HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Safety Notice

## Medical Devices

# VITEK®2 Identification (ID) / Antimicrobial Susceptibility Test (AST) Cards

### Priority 2 – Warning

**HPRA Safety Notice: SN2019(04)** **Issue Date: 30th January 2019**

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|---|---|
| bioMerieux Inc | V38565 |

| ISSUE |
|---|
| The Health Products Regulatory Authority (HPRA) has been informed of an issue with VITEK®2 Identification (ID) / Antimicrobial Susceptibility Test (AST) Cards.<br><br>bioMérieux has determined that the integrity of the top seal of some VITEK®2 test cards may be compromised. A compromised top seal may lead to moisture ingress and antibiotic degradation (loss of potency).<br><br>A Field Safety Notice (FSN) has been issued advising customers of the issue and the appropriate actions to take. Please refer to the accompanying FSN for further information. |

| ACTION OR RECOMMENDATIONS |
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| The HPRA advises that users:<br><br>1. Refer to the accompanying FSN and follow the instructions provided by the manufacturer |

2. Forward a copy of this Safety Notice and the accompanying FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred
3. Report any adverse incidents associated with these devices to the manufacturer and the HPRA

## TARGET GROUPS

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|---|---|
| Chief Medical Scientists | Laboratory Technicians |
| Clinical Directors | Medical Scientists |
| Clinical Nurse Managers | Microbiologists |
| Hospital Managers / CEOs | Paediatric Consultants |
| Hospital Personnel | Private laboratory and testing facilities |
| Laboratory Managers | Purchasing / Supplies Managers |
| Laboratory Staff | Risk Managers |

## BACKGROUND

VITEK®2 test cards are used in conjunction with VITEK®2 instruments to assess microbial resistance/susceptibility to clinically relevant antibiotics.

bioMérieux has identified an issue with the integrity of the top seal that can allow moisture entry. The manufacturer has determined that a small section of the top seal may be improperly sealed for the card lots indicated. Moisture entry can lead to antibiotic degradation (loss of potency). The anticipated consequence would be elevated MIC results, or false resistant results, for some antimicrobials.

bioMérieux recommends performing a "tug test" prior to use, in order to determine whether the seal is intact. Only card lots pouched on Poucher (P1) are potentially affected. Please see the accompanying FSN for further details regarding the 'tug test'.

The HPRA is issuing this safety notice to raise awareness of this issue.

## MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

bioMerieux UK Ltd
Grafton Way
Basingstoke
RG22 6HY
United Kingdom

Telephone: +44-1-256-461-881
E-mail: uktechnical@biomerieux.com
Website: www.biomerieux.com

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:


Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Ireland

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie