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Certificate of Analysis

Universal Microbe CRM for Environmental Applications

Catalog Number: MIC-UNV
Lot Number: 251021
Manufacture Date: 10/21/2025
Certified Date: 11/6/2025

Expiration: 10/31/2027
Matrix: Microgel Flash Pellet
Hazards: Infectious
Storage: -20 to -10°C

Analyte	Strain #	Method	Certified Activity (MPN or CFU/pellet)	Confidence Limits (MPN or CFU/pellet)
Escherichia coli [1]	NCTC 9001	Colilert® Quanti-Tray®	874 ± 103	437 - 1312
Total Coliform [2]	NCTC 9001/NCTC 8167	Colilert® Quanti-Tray®	1668 ± 237	834 - 2502
Total Coliform [3]	NCTC 9001/NCTC 8167	SM9222B	1300 ± 232	650 - 1950
Fecal Coliform [4]	NCTC 9001	Colilert-18® Quanti-Tray®	802 ± 139	401 - 1203
Pseudomonas aeruginosa [5]	NCTC 12951	Pseudalert® Quanti-Tray®	475 ± 74	238 - 713
Enterococcus faecalis [6]	NCTC 775	Enterolert®	870 ± 164	435 - 1305
Heterotrophic Plate Count [7]	NCTC 775	Simplate®	5840 ± 933	2920 - 8760

Certified Activity: Certified activity is based upon internal analysis with n≥10.

Confidence Limits: Provided as a guide and represent ± 50% of the certified activity.

Uncertainty: The ± 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)

Instructions For Use

Do not open the sample vial until the entire COA has been reviewed. 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). Do not open vial until equilibration is complete. This should take about 15 minutes.
2. Retrieve a 99-100 mL vial of sterile water or phosphate 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, shake gently to dissolve. Full dissolution will take no more than 5 minutes.
4. Mix by inversion, this is your sample for analysis.
5. This CRM has been formulated at high activity levels to allow for use with multiple methods and/or dilution factors. To prepare samples of lower activity, prepare dilutions such as 1:4 or 1:10 from the original 100 mL hydration.

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Traceability Information:

Strain Source Materials: This multiorganism CRM was cultured from *E. coli* NCTC 9001, *K. oxytoca NCTC 8167*, *P. aeruginosa* NCTC 12951, and *E. faecalis* NCTC 775 sourced from PHE in the UK. All are single passes from the primary culture. The associated ATCC number is provided, if available, for informational purposes.

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.

Certification Methods:

[1] *Escherichia coli* MPN was determined after hydration in 99 mL of sterile deionized water when prepared according to instructions and analyzed by IDEXX Colilert® QuantiTray® with 24 hour incubation at 35°C. Units are in MPN/100 mL.

[2] Total coliform MPN was determined after hydration in 99 mL of sterile deionized water when prepared according to instructions and analyzed by IDEXX Colilert® QuantiTray® with 24 hour incubation at 35°C. Units are in MPN/100 mL.

[3] Total coliform CFU was determined after hydration in sterile deionized water and analyzed by SM9222 with membrane filtration on mENDO agar with a 24 hour incubation at 35°C. Units are in CFU/100 mL.

[4] Fecal coliform MPN was determined after hydration in 99 mL of sterile deionized water when prepared according to instructions and analyzed by IDEXX Colilert®-18 Quanti-Tray® incubated at 44.5°C in a circulating water bath for 18 hours. Units are in MPN/100 mL.

[5] *P. aeruginosa* MPN was determined after hydration in 99 mL of sterile deionized water when prepared according to instructions and analyzed by IDEXX Pseudalert® Quanti-Tray® with 24 hour incubation at 38°C. Units are in MPN/100 mL.

[6] *E. faecalis* MPN was determined after hydration in 99 mL of sterile deionized water when prepared according to instructions and analyzed by IDEXX Enterolert® Quanti-Tray® with a 24 hour incubation at 41.0°C. Units are in MPN/100 mL.

[7] Heterotrophic Plate Count MPN was determined after hydration in 99 mL of sterile deionized water and subsequently prepared and analyzed according to the instructions for IDEXX Simplate® Multi-Dose with a 48 hour incubation at 35.0°C. Note: Certified in units MPN/mL, activity was ammended to represent MPN/100 mL for harmonization purposes.

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

Quanti-Tray®, Colilert®, Colilert®-18, Pseudalert®, Simplate®, and Enterolert® are registered trademarks of IDEXX Laboratories, Inc.

Homogeneity: This CRM was thoroughly mixed during production. Batch homogeneity was verified through analysis of samples chosen at random. The entire sample must be hydrated and not subdivided prior to hydration.

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

Jasmine Bellamy

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Hunter Fazler

Hunter Fazler, Quality Assurance Lead