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Certificate of Analysis

E. coli, Total Coliform, and Fecal Coliform CRM

Catalog Number: 9001L
Lot Number: 210428
Manufacture Date: 4/28/2021
Certified Date: 5/25/2021

Expiration: 04/30/2023
Matrix: Flash Pellet
Hazards: Infectious (See MSDS)

Analyte	Strain #	ATCC #	Certified Activity (MPN or CFU/100 mL)	Acceptance Limits (MPN or CFU/100 mL)
Escherichia coli (MPN) [1]	NCTC 9001	11775	120 ± 14	26 - 582
Total Coliform (MPN) [1]	NCTC 9001	11775	120 ± 14	25 - 597
Fecal Coliform (MPN) [2]	NCTC 9001	11775	78 ± 15	13 - 494
Escherichia coli (MF) [3]	NCTC 9001	11775	124 ± 23	31 - 624
Total Coliform (MF) [3]	NCTC 9001	11775	124 ± 23	42 - 300
Fecal Coliform (MF) [4]	NCTC 9001	11775	62 ± 11	11 - 398

Packaging and Storage

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

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.

Precautions: Microbiological Reference Materials are designed for use for quality control in appropriately equipped microbiology laboratories by trained personnel. These reference materials contain viable microorganisms and should be handled according to appropriate biosafety level guidelines and disposed of according to applicable biohazard disposal regulations.

Principle, Explanation, & Reagents

This E. Coli, Total Coliform, and Fecal Coliform certified reference material (CRM) is a dehydrated pure culture of the organism produced by a proprietary process that yields stable, reliable, and cost effective samples that are homogenous and quantifiable. It is a lyophilized sample that must be rehydrated prior to use. Microorganism suspensions preserved by our process retain their viability, biochemical profile, and susceptibility patterns. The ingredients used to prepare the suspension preserve the microorganisms for use when needed. When rehydrated, the samples are ready for immediate use. Inactive ingredients may include: Albumin, Gelatin, Dextrose, Glycerol, Na-L-Ascorbate, Mannitol, Skim Milk, Trehalose, TSB, Na-L Glutamate, Sucrose, Page's Saline.

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 approximately 15 minutes.
2. Retrieve a 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 10 minutes.
4. This is your sample for analysis. Analyze according to your usual laboratory procedures.

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Traceability Information

Strain Source Materials: This CRM was cultured from E. coli, NCTC 9001, sourced from PHE in the UK. It is a single pass from the primary culture. It is a single organism CRM evaluated for three common environmental test parameters. 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.

Certified Activity and Acceptance Limits: Certified activity and acceptance limits are based upon internal analysis with n≥10 with acceptance limits set at 3 standard deviations around the mean. Acceptance limits are provided for informational purposes only.

[1] For Escherichia coli and Total Coliform (MPN), n=10 was analyzed using IDEXX Colilert® QuantiTray® with a 24 hour incubation at 35°C.

[2] For Fecal Coliform (MPN), n=5 was analyzed using IDEXX Colilert®-18 Quanti-Tray® with an 18 hour incubation at 44.5°C in a circulating water bath.

[3] For Escherichia coli and Total Coliform (MF), n=5 was analyzed by SM 9222B plate count on mENDO agar with 24 hour incubation at 35°C.

[4] For Fecal Coliform (MF), n=5 was analyzed by SM 9222D plate count on mFC agar with a 24 hour incubation at 44.5°C in a circulating waterbath.

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

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

Intended Uses

- Validation of media performance
- Validation of analytical methods
- Preparation of working level reference materials, i.e. "check standards"
- Verification of analyst performance
- Detection limit studies

Uncertainty

The ± uncertainty associated with the certified concentration is the expanded uncertainty at 95% confidence interval (CI) with K=2. This expanded uncertainty incorporates contributions from manufacturing, homogeneity, and stability.

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 -10°C to -20°C and is based on results of long-term monitoring.

Lauren Deese

Lauren Deese, Microbiology Technical Manager

Mark Hammersla

Mark Hammersla, President