Inter-laboratory Quality Control Material Data Sheet

GP Batch: 16846-QC-PR12334 **Product Type: Freeze Dried Vial + Butter**

Issue Date: 2 September 2025 **Expiry Date:** 12 March 2028

Test Name	n Values	Assigned Value	Assigned Value Log $_{10}$	Assigned Range
APC Aq (cfu/g)	21	2100	3.33	1200 - 3900
C P Staph Count Aq (cfu/g)	14	260	2.42	120 - 580
Coliforms Count Aq (cfu/g)	23	320	2.50	160 - 610
E coli Count Aq (cfu/g)	17	350	2.55	240 - 530
EB Count Aq (cfu/g)	9	320	2.51	210 - 510
Yeasts&Moulds Count Aq (cfu/g)	19	1000	3.00	590 - 1700

** n Values < 8 are indicative only and should be used with caution*

Intended Use: For use as a control sample for routine laboratory testing of Freeze Dried Vial + Butter

Description: Freeze dried pellet in a 5 ml glass vial with accompanying matrix

Homogeneity: This QC material has been assessed as homogeneous for use in an Inter-Laboratory Proficiency Study

Stability: An expiry period consistent with the shelf life of the product, experience, and technical advice has been applied

Storage: Store sample frozen. Once opened the samples should be discarded

Values: The *Assigned Value* is the consensus mean from an inter-laboratory proficiency round. The *Assigned Range* is 2 standard deviations of *n*. This assigned value and the associated assigned range have been back transformed from log $_{10}$ data with outliers removed; therefore the Assigned Range is asymmetrical and is the range in which 95% of results are expected to lie. *n Values* is the number of results used to calculate both the Assigned Value and Range.

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Instructions for testing Microbiological Quality Control Materials (QCMs)

A **Safety Data Sheet** may be obtained by accessing the Global Proficiency website (www.global-proficiency.com) and going to “QUICKLINKS” on the home page. Here you will find a link to “Chemwatch Safety Data Sheets”. Clicking on this link takes you to “OUTBACK” where you can select “Microbiological SDS” in the left-hand panel to source the SDS applicable to the samples you have ordered. **Please note:** If you are not located in New Zealand, please select your country by clicking on the flag at the top of the OUTBACK page - this ensures the legislation relevant to your country appears in the SDS and also translates the document to the main language of your country. We strongly encourage you to download and read the SDS prior to testing.

1. Remove the vial from the freezer and allow to equilibrate to room temperature for 15 minutes.
2. Re-hydrate each freeze-dried vial by adding 3.0 mL of sterile diluent e.g. (0.1% (w/v) peptone and 0.85% (w/v) NaCl (ISO 6887-1)) at room temperature.
   Please note: Global Proficiency strongly recommends the use of this maximum recovery diluent containing both peptone AND saline to ensure full recovery of the lyophilized microorganisms.
3. Allow standing at room temperature for 10 minutes.
4. While the rehydrated vial is standing at room temperature, use your normal sampling & testing procedures to prepare the sample homogenate:
   - **Butter (via the aqueous phase method)** - weigh **50 g** of butter base product into **42 mL** of sterile diluent.
5. After 10 minutes mix the rehydrated vial contents using a vortex mixer (or shake 25 times in about 7 seconds). It is recommended that a settling period of 30 seconds is allowed to ensure froth is not incorporated into the testing volume.
6. Add **1 mL** of the rehydrated vial to your sample homogenate of butter that has been prepared in step 7. Ensure the 1 mL of the rehydrated vial is added ***prior*** to melting in the water bath to avoid potential adherence of the vial contents to the upper fat layer.
   Note - *butter is usually weighed into a glass bottle or similar.*
7. Melt the test homogenate of butter in water bath as per your normal test procedure. Thoroughly mix the test homogenate during melting; allow the homogenate to settle (do not exceed time recommended by the method), then test from the aqueous (bottom) phase. The sample homogenate should be referred to as 10^0.
8. Prepare appropriate ten-fold dilutions and test as instructed in the test method you are following. Compare results to the Assigned Values and Ranges.

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