Vitroids™

Certified Reference Material for Microbiology

Produced in double accredited laboratory fulfilling ISO/IEC 17025 and ISO Guide 34

Certificate of Analysis

This certificate is designed in accordance with ISO Guide 31 [1].

Product Name:	**Pseudomonas aeruginosa**
Product Number:	**RQC12003-10EA**
Lot:	**LRAA8016**
Expiration Date:	December 31, 2018
Storage Conditions:	Store at -20℃
Biosafety Level:	2
Color of discs:	Red
Passages:	2

Certified values and uncertainties:

Enumeration medium / method	Medium / kit supplier	Procedure	Number of colony forming units (cfu)	
			Certified value I)	Expanded Uncertainty II)
Cetrimide Agar (CET)	Sigma-Aldrich 22470	A)	**13**	**2.79**
Tryptic Soy Agar (TSA)	Sigma-Aldrich 22091	B)	**64**	**8.06**
Tryptic Soy Agar by Membrane Filter (TSA-MF)	Sigma-Aldrich 22091	C)	**30**	**6.82**

Procedures:

A) The test values were obtained from undiluted discs by placing the disc onto the agar plate (see below), leaving to rehydrate (10 to 15 minutes), spreading the resultant drop formed with a loop, and incubating under aerobic conditions at 37.0±0.5 °C for 24±2 hrs on Cetrimide Agar (Sigma 22470).

B)The test values were obtained from undiluted discs by placing the disc onto the agar plate (see below), leaving to rehydrate (10 to 15 minutes), spreading the resultant drop formed with a loop, and incubating under aerobic conditions at 37.0±0.5 °C for 24±2 hrs on Tryptic Soy Agar (Sigma-Aldrich 22091).

C) The test values were obtained from diluting the disc in 100mL of buffer water, filtering and incubating under aerobic conditions at 37.0±0.5 °C for 24±2 hrs on Tryptic Soy Agar (Sigma-Aldrich 22091).

This certified reference material was designed, produced and verified for accuracy and stability in accordance with ISO/IEC 17025 [2] and ISO Guide 34 [3].

I) The certified value represents the unweighted mean cfu per disc value from a statistically relevant number of samples covering the entire production lot. The characterization uncertainty μ(characterisation) represents the dispersion of measurement values, calculated as standard deviation.

II) The combined standard uncertainty, μ(CRM), is calculated as the square root of the sum of squares of the individual contributions, according to: $\mu_{CRM} = \sqrt{\mu_{char}^2 + \mu_{\text{hom}\,ogeneity}^2 + \mu_{stability}^2}$

The expanded uncertainty, U(CRM) is reproted at the 95% confidence level with a coverage factor k=2: U(CRM) = μ(CRM) * k.

ANAB ACCREDITED ISO GUIDE 34 REFERENCE MATERIAL PRODUCER

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

SIGMA-ALDRICH®
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Passages: 2

Description:
Vitroids™ are disc-shaped, microbiological reference materials. Each disc contains a quantified number of microorganisms (colony forming units; cfu), immobilized in a solid water soluble matrix. The discs are sensitive to moisture and supplied in airtight polypropylene tubes containing a dessicant tablet in the cap.

Intended use:
Vitroids™ are suitable for quality controls of culture media, antibiotics, disinfectants, for process and internal quality controls, for food, beverage and environmental testing, as well as for method development and validation in general.
The discs can be used in combination with any medium suitable for the microorganism provided in Vitroids™ disc format and with any volume; however, please note, the certified colony forming units (cfu) value is method and media specific. If Vitroids™ are to be used for media and methods other than those stipulated above in the certified values section, you are advised to calibrate the discs for the conditions in your own laboratory.

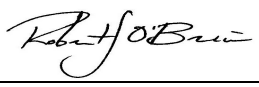
Storage and handling:
Store the Vitroids™ tubes unopened at -20°C until final use. (Once a tube has been opened, the enclosed disc should be used within 30 days).
Vitroids™ are water soluble and therefore easily reconstituted:
1) Remove the tube(s) to be used from the freezer and allow the disc(s) to reach ambient temperature (5 to 10 minutes) before use. Do not refreeze, and use the disc(s) within one hour of transfer to ambient temperature.
2) Open the tube and remove the Vitroid™ by inverting the tube over the medium to be used. Vitroids™ can be re-hydrated on solid medium or in liquid medium or buffer, respectively. Please do not re-hydrate the discs directly in distilled water. Instead, re-hydrate in a small volume of buffer (e.g. maximum recovery diluent), and transfer the entire volume into distilled water.
3) Leave at room temperature to re-hydrate (for 10 to 15 minutes) and ensure that the disc is completely dissolved.
4) Solid media: spread the resulting drop with a loop over the entire plate. Liquid media: mix thoroughly.
5) Test and incubate the sample in accordance with routine enumeration procedures.

Stability:
Long term stability is analyzed by re-testing samples stored at the recommended storage temperature every 4 months over the entire shelf life using the same methods as mentioned in the certified values section. Short term stability is analyzed by the simulation of product shipment at elevated temperatures. The uncertainty related to the stability of the product, μ(stability) is comprised of the uncertainty of short term stability and the uncertainty of long term stability and an integral part of the expanded uncertainty stipulated in the certified values section.

Homogeneity:
Homogeneity is tested and confirmed by analysis of a statistically relevant number of samples covering the entire production lot by means of statistical models (e.g. ANOVA). The uncertainty related to the homogeneity of the product, μ(homogeneity) is an integral part of the expanded uncertainty value stipulated in the certified values section.

Hazardous information:
Please refer to the Safety Data Sheet (available online: http://go.sigmaaldrich.com/vitroids).

References:
[1] ISO Guide 31, Reference materials - Contents of certificates and labels
[2] ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
[3] ISO Guide 34, General requirements for the competence of reference material producers
[4] ISO 7218, Microbiology of food and animal feeding stuffs - General requirements and guidance for microbiological examinations



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