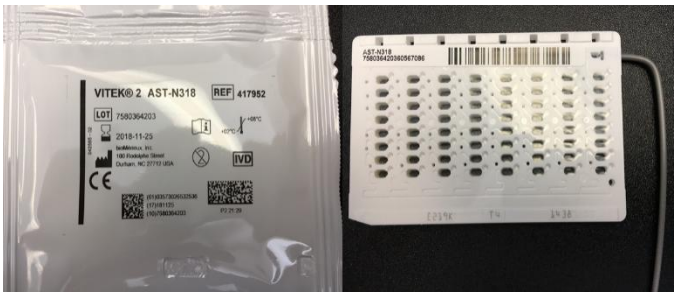
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

VITEK® 2 Gram-Negative AST cards

Priority 2 – Warning



HPRA Safety Notice: SN2017(27) **Issue Date: 14th July 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
bioMérieux Inc	V32121

ISSUE

The Health Products Regulatory Authority (HPRA) has been informed of an issue in relation to VITEK® 2 Gram-Negative AST cards.

The manufacturer has identified the potential for false susceptible colistin results to be generated. A false susceptible result could have a negative influence on the treatment decision as the incorrect drug may be chosen for therapy.

A Field Safety Notice (FSN) has been issued advising customers of the appropriate actions to take. Please refer to accompanying FSN.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

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

The manufacturer investigated VITEK® 2 Gram-Negative AST cards following a recent joint recommendation from EUCAST/CLSI. The manufacturer has identified a high rate of very major errors (false susceptible results) for colistin (cs01n) when compared to agar dilution and broth-microdilution.

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

Please note that this product is also affected by the issue identified in HPRA Safety Notice SN2017(25) issued on 13th July 2017.

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