

Instructions for Catalog # 080C Potable Water Coliform MicrobE™

Revision 061715

Description:

- This set of standards consists of ten glass vials (Sample 1 through Sample 10) each containing one gelatin tablet and a desiccant pouch. The bacteria are contained in the gelatin tablet. Ten sterile, 100-mL hydrating fluids are also provided with each set.
- The glass vials containing the bacteria should be stored at $4\pm2^{\circ}$ C.
- The hydrating fluid can be stored at room temperature.
- Various aspects of this proficiency testing scheme may be subcontracted. When subcontracting occurs, it is performed by a competent subcontractor and ERA is responsible for subcontracted work.

Before you begin:

- The bacteria are in a lyophilized form in the gelatin tablets and each sample must be rehydrated per the following instructions prior to analysis.
- The hydrating fluids provided are <u>not</u> intended to be used as sample test vessels. The containers with hydrating fluid are provided for the purpose of creating the samples. Using these containers may present difficulty when interpreting sample results for some tests. ERA would suggest transferring the sample to your routine sample containers to avoid misinterpretation of results.
- 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 negative rates for method(s) they use for monitoring total coliforms . . . with the intent that if the method they choose has an unacceptable false-positive or negative rate, another method can be used." 40 CFR 141.21 f.3.12
- To avoid reporting any false positive results, follow the coliform verification steps as indicated in the method you are using. Both typical and atypical colonies need to be verified.
- This standard contains viable microorganisms and should be analyzed **immediately** after being hydrated.
- You must report values for Total Coliforms, Fecal Coliforms and E. coli for each analyte that you are seeking accreditation. We are not allowed to assume, for example, that if you reported a sample as Fecal Coliform positive that you also intended to report the same sample as Total Coliform positive.

Instructions:

- 1. Remove the vials from refrigeration and allow them to warm to room temperature.
- 2. Carefully open the hydrating fluid that has been stored at room temperature.
- 3. Open the appropriate bacteria sample vial and aseptically transfer the gelatin tablet into the hydrating fluid bottle
- 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. Prepare all ten samples as above.
- 8. Analyze the inoculated samples using your normal procedures.
- 9. Report your results as presence or absence based on the 100 mL samples prepared.
- 10. Remember to report results for Total Coliforms, Fecal Coliforms and E. coli for each sample if you are seeking accreditation for all analytes.

Safetv:

- 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.

LIMITED USE LABEL LICENSE

PLEASE READ THIS AGREEMENT.

THIS LIMITED USE LABEL LICENSE ("LULL") IS BETWEEN ENVIRONMENTAL RESOURCE ASSOCIATES, INC. ("ERA"), AND YOU (THE "END USER"). THIS LULL GOVERNS THE TERMS UNDER WHICH THE END USER MAY PURCHASE OR OTHERWISE OBTAIN PRODUCTS ("PRODUCTS") FROM ERA PURSUANT TO THIS LULL. THE PRODUCTS INCLUDE CERTAIN MATERIALS OWNED BY A THIRD PARTY ("LICENSOR") WHICH HAS GRANTED A LICENSE TO ERA FOR THE PURPOSE OF THIS LULL. ERA IS WILLING TO GRANT END USERS THE RIGHT TO PURCHASE AND USE THE PRODUCTS ONLY IF THE END USER ACCEPTS ALL OF THE TERMS OF THIS LULL.

IF YOU ARE ACTING ON BEHALF OF A CORPORATION OR OTHER ENTITY, THEN YOU REPRESENT THAT YOU HAVE THE AUTHORITY TO ENTER INTO THIS LULL ON BEHALF OF THAT CORPORATION OR ENTITY. IN SUCH EVENT, "YOU" REFERS TO YOUR CORPORATION OR ENTITY. BY ACCESSING AND USING THE PRODUCTS, THE END USER ACKNOWLEDGES THAT THE END USER HAS READ THIS LULL, UNDERSTANDS IT, AND AGREES TO BE BOUND BY IT. IF THE END USER DOES NOT AGREE TO ANY OF THE TERMS IN THIS LULL, THE END USER SHOULD NOT UTILIZE THE PRODUCTS.

- 1. SCOPE OF USE. You may only use the Products provided to you for the purpose of carrying out a proficiency testing program in your laboratory. The Products are not intended for use in humans. End User agrees that Products designated as Biosafety Level 2 or 3 constitute known pathogens and that other Products not so designated and may be pathogenic under certain conditions. End User assumes all risk and responsibility in connection with the receipt, handling, storage, disposal, transfer and use of the Products including without limitation taking all appropriate safety and handling precautions to minimize health or environmental risk. End User agrees that any activity undertaken with the Products will be conducted in compliance with all applicable guidelines, laws and regulations.
- 2. RESTRICTIONS. End User may not use, copy, modify or transfer the Products, to others in whole or in part except as expressly provided in this LULL. The Products contain trade secrets and intellectual property of ERA and the Licensor, and the End User may not reverse engineer, replicate, alter, or tamper with the Products, or authorize any third party to do any of the foregoing. The rights granted hereunder to the End User are personal to the End User, and any attempt by the End User to transfer any of the rights, duties, or obligations hereunder is void and shall terminate this LULL. An End User may not rent, lease, loan, resell for profit, or distribute the Products, or any part thereof in any way.
- 3. OWNERSHIP. The Products are the property of ERA. The Products are provided to the End User for use only under the terms of this LULL, and ERA and the Licensor reserve all rights not expressly granted to the End User.
- **4. TERMINATION.** This LULL will terminate immediately without notice to the End User if the End User breaches a term of this LULL, or if the End User does not pay ERA, any amounts owed by End User. Further, in the event of a termination or expiration of any agreement between ERA and the Licensor on all or a part of the Products, the End User's right to access and use the Products may also terminate or expire.
- 5. WARRANTY DISCLAIMER. THE PRODUCTS SHALL BE COVERED BY THE APPLICABLE ERA STANDARD WARRANTY, A COPY OF WHICH IS SUPPLIED WITH THE PRODUCTS OR UPON REQUEST. NO OTHER WARRANTIES ARE PROVIDED BY ERA OR THE LICENSOR OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TYPICALITY, SAFETY, ACCURACY, AND NON-INFRINGEMENT. END USER'S REMEDIES UNDER ERA WARRANTY ARE LIMITED TO REPAIR OR REPLACEMENT OF THE PRODUCT THAT FAILED TO CONFORM TO ERA'S APPLICABLE STANDARD WARRANTY PROVIDED THAT SUCH FAILURE IS REPORTED TO ERA WITHIN FIVE WORKING DAYS OF END USER'S RECEIPT OF THE PRODUCT.
- **6. COMPLIANCE WITH LAW.** END USER IS SOLELY RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE FOREIGN AND DOMESTIC, FEDERAL, STATE, AND LOCAL STATUTES, ORDINANCES, AND REGULATIONS.
- 7. EXPORT LAW. The Products are subject to U.S. export control laws and may be subject to export or import regulations in other countries. End User shall not to export the Products under any circumstances whatsoever. In any case, the End User will indemnify and hold ERA, its affiliated companies, and the Licensor harmless from any and all claims, losses, liabilities, damages, fines, penalties, costs and expenses (including attorney fees) arising from, or relating to, any breach by the End User of the End User's obligations under this section.
- 8. LABORATORY QUALIFICATION ASSURANCE. The microorganisms and subsequent growth on culture media deriving from the Products, are considered to be bio-hazardous. Government agencies do regulate the disposal of these materials. By entering into this LULL, End User confirms that its laboratory procedures comply with the handling and disposal of these bio-hazardous materials, and that End User's laboratory staff is qualified and properly trained to receive, process and store lyophilized microorganisms. End User acknowledges that the lyophilized microorganisms are for in-vitro use only and are to be used according to their intended use.
- 9. INDEMNIFICATION. End User hereby agrees to indemnify, defend and hold ERA, its affiliated companies, and the Licensor harmless against any third party claims, losses, expenses, and damages (including reasonable attorney's fees) arising out of or relating to the use, receipt, handling, storage, transfer, disposal and other activities related to the Products. Any resolution of a claim subject to this indemnification agreement will be subject to written consent by ERA.
- 10.LIMITATION OF LIABILITY. IN NO EVENT WILL ERA, OR THE LICENSOR BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES OF ANY KIND IN CONNECTION WITH OR ARISING OUT OF THIS LULL OR PRODUCTS (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, STATUTE OR OTHERWISE) EVEN IF ERA OR THE LICENSOR HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL ERA'S AND THE LICENSOR'S CUMULATIVE LIABILITY EXCEED THE FEES PAID BY END USER UNDER THIS LULL FOR THE TWELVE (12) MONTH PERIOD PRECEDING THE DATE OF THE EVENT GIVING RISE TO THE CLAIM. End User agrees that the limitations of liability set forth in this LULL shall apply even if a limited remedy provided hereunder fails of its essential purpose.
- 11.INTELLECTUAL PROPERTY. ERA and the Licensor shall retain ownership of their respective right, title and interest in the Products. The Products are subject to the restrictions noted in the "Scope of Use" section above. End User expressly acknowledges that ERA retains all right, title and interest in any trademarks registered or owned by ERA, the ERA trade name, and the ERA catalog marks. End User expressly agrees not to use any of ERA's trademarks, ERA's trade names, ERA's catalog marks, in any way without ERA's prior written agreement.
- 12.GOVERNING LAW. This LULL shall for all purposes be governed by and interpreted in accordance with the laws of the State of Colorado.
- 13.WAIVER. No failure to enforce any term of this LULL shall constitute a waiver of such term in the future.
- **14.ASSIGNMENT.** Neither this LULL nor any of the End User's rights or obligations hereunder may be assigned by the End User in whole or in part without the prior written approval of ERA. Any other attempted assignment shall be null and void.
- 15.SEVERABILITY. If any part of this LULL is for any reason found to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this LULL shall not be affected.
- 16.COMPLETE AGREEMENT. This LULL is the complete and exclusive statement of the agreement between ERA and the End User, and supersedes any proposal or prior agreement, oral or written, and any other communications between the parties in relation to the subject matter of this LULL. No waiver, alteration or modification of this LULL shall be valid unless made in writing and signed by ERA.