ERA

A Waters Company

Instructions for Catalog # 084
Heterotrophic Plate Count

Revision 061715

Description:

- This standard consists of one glass vial containing one gelatin tablet and a desiccant pouch. The bacteria are contained in the gelatin tablet. One sterile, 100 mL hydrating fluid is also provided.
- The glass vial containing the bacteria should be stored at 4±2°C.
- The hydrating fluid can be stored at room temperature.
- This product is intended to be used as a quality control check of the entire analytical process for the analytes/matrix included in the standard.
- ERA suggests that when subsampling this product prior to analysis you use a minimum sample size of at least 0.2 mL. Using a smaller sample size may invalidate the assigned value and/or uncertainty shown on the certificate of analysis.
- The hydrated sample contains Heterotrophic bacteria at 5 to 500 CFU/mL and/or 5 to 500 MPN/mL.

Helpful Hints:

- The bacteria are in a lyophilized form in the gelatin tablet and each standard must be hydrated per the following instructions prior to analysis.
- ERA recommends that the quality control guidelines in *Standard Methods for the Examination of Water and Wastewater*, Section 9020B be followed to determine media acceptability prior to analysis.
- "EPA strongly recommends that laboratories evaluate the false-positive and false-negative rates for methods they use for monitoring coliforms… with the intent that if the method they choose has an unacceptable false-positive or false-negative rate, another method can be used." – 40 CFR 141.21 F.3.12
- As this standard (once hydrated) contains living organisms, it must be analyzed **immediately** following hydration. Certified values on samples not analyzed immediately after hydration cannot be guaranteed.

Instructions:

1. Remove the vial from refrigeration and allow to warm to room temperature.
2. Carefully open the hydrating fluid that has been stored at room temperature.
3. Open the bacteria sample vial and aseptically transfer the gelatin tablet into the hydrating fluid.
4. Properly dispose of the empty glass vial and desiccant pouch.
5. Reseal the bottle that now contains the bacteria sample.
6. With the bottle tightly closed, shake the sample for a few seconds. Observe the sample to confirm that the gelatin tablet has dissolved. If the tablet has not completely dissolved, shake for a few more seconds.
7. Analyze the inoculated sample using your normal procedures.

Safety:

- ERA products may be hazardous and are intended for use by professional laboratory personnel trained in the competent handling of such materials. Responsibility for the safe use of these products rests entirely with the buyer and/or user. If you need a Material Safety Data Sheet for any ERA product, please call toll free at 1-800-372-0122.
- **ERA Microbiology standards contain live microorganisms** and should be used only by individuals with bacteriological training.
- Properly disinfect any spills and sterilize used containers by autoclaving before disposal.

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Certificate of Analysis

Product: Heterotrophic Plate Count
Catalog Number: 084
Lot No. S268-084
Issue Date: January 7, 2019
Expiration Date: [1] 02/2020
Revision Date: Orginal

Product use instructions are included as part of the certification packet and are paginated separately from this Certificate of Analysis. Please reference the product use instructions for catalog #084 revision 061715.

Certification

Parameter	Certified Value[2]	Uncertainty[3]	QC Performance Acceptance Limits™[4]	PT Performance Acceptance Limits™[5]
Heterotrophic Plate Count	**CFU/mL**		**CFU/mL**	**CFU/mL**
Heterotrophic Bacteria	257	-14%, +16%	184 - 361	140 - 472
Heterotrophic Plate Count (MPN)	**MPN/mL**		**MPN/mL**	**MPN/mL**
Heterotrophic Bacteria	193	-23%, +30%	105 - 357	69.1 - 541

Analytical Verification

Parameter	Certified Value	Proficiency Testing Study[6] Mean Recovery	%	n	Organism Identification[7]
Heterotrophic Plate Count	**CFU/mL**	**CFU/mL**			
Heterotrophic Bacteria	257	257	100%	27	Kocuria rhizophila, NCIMB 8553
Heterotrophic Plate Count (MPN)	**MPN/mL**	**MPN/mL**			
Heterotrophic Bacteria	193	193	100%	15	Kocuria rhizophila, NCIMB 8553

1. The certified values are monitored and purchasers will be notified of any significant changes resulting in recertification or withdrawal of this certified reference material during the period of validity of this certificate.

2. The Certified Values for this sample are the mean reported concentrations for these analytes from ERA's proficiency testing study.

3. The stated uncertainty is the total propagated uncertainty at the 95% confidence interval. This is represented as a percentage above and below the certified value. This uncertainty is based on analytical verification of this product by ERA using common analytical methods for the quantitative evaluation of microbiological samples, multiplied by a coverage factor which is equal to the Student t factor at a 95% confidence interval at n-1 degrees of freedom. The uncertainty applies to the product as supplied and does not take into account optional dilutions and/or preparations the laboratory may perform while using this product.

4. The QC Performance Acceptance Limits (QC PALs™) are based on actual historical data collected in ERA's Proficiency Testing program. The QC PALs™ reflect any inherent biases in the methods used to establish the limits and closely approximate a 95% confidence interval of the performance that experienced laboratories should achieve using accepted environmental methods. Use the QC PALs™ to realistically evaluate your performance against your peers.

5. The PT Performance Acceptance Limits (PT PALs™) are calculated using the regression equations and fixed acceptance criteria specified in the USEPA National Standards Criteria Document and/or the NELAC proficiency testing requirements. Use the PT PALs™ when analyzing this QC standard alongside USEPA and NELAC compliant PT standards. Please note that many PT study acceptance limits are concentration dependent (some non-linearly) and, therefore, the acceptance limits of this QC standard and any PT standard may differ relative to their difference in concentrations.

6. The Analytical Verification data include the mean value, percent recovery and number of data points reported by the laboratories in our Proficiency Testing study compared to the Certified Values.

CFU = Colony Forming Units.

MPN = Most Probable Number.

7. In order to assure identity and traceability, reference cultures used for these quality control samples come from a recognized national collection. These organisms meet all requirements specified in the NELAC proficiency testing requirements.

If you have any questions or need technical assistance, please call 1-800-372-0122 or email info@eraqc.com.

Certifying Officer: Brian Miller

ACCREDITED

REFERENCE MATERIAL PRODUCER
CERT # 1539.03

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