

20th December 2017

Advisory Notice – Staphylococcus + VRE (8-well) panel to be IVD marked

Dear AusDiagnostics Customers,

The Staphylococcus + VRE (8-well) panel will be IVD marked for use in Australia and Europe, and an IFU will be released to reflect these changes. Please find the Staphylococcus + VRE (8-well) product details below:

Staphylococcus + VRE (8-well)

Catalogue number of product: REF 21340 REF 01

Document ID of IFU: 21340r01

Regulatory status of updated product: IVD use in Australia and Europe

Assay	Sensitivity % (95%CI)	Specificity % (95%CI)
S.aureus	100.0 (96.8-100.0)	100.0 (95.6-100.0)
mecA	99.8 (98.4-100.0)	99.6 (97.6-100.)
vanA	100.0 (71.7-100.0)	100.0 (99.4-100.0)
vanB	100.0 (59.8-100.0)	100.0 (75.9-100.0)
E.faecium	100.0 (39.6-100.0)	100.0 (69.9-100.0)
E.faecalis	100.0 (90.2-100.0)	99.3 (98.3-99.8)

Effective date of change: 20th December 2017

Please don't hesitate to contact us on 02 96988030 or at support@ausdiagnostics.com if you have any further queries or require any assistance.