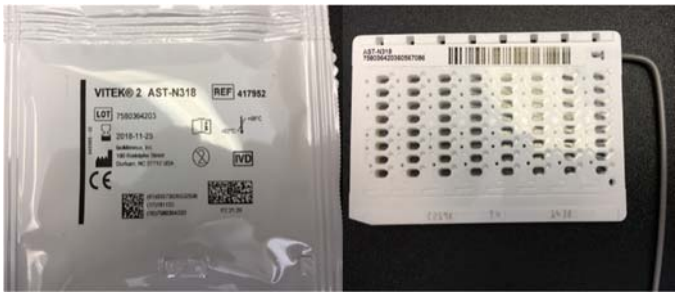
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

VITEK® 2 Identification / Antimicrobial Susceptibility Test Cards



Priority 2 – Warning

HPRA Safety Notice: SN2017(25) **Issue Date: 13th July 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
bioMérieux Inc	V31635

ISSUE

The Health Products Regulatory Authority (HPRA) has been informed of an issue in relation to VITEK® 2 Identification / Antimicrobial Susceptibility Test Cards.

The manufacturer has identified that the integrity of the white pouch containing the VITEK® 2 test cards may be compromised. A compromised test card pouch can lead to moisture entry which can impact the test card reagents and cause antibiotic degradation (loss of potency).

A Field Safety Notice (FSN) was issued in April 2017 advising customers of this issue. A follow-up FSN was issued in May 2017 advising that an additional lot is affected by this issue. Please refer to accompanying FSNs.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSNs and follow the instructions provided by the manufacturer.
2. Forward a copy of this Safety Notice and the accompanying FSNs to all relevant personnel within your organisation and to any organisation / person where these devices have been transferred.

3. Report any adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Chief Medical Scientists	Laboratory technicians
Clinical Directors	Microbiologists
Clinical Nurse Managers	Public and Private Hospitals
Hospital Managers / CEOs	Purchasing / Supplies managers
Hospital personnel	Private laboratory and testing facilities
Laboratory Managers	Risk Managers
Laboratory staff	

BACKGROUND

VITEK® 2 test cards are used in conjunction with VITEK® 2 instruments to assist in the identification of microbial agents and assess microbial resistance/susceptibility to clinically relevant antibiotics.

The manufacturer has indicated that some card pouches may exhibit a visual defect. As per the accompanying FSN, some pouches which passed visual inspection failed further integrity tests. Please refer to the accompanying FSNs for details of affected lots.

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

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

bioMérieux UK Ltd
Grafton Way
Basingstoke
RG22 6HY
United Kingdom

Telephone: + 44 1 256461 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

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