

20th December 2017

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

Dear AusDiagnostics Customers,

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

Staphylococcus + VRE (8-well)

Catalogue number of product: REF 21341 REF 02

Document ID of IFU: 21341r01

Regulatory status of updated product: IVD use in Europe only.

| Assay | Sensitivity % (95%CI) | Specificity % (95%CI) |
|---------------------------|-----------------------|-----------------------|
| RUO: Staphylococcus (tuf) | In progress | In progress |
| S.aureus | 100.0 (96.8-100.0) | 100.0 (95.6-100.0) |
| GseA | 100.0 (89.3-100.0) | 97.6 (93.6-99.2) |
| mecA | 99.8 (98.4-100.0) | 99.6 (97.6-100.) |
| Mec LGA251 | 100.0 (82.2-100.0) | 100.0 (97.4-100.0) |
| PVL | 100.0 (87.0-100.0) | 100.0 (97.3-100.0) |

*The Staphylococcus (tuf) assay is marked for performance evaluation use only (i.e. “RUO”) until sufficient clinical performance data has been obtained.

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.