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Certificate of Analysis

E. coli , Total Coliform, and Fecal Coliform CRM

Catalog Number: 9001L
Lot Number: 230418
Manufacture Date: 04/18/2023
Certified Date: 4/28/2023

Expiration: 4/30/2025
Matrix: Flash Pellet
Hazards: Infectious (See MSDS)

Analyte	Strain Designations	Certified Activity	Uncertainty	Standard Deviation	Acceptance Limits
		---------units are MPN or CFU/100 mL---------			
E. coli (MPN) [1]	NCTC 9001 ATCC 11775 WDCM 00090	182	22	25	108 - 256
Total Coliform (MPN) [1]		182	22	25	108 - 256
Fecal Coliform (MPN) [2]		107	19	23	37 - 177
E. coli (MF) [3]		183	26	34	81 - 284
Total Coliform (MF) [3]		183	26	34	81 - 284
Fecal Coliform (MF) [4]		102	18	25	26 - 178

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

Acceptance Limits: Acceptance limits are established around the certified activity and represent ± 3 log standard deviations from the results of competent laboratory participants in accredited PT studies conducted by NSI Lab Solutions.

Uncertainty: The ± uncertainty associated with the certified activity is the expanded uncertainty at 95% confidence interval (CI) with K=2 in Butterfield's buffer. 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.

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.

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.

Certification Methods:

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

[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

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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