HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

ETEST® Teicoplanin 256 (TP) SPB and Foam packaging

Priority 2 – Warning

HPRA Safety Notice: SN2017(44) **Issue Date: 21st December 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
bioMérieux Inc	V34163

ISSUE

The HPRA has been informed of an issue in relation to ETEST® Teicoplanin 256 (TP) SPB and Foam packaging products, Ref: 412461 and 522018.

The manufacturer has identified the potential for false susceptible Teicoplanin results to be generated for Coagulase Negative Staphylococci (CoNS). A false susceptible result could have a negative impact 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 for further information.

In relation to tests previously performed, as per the FSN bioMérieux Inc advise '*to identify any possible false Susceptible results that may have occurred, to analyze the related risks and to determine appropriate actions, if relevant*". This advice is applicable to results recently generated for both within and recently expired batches. Please note that the batches listed in the accompanying FSN are only those within expiry date.

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 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 events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Chief Medical Scientists	Medical Scientists
Clinical Directors	Microbiologists
Hospital Managers / CEOs	Public and Private Hospitals
Hospital personnel	Purchasing Managers
Laboratory Managers	Risk Managers
Laboratory staff	Supplies Managers
Laboratory Technicians	

BACKGROUND

ETEST® is used in conjunction with agar media to determine the minimum inhibitory concentration (MIC) of antimicrobial agents to specific microorganisms.

The manufacturer has identified an underestimation of MIC values by at least 1 dilution for CoNS. There is a risk of false susceptible results due to this underestimation.

The HPRA is issuing this safety notice to raise awareness of this issue. Please refer to the accompanying FSN for further information.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **distributor** 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

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