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Certified Reference Material Data

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:	ESCG200
Production Date:	22 June 2022
Expiration Date:	2 November 2022
Volume:	1.326 ml +/- 23 ul
Suspension media:	Buffered saline solution
Sterilisation method:	Gamma Irradiation.

(Counts (Method Ref: CG014)	Mean (i)	St.Dev.(ii)	Expanded Uncertainty(iii)
Cryptosporidium count	200	2.0	5.1
<i>Giardia</i> count	202	3.9	8.6
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:	10 May 2022
Purification method:	Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism:	Giardia lamblia
Strain:	H3
Source:	Gerbil
Shed date:	09 June 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

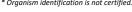
Stability testing has been conducted on batch ESCG100-32 of EasySeed[™] at 4 months and 12 days. EasySeed[™] with an assigned property value in terms of its known count value is used as a quality control reference material. This CRM has been produced by flow cytometry and is traceable to natural numbers.

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



Certificate of Analysis

Batch Number: B 754



Storage and Handling: Store EasySeed[™] at 2-8°C.

Description:

EasySeed[™] contains non viable precise known counts of *Cryptosporidium and Giardia*.

Intended Use:

EasySeed[™] is a biological certified reference material containing a precise number of non-viable *Cryptosporidium* and *Giardia*. It is designed for use as a quantitative quality control sample.

Instructions for Use: (refer to the corresponding Product Insert for more details)

Seeding the sample (use one tube of EasySeed[™])

- 1. Remove and keep the tube cap.
- 2. Add 2mL 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 3mL 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 fluorescent *Cryptosporidium* and *Giardia* detected.
- 11. Calculate the *Cryptosporidium* and *Giardia* recovery using the following formulae:-

Cryptosporidium Recovery (%) = <u>Cryptosporidium detected x 100</u> number of Cryptosporidium in EasySeed[™] as per Certificate of Analysis

Giardia Recovery (%) = <u>Giardia detected x 100</u> number of Giardia in EasySeed™ as per Certificate of Analysis

Safety information:

EasySeed[™] 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:

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Lucy Millican Quality Manager 30 June 2022





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