

Certificate of Analysis

Product Description: NATtrol™ Pneumonia Panel – Quantifiable Bacteria*
Catalog Number: NATPPQ-BIO
Lot Number: 321261
Expiration Date: 2019/04/23
Storage Temperature: 2-8°C

Contents:

<i>A. baumannii</i>	<i>K. pneumoniae</i> (KPC2)	<i>S. agalactiae</i>
<i>E. cloacae</i>	<i>K. pneumoniae</i> (OXA-48)	<i>S. aureus</i> (MRSA)
<i>E. coli</i>	<i>K. pneumoniae</i> (NDM-1)	<i>S. marcescens</i>
<i>H. influenzae</i>	<i>M. catarrhalis</i>	<i>S. pneumoniae</i>
<i>K. aerogenes</i>	<i>P. aeruginosa</i> (VIM-1)	<i>S. pyogenes</i>
<i>K. oxytoca</i>	<i>P. mirabilis</i>	Negative Control

Use Universal Precautions!

Product Description: NATtrol™ products are manufactured specifically for use as full process positive controls and calibrators in nucleic acid tests including PCR, TMA, Branched Chain DNA and other assays. NATtrol™ products are prepared from purified microorganisms that are grown in either cell culture, microbial culture or isolated from the plasma of infected individuals. Once purified, the microorganism is chemically and/or enzymatically treated to alter its surface proteins. This treatment results in a completely intact microorganism that is unable to bind, penetrate or infect a host cell. This particle while modified on its surface, still retains a complete genome, making it the ideal control for all steps of amplification assays.

Inactivation: All NATtrol™ microorganisms inactivated using a validated procedure.

Target Concentration: Real-time PCR assay used is qualitative.

Physical Analysis: Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods. Heat inactivated bovine based source materials used in the manufacture of this product meet applicable USDA requirements for abattoir sourced animals, traceability and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and post mortem at the abattoir as required by the USDA.

CAUTION: NOT FOR USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, quality assurance or further manufacturing use only. These products are NOT intended for use in the manufacturing or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

Statement of Conformance:

The results reported in this Certificate of Analysis have been certified by ZeptoMetrix's Quality Assurance department as accurately reflecting the data contained in the batch production and testing records.

*Pat.: <http://www.zeptometrix.com/patent-information/>