

Safety Notice

Medical Devices

**ThermoScientific
Oxoid CAZ10
CEFTAZIDIME,
CT1629B
Priority 2 – Warning**

HPRA Safety Notice: SN2017(33)

Issue Date: 27th September 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Thermo Fisher Scientific / DCC Vital	V33196

ISSUE

The Health Products Regulatory Authority (HPRA) has been informed of a product removal for 12 lots of ThermoScientific™ Oxoid™ CAZ10 CEFTAZIDIME, CT1629B. The manufacturer has confirmed the potential for false resistant ceftazidime results to be reported.

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 users to:

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 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 FSN 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
Microbiologists
Laboratory technicians

Laboratory Managers
Laboratory staff
Medical Scientists
Private laboratory and testing facilities
Private hospitals
Purchasing / Supplies managers
Risk Managers

BACKGROUND

ThermoScientific Oxoid CAZ10 CEFTAZIDIME disks are used in antimicrobial susceptibility testing. The manufacturer has initiated a product recall for 12 lots of this device following identification of antibiotic degradation in lots stored at 8°C between 2 and 3 years of shelf life. The manufacturer has instructed users to destroy all impacted lots.

The manufacturer has advised that the need for a retrospective review should be determined by an appropriate technical expert.

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:

Thermo Fisher Scientific Microbiology
Wade Road,
Basingstoke,
Hants, RG24 8PW,
United Kingdom.

Telephone: +44-1-256-8411-14
E-mail: microbiology.techsupport.uk@thermofisher.com

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

DCC Vital,
South County Business Park,
Leopardstown,
Dublin 18,
Ireland.

Telephone: +353-1-290-7000
E-mail: quality@fannin.eu

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: +353-1-676-4971
Fax: +353-1-634-4033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie