasySeed, ColorSeed and the Proficiency Testing products are qualified Certified Reference Materials (CRMs).

The new Certificate of Analysis for these products state each unit's value and associated uncertainty plus a statement of metrological traceability.

Please note that EasySeed, ColorSeed

AND THE CUSTOM-MADE PROFICIENCY TESTING PRODUCTS CONTINUE TO BE PRODUCED WITH ACCURACY AND PRECISION BATCH AFTER BATCH.

Advantages of BioPoint CRMs



ACCURATE



PRECISE



EFFICIENT



CONSISTENT

- PREMIUM QUALITY
- USE WITH COMPLETE CONFIDENCE IN YOUR LABORATORY
- MULTI LABORATORY STANDARDIZATION
- RESULTS OF TESTING COMPARABLE WORLDWIDE
- VALIDATE YOUR METHODS, PERSONNEL AND EQUIPMENT

WHAT HAS CHANGED

is the how the information is presented on the new Certificate of Analysis with additional information for each batch. Please see the explanation below.

DEFINITIONS

Traceability

"Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty."

ISO Guide 99:2007; International Vocabulary of Metrology — Basic and General Concepts and Associated Terms (VIM)

Certified Reference Material (CRM)

"Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value

of the specified property, its associated uncertainty, and a statement of metrological traceability." ISO/Guide 30:2015; Reference Materials — Selected Terms and Definitions

Measurement Uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

ISO Guide 99:2007; International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM)

Expanded Measurement Uncertainty

Product of a combined standard measurement uncertainty and a factor larger than the number one

NOTE: The term "factor" in this definition refers to a coverage factor. ISO Guide 99:2007; International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM)

IMPORTANT NOTICE

bio point **ColorSeed™**
Certificate of Analysis
Batch Number: **8271**

Certified Reference Material Data
This certificate is designed in accordance with ISO Guide 31:2015

General
Solely: This product is non-hazardous.
Storage: 2-8°C. Do not freeze.
Catalogue Number: C300101, C300102, C300103, C300104, C300105, W-300106, W-300107

Preparation Date: 27 June 2019
Expiration Date: 28 October 2019
Volume: 1.051 ml +/- 12 ul
Suspension media: Buffered saline solution.
Sterilization method: Gamma Irradiation.

Counts (labelled net count)	Mean (I)	St.Dev. (II)	Expanded Uncertainty (III)
Cryptosporidium count	100	1.9	4.4
Giardia count	98	2.1	4.5

DAPI staining:
Cryptosporidium % +ve 100 %
Giardia % +ve 98 %

Stock specifics*
Organism: Cryptosporidium parvum
Strain: Iowa
Source: Bovine
Shed date: 06 May 2019
Purification method: Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*
Organism: Giardia lamblia
Strain: HS
Source: Gerbil
Shed date: 29 May 2019
Purification method: Sucrose and Percoll density gradient centrifugation

Certified Values and Uncertainties
Enumeration Method
A1: Cytoc f
The count values have been obtained by taking a randomised significant sample of each batch and enumerating cysts and oocysts by flow cytometric analysis.
B1: Stability Ref. Exp #1421
Stability testing has been conducted on batch C300106/36 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 national numbers.
C: The certified value represents the unweighted mean counts from a statistically relevant number of samples covering the entire product batch. The characterization uncertainty μ (characterisation) represents the dispersion of measurement values, calculated as standard deviation.
D: The Standard Deviation is a measure of variability within the batch.
E: Combined standard uncertainty, μ CRM, is calculated as the square root of the sum of squares of the individual contributions (characterisation, homogeneity, stability), according to:
The Expanded uncertainty, U(CRM) is reported at the 95% Confidence Level with a coverage factor $k=1.96$: $U(CRM) = \mu(CRM) \times k$

NATA Accredited for compliance with ISO 17025
Accreditation Reference Number: 19003
Accreditation Date: 2018

Issue 1
June 2019
Page 1 of 1

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™)

- Remove and keep the tube cap.
- Add 2ml of 0.85% NaCl to the tube.
- Replace cap and vortex for 30 seconds.
- Remove and keep cap and pour tube contents into sample.
- Add 5 ml of reagent grade water to the empty tube.
- Replace cap and vortex for 30 seconds.
- Remove and keep cap and pour tube contents into sample.
- Repeat steps 5, 6 and 7 once more.

Sample Analysis

- Analyse the sample as per the laboratory Standard Operating Procedure.
- Record the number of red fluorescent Cryptosporidium and Giardia detected.
- Separately record the number of green fluorescent Cryptosporidium and Giardia detected.

Cryptosporidium Recovery (%) =
 $\frac{\text{Number of Cryptosporidium detected} \times 100}{\text{Number of Cryptosporidium in ColorSeed™ as per C of A}}$

Giardia Recovery (%) =
 $\frac{\text{Number of Giardia detected} \times 100}{\text{Number of Giardia in ColorSeed™ as per C of A}}$

13. Calculate the number of naturally occurring Cryptosporidium and Giardia in the signal sample using the following formulae:

Cryptosporidium =
 $\frac{\text{Number of Cryptosporidium detected} \times \text{ColorSeed™ Cryptosporidium recovery (from step 12)}}{\text{Giardia =
 $\frac{\text{Number of Giardia detected} \times \text{ColorSeed™ Giardia recovery (from step 12)}}{\text{Certificate of Analysis}}$$

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] ISO 7024 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:
[Signature]

Manufacturer by:
BioPoint Pty Ltd
Unit 1, 35-41 Waterloo Rd, Macquarie Park, 2113, Australia
Tel: 61 61 2 8877 9127
www.biopoint.com.au

Issue 1
June 2019
Page 1 of 1

1 The counts are produced by flow cytometry to provide metrological traceability in your testing.

2 In addition to the Standard deviation for each batch there is now an Expanded Uncertainty of Measurement Value. This value has been calculated using the QC flow cytometer enumerated values for each batch as well as stability data values to cover the shelf life of the product.

3 Further explanation of the enumeration methods and measurement uncertainty calculations.

4 NATA accreditation details

5 Further information on storage, description and the Intended use

6 Instructions for Use - note these have not changed and are described in more detail in your product insert

7 Safety Information and references to the terminology used. See below for definitions explained.

8 Quality Signed out and contact details.



Unit 1, 35-41, Waterloo Rd,
Macquarie Park, NSW, 2113 - Australia.

Tel.: +61 2 8877 9127

info@biopoint.com.au



WWW.BIOPPOINT.COM.AU

