



REFERENCE MATERIAL CERTIFICATE



A2LA Accredited
Reference Material Producer
Certificate Number 3189.03

This certificate supersedes all previous issues.

Product Name FM0031 Gram +ve Daily Control

Batch Number RM5197

Hazard Information This material contains micro-organisms. Please take suitable precautions at all times when handling this reference material. Please download Safety Data Sheet via below link:
[SDS Microbiological Reference Material](#)

Description of the Material Generic powder

Presentation

Number of Units provided:	Each set is heat sealed in a plastic bag
Each unit consists of:	Five (5)
Units are contained in:	10-12 g
	Plastic sachet

Target Organism Content

Organism Name (IFM Number)
Bacillus cereus (1600)
Lactiseibacillus rhamnosus (1504)
Staphylococcus aureus (3004)

<i>Intended Use</i>	Microbiological Reference Material
<i>Instructions for Use</i>	<p>Store unopened material at 3 °C - 5°C protected from light until used. Use aseptic technique at all times.</p> <p>Accurately weigh a minimum of 10 g of powder and prepare a working solution using Peptone Water or Butterfields Solution. While the most common dilution is 1:10, any ratio can be used to yield desired counts. The presented powder is ready-to-test as presented.</p> <p>Once prepared, materials must be stored between 3 °C - 5°C protected from light. Mix thoroughly before testing to resuspend settled product. Materials must only be used on the day of preparation.</p> <p>Values quoted in this certificate do not apply when the reference material is used in a manner contrary to the instructions. Values quoted have been statistically verified using the instructions described above. The specified volume in the instructions is the minimum sample size required to yield the defined quantitative parameters.</p>
<i>Date of Certification</i>	November 28, 2024
<i>Certificate Expiry</i>	February 26, 2025 This material will be recertified after this expiry date.
<i>Product Expiry</i>	March 31, 2025

Certified values and their uncertainties

Data was log transformed prior to applying statistical processes. The assigned value is the average of results on the declared day of test. The uncertainty of the assigned value is the largest standard error of each conducted test series. The lower limit takes into account the expected decline of the microbe levels over the certification interval. These have been calculated using all factors as described in ISO 17034.

Tests were conducted on: November 18, 2024
5 replicate data points were used to generate this certificate

Results are expressed as cfu/g of material that is "ready-to-test".

Test Name (Method Reference)	Assigned Value	Uncertainty of the Assigned Value (log)	Standard Deviation (log)	Calculated Limits for Daily Control Purposes	
				High limit	Low limit
Bacillus (IFM0719.2)	2.6E+04	0.02	0.05	9.1E+04	6.4E+03
Coag +ve Staph (IFM0716.1)	1.4E+02	0.06	0.13	3.2E+02	3.5E+01
Lactic (IFM0710.3)	8.3E+03	0.06	0.14	9.8E+04	5.0E+02
SPC (IFM0701.3)	1.5E+04	0.03	0.06	3.5E+04	4.3E+03

Additional Test Comments/Information

*Test Names marked with an * are not within the scope of accreditation*

Authorised By

Trevor Rumbekuan, Production Officer

Control Chart for:

Bacillus (IFM0719.2)

Certification Date: 28/11/2024

Expiry: 26/02/2025

CRM Solution Preparation Date	Test Date	Details of settings / dilutions	Media Name and Batch / Method details	Date / Initials	Count obtained	less than	6364	to	23277	to	40191	to	57104	to	74017	to	90931	more than	90931	FM0031 Gram +ve Daily Control	
						6365	23278	40192	57105	74018	90931	RM5197									
																				Date / Initials	
Assessed and reviewed by:			Comments:																		

Control Chart for:

Coag +ve Staph (IFM0716.1)

Certification Date: 28/11/2024

Expiry: 26/02/2025

CRM Solution Preparation Date	Test Date	Details of settings / dilutions	Media Name and Batch / Method details	Date / Initials	Count obtained	less than	35	to	92	93	to	148	149	to	205	206	to	262	263	to	319	more than	319	FM0031 Gram +ve Daily Control
																								Date / Initials
Assessed and reviewed by:			Comments:																					

Control Chart for:

Lactic (IFM0710.3)

Certification Date: 28/11/2024

Expiry: 26/02/2025

less than	502	
503	to	20066
20067	to	39630
39631	to	59193
59194	to	78757
78758	to	98321
more than	98321	

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CRM Solution Preparation Date	Test Date	Details of settings / dilutions	Media Name and Batch / Method details	Date / Initials	Count obtained									

Assessed and reviewed by:

Comments:

Control Chart for:

SPC (IFM0701.3)

Certification Date: 28/11/2024

Expiry: 26/02/2025

CRM Solution Preparation Date	Test Date	Details of settings / dilutions	Media Name and Batch / Method details	Date / Initials	Count obtained	less than	4317	4318	to	10488	10489	to	16660	16661	to	22831	22832	to	29002	29003	to	35173	more than	35173	FM0031 Gram +ve Daily Control	
																										Date / Initials
Assessed and reviewed by:			Comments:																							