nsi lab solutions
protect more. test more.
7212 ACC Blvd. | Raleigh, NC 27617 | 800.234.7837

Certificate of Analysis

Pathogen Cocktail CRM

Catalog Number: FM-715
Lot Number: 250622
Manufacture Date: 06/23/2025
Certified Date: 07/09/2025

Expiration: 6/30/2027
Matrix: Flash Pellet
Hazards: Infectious
(See MSDS)

Analyte	Strain Designations	Certified Activity	Uncertainty	Standard Deviation	Confidence Limits	Combined Confidence Limits
		---------units are CFU/pellet---------				
E. coli O157:H7	NCTC 12900 ATCC 700728	25020	1917	2944	12510 - 37530	
Listeria monocytogenes	NCTC 7973 ATCC 35152	23760	3204	4872	11880 - 35640	39420 - 118260
Salmonella enterica	NCTC 6676 ATCC 49215	30060	2574	4055	15030 - 45090	

Certified Activity: Certified activity is based upon internal analysis with n≥5.

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 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 O157:H7, Listeria monocytogenes, and Salmonella enterica certified reference material (CRM) is a dehydrated pure culture of the organisms 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 an appropriate volume of hydration fluid (ex. sterile DI water, butterfields buffer 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.

nsi lab solutions
protect more. test more.
7212 ACC Blvd. | Raleigh, NC 27617 | 800.234.7837

Catalog Number: FM-715
Lot Number: 250622

Traceability Information:

Strain Source Materials: This CRM was cultured from S. enterica (NCTC 6676), L. monocytogenes (NCTC 7973), and E. coli O157:H7 (NCTC 12900) 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:

For S. enterica, E. coli O157:H7, and L. monocytogenes, the mean of the data set with n≥5 was determined by spiral plating on selective agar and incubating for 24-48 hours at 35°C.

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

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.

Jasmine Bellamy

Jasmine Bellamy, Microbiology Production Manager

Hunter Fazler

Hunter Fazler, Quality Assurance Lead