上海育惠原化学有限公司
地址：上海嘉定工业区叶城路 1630 号 7 幢 2595 室
QQ：2447084087，微信：anacrm
Website: www.anacrm.com

分析证明书

菌落总数 质控样

产品编号：HPCQC　　保质期：　2023-10-31
产品批号：　220410　　危险性：感染

项目	确认值 (MPN or CFU/mL)	接受区间 (MPN or CFU/mL) 供水　/　污水
异养物 - IDEXX simplate	167 ± 15	58 - 123　/ 75 - 258
异养物 - 平皿计数法	166 ± 33	98 - 206 / 20 - 312

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

该有证标准物质为5mL玻璃瓶真空封装的快速冻干样，需水解使用. 该标准物质必须整片分析，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

在认真阅读本COA前切勿打开样品.稀释后仅有30分钟的分析时间

1，　冰箱取出，回温15分钟至室温.。其他准备就绪前勿打开样品，潮气可能破坏样品。
2，　样品一旦回温至室温, 打开样品转移至99mL缓冲液中. 该过程可以用无菌镊子夹取或直接倒入
3，　一旦转移完成，盖紧瓶盖，回旋震荡以使样品5分钟内完全水解
4，　上下翻转10次混匀， 所得即为要分析的溶液
5，　浏览证书浓度，根据分析方法确定是否需要稀释

原则、解释、试剂

该菌落总数标准物质是一个有机物脱水产品，该产品具有稳定的，均匀，可信赖，经济实惠等特点，该标准物质 是 脱水干燥产品， 必须水解使用。 我们的程序过程使微生物悬浮液保持可显性，生化性，及感受性。为使该样品水解并保存特性供立即使用，用到的非活性原料成分可能包括：白蛋白，明胶，葡萄糖，甘油，Na-L-抗坏血酸，甘露糖醇，脱脂乳，海藻糖，TSB，Na-L-谷氨酸盐，蔗糖，佩吉盐等

溯源、用途、不确定度、均匀性、稳定性、保质期

见英文证书

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Certificate of Analysis

HPC Control CRM

Catalog Number: HPCQC
Lot Number: 220410
Manufacture Date: 4/10/2022
Certified Date: 4/21/2022

Expiration: 10/31/2023
Matrix: Flash pellet
Hazards: Infectious

Analyte	Strain #	ATCC #	Certification Method	Certified Activity CFU or MPN/mL	Acceptance Limits(cfu or MPN/mL) CFU or MPN/mL	
					2*SD	3*SD
Heterotrophic Organisms [1]	NCTC 775	19443	IDEXX Simplate® (MPN/mL)	167 ± 15	106 - 227	75 - 258
Heterotrophic Organisms [2]			Plate Count (CFU/mL)	166 ± 33	68 - 264	20 - 312

Packaging and Storage

Sample vial must be stored unopened at -20°C to -10°C. Activity, uncertainty, and stability are based upon this storage temperature.

The Heterotrophic Plate Count CRM is a lyophilized quick dissolve sample packaged in a 5 mL glass vial under vacuum that must be rehydrated prior to use. This CRM must be 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.

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 about 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 transfer the pellet to the hydration fluid. This transfer may be performed with sterile tweezers or simply by inverting the open sample vial over the hydration fluid.

3) Once the transfer is complete, cap the hydration fluid vial. Swirl the sample to dissolve. Full dissolution should take no longer than 5 minutes.

4) Mix by inversion several times. This is your sample for analysis.

5) Review certified activity to determine if a dilution of the hydrated sample is required for your method. Analyze according to your usual laboratory procedures.

Principle, Explanation, & Reagents

This HPC standard 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 dried 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.

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Catalog Number: HPCQC
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Traceability Information

Strain Source Materials: This CRM was cultured from E. faecalis, NCTC 775, sourced from PHE in the UK. It is no more than three passes from the primary culture. It is a single organism CRM evaluated for one common environmental test parameter: Heterotrophic Organisms. 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 limits set at 2 or 3 standard deviations around the mean. You should choose which limits meet your rrequirements.

[1] HPC, the mean of the data set with n≥10 was 280 MPN/mL with standard deviation of 37 MPN/mL when prepared according to and analyzed by IDEXX Simplate® with 48 hour incubation at 35°C.

[2] For HPC using plate count agar, the mean of the data set with n=5 was 344 CFU/mL with standard deviation of 23 CFU/mL when prepared according to instructions.

While this CRM is applicable to other analytical methods, results may differ from those determined during our certification process.

Simplate® a registered trademark of IDEXX Laboratories, Inc.

Intended Uses

- Validation of media performance
- Validation of analytical methods
- Verification of analyst performance
- Preparation of working level reference materials, i.e. "check standards"
- 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 -20°C to -10°C and is based on results of long-term monitoring.

Lauren Deese

Lauren Deese, Microbiology Technical Manager

Mark Hammersla

Mark Hammersla, President