

Nucleic Acid Techniques – Bacterial Identification

The analytical method of Nucleic Acid Techniques (NAT) used to rapidly characterize bacteria species during in-process and release testing for drug product manufacturing is quickly and reliably replacing traditional compendial methods.

MicroSafe Services from Millipore provides a validated NAT method for bacterial identification based on recent advances in rapid, molecular-based sequencing technologies for accurate and specific screening and identification. This method can be applicable to all areas of your process where identification is necessary to assist with faster product release, further understanding of your process and implementation of corrective actions.

What Products Should be Tested?

Our method for bacterial identification is dependent on the product submitted to be tested. Please contact us so we can determine whether the method can be validated for your product.

Study Design

MicroSafe Services from Millipore uses the MicroSeq[®] RNA Gene Kit to identify thousands of bacterial species based on the sequence of their 16S ribosomal RNA rRNA genes. Genomic DNA extracted from bacteria is amplified using PCR and subsequently sequenced. Genomic DNA extracted

from bacteria is amplified using PCR and subsequently sequenced. The MicroSeq kit has been validated for:

- *Bacillus subtilis*
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Salmonella typhimurium*
- *Staphylococcus aureus*
- *Acholeplasma laidlawii*
- *Mycoplasma fermentans*
- *Mycoplasma hyorhinis*
- *Mycoplasma orale*
- *Mycoplasma synoviae*

Based on these results, the kit (PCR and Sequencing) is capable of identifying more than a thousand microorganisms.

Your
partner for
critical testing in
microbiology

Assay Duration: 2 days

Sample Type: Bacterial colonies of broth cultures

Sample Size: Bacterial colony or 0.5 mL broth

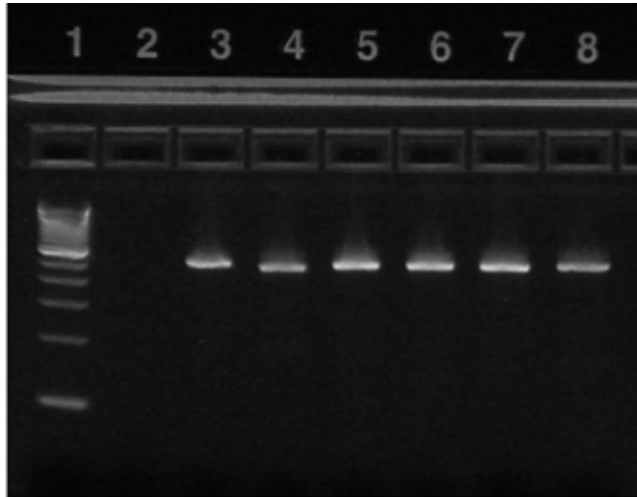


Figure 1. Example of PCR product formation.
Lane 1: DNA marker Lane 2: Negative template control
Lane 3: Positive microorganism

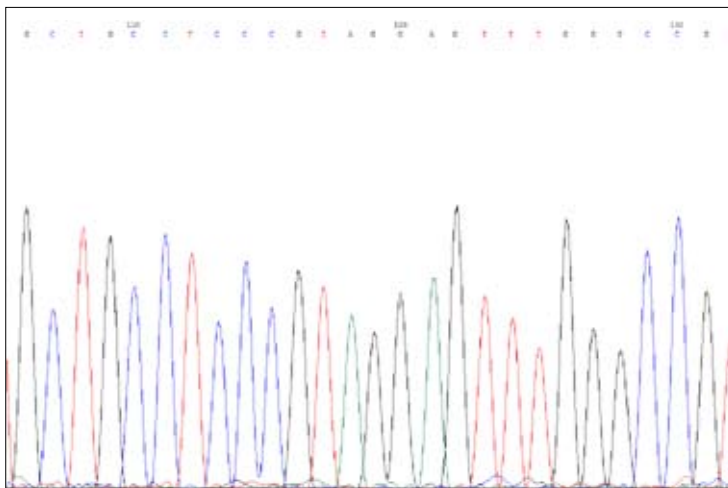


Figure 2: Part of a sequence of a microorganism.

Regulatory Compliance

- EP 2.6.21 Nucleic Acid Amplification Technique

Final Report

MicroSafe Services from Millipore can provide each client with the following final reports:

- GLP report that includes all raw data, protocol methods and final result.
- GMP report that includes a certificate of results.

Custom Assays

We understand that no production plant is identical and that every process is unique. Using a combination of practical experience and a scientific approach, we will customize bacterial identification testing methods to meet your specific requirements including scientifically sound data that will be accepted by regulatory authorities around the globe.

Your Partner in Microbiology

MicroSafe Services from Millipore delivers a complete range of critical testing and consultancy services for the development and production of biopharmaceuticals. Leaders in the field of microbiology including *in vitro* virology testing, our staff of accomplished scientists, engineers and microbiologists will help you meet your specific critical testing requirements throughout every phase of drug production. All testing is conducted under GMP and/or GLP certifications as well as our own internal quality system.

SAFETY RELIABILITY QUALITY CUSTOMER RELATIONSHIP FEEDBACK & SUPPORT

Let Us Be Your Critical Service Provider

For more information on our critical support services, please contact Millipore at:

MILLIPORE

Millipore is a registered trademark of Millipore Corporation. MicroSafe is a service mark of Millipore Corporation or an affiliated company.

MicroSeq is a trademark of Applera Corporation or its subsidiaries in the US and/or certain other countries.

Lit. No. SDS0001ENEU Rev. - 10/06 06-372
© 2006, Millipore Corporation, Billerica, MA 01821 U.S.A. All rights reserved.

Niels Bohrweg 11 – 13
2333 CA Leiden, The Netherlands
Tel: +31 71 523 1886
Fax: +31 71 523 5980
E-mail: ms_info@millipore.com
Web: www.millipore.com/microsafe