

18 May 2017

Advisory Notice – CSF Products IVD status updated

There will be a future update to a product you may order, and a new template and IFU will be released to reflect these changes. Please find the products, and details of the changes below:

CSF (16-well)

Catalogue number of product: REF 27050 REF 03

New Document ID of IFU: 27050r01

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

Reason/s for change(s):

- IVD marked for use in Australia and Europe
- New H.influenzae assay - developed to reduce the potential for false positive results
- H.influenzae, L.interrogans, and LMO assays have minimal validation data. Therefore these assays are for performance evaluation only (i.e. RUO) until sufficient clinical performance data has been obtained

Viral CSF (8-well)

Catalogue number of product: REF 27092 REF 01

New Document ID of IFU: 27092r03

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

Reason/s for change(s):

- CE IVD marked for use in Europe
- Update of performance data in IFU
- EBV target no longer RUO

Effective date of change: 31st May 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 with the update procedure.