

25th September 2017

Advisory Notice – CRE panel to be IVD marked

Dear AusDiagnostics Customers,

The CRE (16-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 CRE (16-well) product details below:

CRE (16-well)

Catalogue number of product: REF 21098 REF 02

Document ID of IFU: 21098r01

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

Assay	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)
pan-VIM	98.6% (91.3-99.9)	99.5% (98.5-99.8)
pan-IMP	100.0% (94.8-100.0)	99.7% (98.7-99.9)
KPC	98.0% (93.7-99.5)	99.8% (99.0-100.0)
NDM-1	98.1% (92.8-99.7)	100.0% (99.2-100.0)
IMI	100.0% (62.9-100.0)	99.7% (98.1-100.0)
SME	100.0% (31.0-100.0)	100.0% (98.6-100.0)
GES	100.0% (82.2-100.0)	100.0% (98.5-100.0)
GES (ESBL)	100.0% (19.8-100.0)	100.0% (98.6-100.0)
OXA-23 like	100.0% (83.4-100.0)	100.0% (97.3-100.0)
OXA-48 like	100.0% (94.2-100.0)	99.8% (98.4-100.0)
OXA-51 like	100.0% (78.1-100.0)	100.0% (96.1-100.0)
OXA-58	100.0% (5.5-100.0)	100.0% (96.6-100.0)
pan-CMY	96.9% (82.0-99.8)	100.0% (96.8-100.0)
CTX-M group 1	99.1% (94.6-100.0)	99.6% (97.3-100.0)
CTX-M group 9	100.0% (90.0-100.0)	100.0% (98.5-100.0)

Effective date of change: 29th September 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.