

23rd August 2016

Product Notification

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

Name of product affected: Faecal Bacteria and Parasites (8-well)

Catalogue number of product: REF 25040 VER 01

Regulatory status of the product has been updated

New regulatory status: IVD use in Australia and European Union

New IFU: 25040r01 (available online on our website: <http://www.ausdiagnostics.com/>

<http://www.ausdx.com/qilan/ADMMainGeneList.jsp?ProductID=2062&CatNo=2504001>)

Updated template is available on the website. Please download.

Faecal Bacteria and Parasites (8-well) key performance data:

Assay	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)
Shigella	100.0 (87.7 - 100.0)	99.8 (99.0 - 100.0)
Salmonella*	100.0 (67.9 - 100.0)	100.0 (90.4 - 100.0)
Campylobacter	99.5 (96.6 - 100.0)	99.1 (98.1 - 99.6)
Shiga Toxin 2*	94.7 (71.9 - 99.7)	100.0 (97.4 - 100.0)
Shiga Toxin 1*	82.4 (55.8 - 95.3)	100.0 (97.4 - 100.0)
E.coli O157*	100.0 (46.3 - 100.0)	100.0 (99.1 - 100.0)
Cryptosporidium	100.0 (90.0 - 100.0)	100.0 (99.5 - 100.0)
Giardia (18S)	100.0 (93.4 - 100.0)	99.4 (97.5 - 99.9)
C.difficile	98.0 (92.2 - 99.6)	99.7 (98.1 - 100.0)
E.histolytica*	83.3 (36.5 - 99.1)	100.0 (99.2 - 100.0)

Date effective of change: 23rd of August 2016

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