

23rd August 2016

Product Change Notification

There will be a future update to a product you order. Please find the products, and details of the change below:

Name of products affected: Viral (8-well)

Catalogue number of product: REF 27093 VER 01

Regulatory status of the parechovirus assay in the product has been updated

New regulatory status: IVD use in Australia and European Union for Parechovirus. Hence all targets of this product are currently for IVD use in Australia and European Union

New IFU: 27093r02 (available online on our website: [http://www.ausdiagnostics.com/
http://www.ausdx.com/qilan/ADMMainGeneList.jsp?ProductID=1817&CatNo=2709301](http://www.ausdiagnostics.com/http://www.ausdx.com/qilan/ADMMainGeneList.jsp?ProductID=1817&CatNo=2709301))

Reason for change:

- More clinical data for Parechovirus has allowed us to IVD mark this assay:

	Parechovirus
True Positive	30
True Negative	175
Sensitivity %	88.2 (95%CI: 71.6-96.2)
Specificity %	98.3 (95%CI: 94.8-99.6)

Date effective of change: 23rd of August 2016

Please don't hesitate to contact us should you have any further queries or require any assistance with the update procedure.