# STABILITY STUDY: Thermal Stress Validation

**Product(s)**: VITEK® 2 Gram Negative Susceptibility test kits
VITEK® 2 Gram Positive Susceptibility test kits
VITEK® 2 Streptococcus Susceptibility test kits
VITEK® 2 Fungal Susceptibility test kits
VITEK® 2 Identification test kits

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**Background**:

Shelf life for the aforementioned products is based on stability study results carried out in accordance with bioMérieux corporate guidelines. Internal corporate guidelines are based on FDA regulations 21CFR 211.166 (Stability testing), 21CFR 809.10 (Labeling for *in vitro* Diagnostics), FDA Guidance on Shelf Life of Medical Devices, Drug Stability and European regulation/standard prEN 13640. These studies were performed in real time on three lots by bioMérieux, Inc. Research & Development Microbiology and/or Industrialization during Thermal Stress Validation.

Stressed-product testing was performed to simulate extreme shipping and handling conditions that may occur during delivery. Stressed cards were tested at the regular shelf intervals to at least 9 or 18 months (depending on the shelf life of the product). All test kits for shelf life & thermal stress were kept at the recommended storage temperatures (2 - 8° C) prior to testing. The cards from shelf life testing served as the control for the stress testing. These studies confirm product performance is maintained until expiration date.

**Summary of Thermal Stress Validation**:

Thermal stress performance was tested at a minimum of four points 1) Initial, 2) early in shelf , 3) mid-point, 4) end point (expiration date). The testing has demonstrated the aforementioned test kits perform as expected when tested to the thermal stress conditions listed below,

| Temperature | Duration |
|---|---|
| < -5° C | 2 days |
| 18 - 25° C | 8 days |
| 35 - 39° C | 2 days |

**PLEASE NOTE**: This document in no way authorizes the storage of the aforementioned test kits at any other storage condition than is labeled on the product (2 - 8° C), nor does it authorize the use of the test kits beyond the expiration date. Testing was performed to simulate conditions that may occur during shipping.

On behalf of bioMérieux, Inc. Hazelwood, MO
Denise Johannesman –Director Quality Operations

Denise Johannesman 18 Mar 2013
Signature / Date

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**bioMérieux, Inc.**
595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700
http://www.biomerieux-usa.com