

Certificate of Analysis

E. coli, Total Coliform, and Fecal Coliform CRM

Catalog Number: 9001H
Lot Number: 260323
Manufacture Date: 03/23/2026
Certified Date: 04/02/2026

Expiration: 03/31/2028
Matrix: Flash Pellet
Hazards: Infectious
(See MSDS)

<u>Analyte</u>	<u>Strain Designations</u>	<u>Certified Activity</u>	<u>Uncertainty</u>	<u>Standard Deviation</u>	<u>Confidence Limits</u>
-----units are MPN or CFU/100 mL-----					
<i>E. coli</i> (MPN) ¹		1529	180	417	764 - 2293
Total Coliform (MPN) ¹		1529	180	417	764 - 2293
Fecal Coliform (MPN) ²	NCTC 9001	931	175	151	465 - 1396
<i>E. coli</i> (MF) ³	ATCC 11775	1310	203	132	655 - 1965
Total Coliform (MF) ³	WDCM 00090	1310	203	132	655 - 1965
*Fecal Coliform (MF) ⁴		295	50	93	148 - 443

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 $K=2$ 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.

Catalog Number: 9001H

Lot Number: 260323

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.

***Corrected Standard Deviation and Uncertainty values for analyte Fecal Coliform(MF) -JAB 5/14/26**

Jasmine Bellamy

Jasmine Bellamy, Microbiology Production Manager

Hunter Fazler

Hunter Fazler, Quality Assurance Lead