HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

VITEK® 2 Gram-Positive Identification Test Kit

Priority 2 – Warning

HPRA Safety Notice: SN2017(35) **Issue Date: 26th October2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
bioMérieux Inc	V33032/V33570

ISSUE

bioMérieux issued a Field Safety Notice (FSN) in August 2017 advising users to refrain from using affected lots of this device. Please see accompanying FSN-1.

Following further investigation the manufacturer has recently issued a follow up FSN advising users that all impacted lots are acceptable for use provided additional actions are taken at a local level. Please refer to accompanying FSN-2 for further instructions.

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 those that need to be aware within your organisation or to any organisation / person to which/whom these devices have been transferred.
3. Acknowledge receipt of the FSNs if you have not already done so.
4. Report any adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

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

BACKGROUND

VITEK® 2 test cards are used in conjunction with VITEK 2 instruments to assist in the identification of microbial agents.

The manufacturer has identified the potential for the misidentification of organisms when using certain lots of this device. The manufacturer is providing users with additional advice enabling the continued use of the 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