IRISH MEDICINES BOARD

Notice Information: Medical Devices - Advisory 19 July 2004

Part 1. Product Information

a)	Title:	Commercial Automated Antimicrobial Susceptibility Tests and Disc Diffusion Tests for the Detection o
b)	Product Name/Type:	Commercial Automated Antimicrobial Susceptibility Tests and Disc Diffusion Tests for the Detection of VRSA (vancomycin-resistant Stapphylococcus aureus)
c)	Reference:	SN2004(05)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	Hospital CEO's; Risk Managers; Infection Control Managers; Medical Laboratory Managers; Microbiology Departments

Part 3. Problem/Issue

a)	Problem/Issue:	Inconsistent detection of vancomycin resistance by automated susceptibility systems have raised the concerns that additional vancomycin-resistant Stapphylococcus aureus (VRSA) infections may occur and be missed.

Part 4. Background Information

a)	Background Information:	The Food and Drud Administration (FDA) in the USA has become aware of an incident of VRSA from a patient in the USA, which brings the documented number of VRSA isolates to three. The investigation showed inconsistent detection of vancomycin resistance by commercial automated susceptibility system. This has raised the concern that additional VRSA infections may occur and be missed when these systems are been used for reporting Staphylococcus aureus resistance and susceptibility profiles. The FDA indicate that until automated and other commercial systems can be evaluated for reliability with relevant organisms, clinical laboratories performing such tests should be aware of this potential short coming of these systems and should use methods that have been shown to reliably detect the strains that have been described. The FDA recommends the use of non-automated Minimum Inhibitory Concentration (MIC) methods (e.g. broth microdilution or agar dilution) with a full 24-hour incubation before reading results. Please refer to: http://www.fda.gov/cdrh/oivd/letters/062904-vrsa1.html The IMB is currently in the process of investigating the impact of these findings on the Irish market. We are in the process of contacting the manufacturers of the affected systems: to determine what devices are on the Irish market to ensure that manufacturers advise their customers of this issue and provide clear guidance on the appropriate recommendations and actions to avoid potential problems.

Part 5. Action to be taken

a)	Action to be taken:	Ensure that all relevant laboratory staff is notified of this issue. Perform further confirmatory tests for suspected cases of VRSA. Contact the manufacturer of the automated system that is in use in your hospital and determine the action recommended by the manufacturer. Advise the manufacturer of any inconsistencies in the detection of VRSA that you have observed to date. Advise the IMB of the system that is in use in your hospital.

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a Medical Device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: vigilance@imb.ie Website: www.imb.ie SN2004(05): Commercial Automated Antimicrobial Susceptibility Tests and Disc Diffusion Tests for the Detection of VRSA

Part 7. Keywords

a)	Keywords:	Commercial Automated Antimicrobial Susceptibility Tests and Disc Diffusion Tests for the Detection of VRSA, vancomycin-resistant Stapphylococcus aureus