EasySeed™

Certificate of Analysis

Certified Reference Material Data

Batch Number: B 692

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: ESCG100, ESCG100-5
Production Date: 6 February 2020
Expiration Date: 18 June 2020
Volume: 1.289 ml +/- 27 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:**	**98**	**1.6**	**4.3**
***Giardia* count:**	**99**	**1.3**	**4.4**

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: 15 January 2020
Purification method: Discontinuous sucrose and cesium chloride centrifugation gradients.

Stock specifics*

Organism: *Giardia lamblia*
Strain: H3
Source: Gerbil
Shed date: 15 January 2020
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=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 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 (%) =**
Cryptosporidium detected x 100
number of *Cryptosporidium* in EasySeed™ as per Certificate of Analysis

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

Lucy Millican

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