



## **Certificate of Analysis**

### **Prepared Media, Test Kits, and Reagents**

|                  |   |
|------------------|---|
| Product Name     | BNP RBA Kit   |
| Container Size   | 15X100mm nutrient plate, 15X100mm CA staining plate |
| Catalog #        | BNPRBA100   |
| TSA Lot #        | 2150021   |
| MTT Lot #        | MKBH0595V, 000331-24038                             |
| Agar Lot #       | 07M0551V  |
| Blood Lot#       | 143639-1  |
| Certificate Date | 01/21/2013  |

This product has been manufactured and packaged in accordance with Current Good Manufacturing Practices (cGMP) as specified in Title 21, Code of Federal Regulations (CFR), Part 820 "Quality System Regulation".

NanoLogix is registered with the US FDA as a medical device manufacturer.

Representative samples of this lot were tested and found to meet or exceed the performance criteria in the NanoLogix Quality Control Manual (NQCM) and the Clinical Laboratory Standards Institute (CLSI) performance standards in document M-22, "Quality Control for Commercially Prepared Microbiological Culture Media" when applicable.

### **Performance Testing**

| <b>Test Organism</b>            | <b>Strain Number</b> | <b>Results</b>           |
|---------------------------------|----------------------|--------------------------|
| <i>Klebsiella pneumoniae</i>    | ATCC® BAA-1144       | Growth/Positive Staining |
| <i>Streptococcus pyogenes</i>   | ATCC® 12344          | Growth/Positive Staining |
| <i>Streptococcus agalactiae</i> | ATCC® 12386          | Growth/Positive Staining |

ATCC® is a registered trademark of the America Type Culture Collection, Manassas, VA 20108, USA

Dilutions of the above challenge organisms were prepared according to guidelines described in the NQCM technical information sheet. Incubation temperature, atmosphere, and duration are appropriate to the individual test organism and are also described in NQCM.

### **Physical Characteristics**

Nutrient plate appearance: Cherry red, opaque; with no precipitate, chips, or debris. The outline of the membrane is visible. Consistency is firm, not soft.

CA staining plate appearance: Clear, slightly opalescent, yellowish green; with no precipitate, chips, or debris.

### **Product Expiration Date**

NanoLogix utilizes an innovative vacuum sealed packaging system that has proven to increase the shelf life and quality of our media based products. Third party testing is underway to determine product performance during storage conditions. Progress and results will be documented as they are available. Industry standard (90 day) expiration dates will be noted as a minimum shelf life until further testing results are available.

### **Limited Warranty**

The quality and performance of this product is warranted to meet the stated specifications and uses set forth in the labeling and product information sheets if used as intended, stored as directed, and used before the expiration date. NanoLogix's sole obligation under this limited warranty is for refund of the purchase price or replacement of any defective product, as determined by NanoLogix in its sole discretion.

The forgoing warranty shall commence on the date of delivery of each product to the initial purchaser from NanoLogix and expire six (6) months thereafter, except for products that are subject to an expiration date, in which case the period shall expire on the expiration warranty date of the product.

The foregoing warranty does not apply to any product which has been modified in any way by any purchaser or 3rd party and does not cover any defect, malfunction, or damage resulting from: 1) accident, neglect, or willful mistreatment of any product; 2) failure to properly store or handle any product; 3) failure to use, operate, service, or maintain any product in accordance with NanoLogix's applicable guidelines; and 4) failure to use or apply proper reagents or chemicals in or to any product. NanoLogix shall pay the costs of return shipment of defective product to NanoLogix that are actually and reasonably incurred by a purchaser with respect to any products replaced under this warranty.

Customers should inspect all incoming products carefully upon receipt and before use. If the product has been exposed to extreme temperatures or if the outer bag or container has been damaged in any way, product integrity and performance may be adversely affected and NanoLogix should be notified immediately.

**DISCLAIMERS: THE FOREGOING LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, EXPRESS, OR IMPLIED, INCLUDING ANY WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTIES OF MERCHANTABILITY.**

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John W. Tracy, Jr.  
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NanoLogix

