

Safety Notice

Medical Devices

ETEST® COLISTIN **Priority 2 – Warning**

HPRA Safety Notice: SN2016(25)

Issue Date: 15 August 2016

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
bioMerieux Inc	V28694

ISSUE

bioMerieux issued a field safety notice (FSN) in August 2016, advising of an issue whereby there is a potential hazard of obtaining a false susceptible result when ETEST COLISTIN strips are used in conjunction with some Mueller Hinton agars. The affected lots of ETEST COLISTIN available on the Irish market and within expiry are provided in the accompanying FSN. The manufacturer has indicated that these lots were placed on the Irish market from October 2011.

This issue does not apply to ETEST COLISTIN strips that are used for the susceptibility testing of *Enterobacteriaceae spp.*, when they are used in conjunction with Mueller Hinton-E agar (MH-E) agar manufactured by bioMerieux.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSN and follow the instructions provided.
2. For tests previously performed, customers should identify any possible false susceptible results, analyse the related risks and determine appropriate actions if relevant.
3. Forward a copy of this Safety Notice and the FSN to all relevant personnel.
4. Forward a copy of this Safety Notice and the FSN to any other persons/organisations where these devices have been transferred.
5. Report any concerns regarding this product (or any other medical device) to the HPRA.

TARGET GROUPS

Chief Medical Scientists
Clinical Directors
Hospital Managers / CEOs
Hospital personnel
Intensive Care Units
Hospital managers / CEOs
Microbiologists
Lab technicians

Laboratory Managers
Laboratory staff
Medical Scientists
Purchasing Managers
Supplies Managers
Risk Managers
Public and Private Hospitals

BACKGROUND

The FSN is being issued as a result of data generated to date from an ongoing investigation which was initiated after bioMerieux was alerted to a potential underestimation of the MIC values for *Enterobacteriaceae* and *Acinetobacter spp.* when ETEST COLISTIN strips are used.

Based on data available to date, bioMerieux has identified the following:

- The performance of ETEST COLISTIN strips is dependent on the Mueller Hinton agar used
- ETEST® COLISTIN strips performed well with *Enterobacteriaceae* spp. if used in conjunction with MH-E agar supplied by bioMerieux
- There is a potential for false susceptible results when ETEST COLISTIN strips are used in conjunction with some Mueller Hinton agars; this excludes *Enterobacteriaceae* spp. tested on MH-E agar supplied by bioMerieux

The manufacturer's investigations into this issue is currently ongoing and they have advised that the data provided in the FSN is preliminary. The HPRA is issuing this safety notice to raise awareness of this issue. We may provide an update in due course.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

bioMerieux UK Ltd
Grafton Way,
Basingstoke,
RG22 6HY,
United Kingdom

Telephone: + 44 1 256461 881
E-mail: UKVIGILANCE@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