

Certificate of Analysis

Multi-Organism Microgel Flash™ CRM

Catalog Number: FM-750

Lot Number: 260205

Manufacture Date: 02/05/2026

Certification Date: 02/18/2026

Expiration: 02/29/2028

Matrix: Flash Pellet

Storage: -20°C to -10°C

Hazards: Infectious

90 mL hydration in Butterfield's Buffer:

<u>Analyte</u>	<u>Certification Method</u>	<u>Certified Activity</u> (CFU/mL)	<u>Confidence Limits</u> (CFU/mL)
Aerobic Count	(1) AOAC 990.12, Petrifilm® AC	486 ± 108	243 - 730
Total Coliform	(2) AOAC 991.14, Petrifilm® E.coli/Coliform Count	130 ± 27	65 - 195
<i>E. coli</i>	(3) AOAC 991.14, Petrifilm® E.coli/Coliform Count	52 ± 10	26 - 78
<i>S. aureus</i>	(4) AOAC 2001.05, Petrifilm® Staph-Express	184 ± 35	92 - 275
Yeast	(5) AOAC RI 121301, Petrifilm® Rapid Yeast/Mold	144 ± 29	72 - 216
Mold	(5) AOAC RI 121301, Petrifilm® Rapid Yeast/Mold	59 ± 11	29 - 88
Enterobacteriaceae	(6) AOAC 2003.01, Petrifilm® Enterobacteriaceae	129 ± 28	64 - 193
<i>Bacillus cereus</i>	(7) Spiral plate count, MYP agar	22 ± 2	11 - 33

Certified Activity: Certified activity is based upon internal analysis with $n \geq 10$.

Confidence Limits: Provided as a guide and represent $\pm 50\%$ of the certified activity

Uncertainty: The \pm uncertainty associated with the certified activity is the expanded uncertainty at 95% confidence interval (CI) with $K=2$. This expanded uncertainty incorporates contributions from manufacturing, homogeneity, and stability.

Packaging and Storage: This certified reference material (CRM) is a lyophilized pellet packaged under vacuum in a 5 mL glass vial. This CRM must be re-hydrated and analyzed in its entirety for certified activity and associated uncertainty to be applicable.

Must store unopened at -20°C to -10°C. Activity, uncertainty, and stability is based upon this storage temperature.

Intended Uses: validation of media performance, verification of analyst performance, validation of analytical methods, detection limit studies, daily control chart preparations, preparation of working level reference materials (check standards)

Traceability Information:

Strain Source Materials: The cultures used to manufacture this CRM were sourced from the Public Health of England. The organisms used are *E. coli* (NCTC 9001), *K. oxytoca* (NCTC 8167), *S. aureus* (NCTC 6571), *C. albicans* (NCPF 3255), *A. brasiliensis* (NCPF 2275), and *B. cereus* (NCTC 2599) passaged no more than twice from the primary culture. These organisms, combined at their specific activities, yield the values listed above by the listed methods.

Glassware: All glassware used in the manufacture of our CRMs is Class A. An in-house standard operating procedure is used to verify all glassware prior to it being placed into service. Volumetric pipetors are calibrated every four months by an ISO 17025 accredited calibration laboratory.

Homogeneity: This CRM was thoroughly mixed during production. Batch homogeneity was verified through analysis of samples chosen at random. Results of homogeneity testing confirm no statistically significant pellet to pellet variation.

Stability/Expiration: The stability of this CRM is based on short-term and long-term monitoring of the certified activity. The expiration date is guaranteed to be valid from the manufacture date when stored unopened at -20°C to -10°C and is based on results of long-term monitoring.

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Certification Methods:

- (1) Aerobic count was determined after hydration in 90mL Butterfield's Buffer buffer with a 1 mL inoculum on Petrifilm® Aerobic Count Plates with 48 hour incubation at 35°C.
- (2) Coliform count was determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on Petrifilm® E. coli/Coliform Count Plates with 24 hour incubation at 35°C.
- (3) *E. coli* count was determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on Petrifilm® E. coli/Coliform Count Plates with 48 hour incubation at 35°C.
- (4) *S. aureus* was determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on Petrifilm® Staph-Express plates with a 24 hour incubation at 35°C.
- (5) Yeast and Mold were determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on Petrifilm® Rapid Yeast and Mold Count Plates with a 2 day incubation at 26°C.
- (6) Total Enterobacteriaceae was determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on Petrifilm® Enterobacteriaceae Count Plates with a 24 hour incubation at 35°C.
- (7) *B. cereus* was determined after hydration in 90 mL of Butterfield's buffer with a 1 mL inoculum on MYP agar with a 24 hour incubation at 30°C.

While this CRM may be utilized with other approved analytical methods, results may differ from those determined during our certification process.

Instructions For Use:

Allow no more than 30 minutes to elapse from the completion of hydration and introduction of sample to media.

1. Retrieve a sample from the freezer and allow the capped sample vial to equilibrate to room temperature (15-30°C). This should take about 15 minutes.
2. Retrieve a 90 mL vial of Butterfield's buffer. Once the sample is at room temperature, open the sample vial and aseptically transfer the pellet to the hydration fluid.
3. Once the transfer is complete, cap the hydration fluid vial and mix by inversion several times.
4. Full dissolution will take less than 5 minutes.

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