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分析证明书

埃氏、总大肠菌群、耐热（粪）大肠菌群 质控样

产品编号： 9001H
产品批号： 220509
生产日期: 5/9/2022
分析日期: 5/26/2022

保质期： 2023-11-30
基质： 速溶片
危害： 感染，详见MSDS

项目	Strain#	ATCC#	确认值 MPN(CFU)/100mL	接受区间 MPN(CFU)/100mL
大肠埃希氏菌（MPN）- 酶底物法	NCTC 9001	11775	1452 ± 171	318 - 7013
总大肠菌群（MPN） - 酶底物法	NCTC 9001	11775	1452 ± 171	296 - 7201
耐热大肠菌群（MPN） - 酶底物法	NCTC 9001	11775	630 ± 199	106 - 3994
-	-		±	
大肠埃希氏菌（MF） - 滤膜法	NCTC 9001	11775	1313 ± 202	331 - 6632
总大肠菌群（MF）- 滤膜法	NCTC 9001	11775	1313 ± 202	447 - 3191
耐热大肠菌群（MF） - 滤膜法	NCTC 9001	11775	691 ± 115	121 - 4467

包装及保存

样品必须-10℃ ~ -20℃密封保存。活性、不确定度、稳定性均基于此保存条件设置
该标准物质密封在玻璃瓶中，水解后使用。样品一次整片使用，不可分割使用

注意： 该标准物质用于微生物实验室（具有专业人员及设备）的质量控制。该标物含微生物，操作及弃置应当依照适当的生物安全等级操作指南及微生物危害弃置管制措施。

使用说明

由于微生物的敏感性及水化后只能短时间保存（不超过30分钟），请务必阅读全部的配制说明后再开始操作，请严格按照配制说明操作，以确保微生物可用

1， 回温至室温（15-30℃）（该过程需要15分钟），在回温至室温前不要打开样品瓶，湿气可能损害样品片，影响回收率
2， 一旦至室温，打开样品瓶，将样品片转入99mL无菌缓冲液中（直接倒入或者用无菌镊子）
3， 盖上盖子轻轻震荡水解瓶，在室温条件下水解不超过10分钟（水解过程需震荡以加速溶解）。确认样品片水解完全。翻转10次混合均匀，所得即为要分析的溶液
4， 以贵实验室常规步骤分析

原则、解释、试剂

该标物为脱水产品，经过适当程序制备。稳定、可靠、可量化、均匀且价廉使用前必须水解，依照提供的程序保存，可保持可用性，生化轮廓及敏感性。需要时需用到非活性物质。水解后立即使用。非活性物质可能包括：白蛋白，明胶.....

溯源

原料：原料为埃氏菌 NCTC 编号 9001, 提供ATCC编号（如有），用以评价三种常见环境微生物参数检测
玻璃器皿： 此样品配制过程中涉及的所有玻璃器皿为 A 级. 所有玻璃器皿启用前经过内部标准操作程序校验。移液器按17025认证要求每月校准一次。
确认值 及 接受范围： 确认值基于实验室内部多次（n）测量的平均值，接受范围基于3倍标准偏差设置
1.埃氏菌及总大肠杆菌(MPN), n=10
2. 耐热（粪）大肠菌群 (MPN), n=5
3. 埃氏菌及总大肠杆菌 (MF), n=5
4.耐热（粪）大肠菌群 (MF), n=5
该标物可用于其他方法检测，结果可能有所不同

用途

▪ 验证介质性能 ▪ 质控考核 ▪ 检测极限研究 ▪ 验证分析方法 ▪ 配制工作标准

不确定度

不确定度为 95%置信区间扩展系数 K=2.

均匀性

该标物生产过程中已充分混匀. 批次均匀性按要求随机取样分析建立。该样品必须整体水解，不可分割使用

稳定性/保质期

该标物稳定性基于短期及长期对确认浓度的监测结果。保质期基于 -10 ～ -20°C 保存条件下，长期监测结果，确保保质期内有效

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Certificate of Analysis

E. coli, Total Coliform, and Fecal Coliform CRM

Catalog Number: 9001H
Lot Number: 220509
Manufacture Date: 5/9/2022
Certified Date: 5/26/2022

Expiration: 11/30/2023
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	1452 ± 171	318 - 7013
Total Coliform (MPN) [1]	NCTC 9001	11775	1452 ± 171	296 - 7201
Fecal Coliform (MPN) [2]	NCTC 9001	11775	630 ± 199	106 - 3994
Escherichia coli (MF) [3]	NCTC 9001	11775	1313 ± 202	331 - 6632
Total Coliform (MF) [3]	NCTC 9001	11775	1313 ± 202	447 - 3191
Fecal Coliform (MF) [4]	NCTC 9001	11775	691 ± 115	121 - 4467

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.

Catalog Number: 9001H
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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.

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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