

19th of July 2017

Advisory Notice: Faecal Products Updated

Dear Valued Customer,

We will be making changes to IVD products that you may order. New panel templates and IFUs will be released to reflect these changes (available at www.ausdiagnostics.com under the 'PRODUCTS' menu).

Please find the affected products, and details of the changes listed below:

Faecal Pathogens A (16-well)

Catalogue number of product: REF 25031 (VER 06)

New Document ID of IFU: 25031r03

Reason/s for change(s):

- New campylobacter assay – Increased specificity for pathogenic campylobacter species (*C. jejuni*, *C. coli*, *C. lari*, and *C. doylei*)
- Updated noro-2 assay – increased inclusivity.

Faecal Pathogens B (16-well)

Catalogue number of product: REF 25033 (VER 05)

New Document ID of IFU: 25033r03

Reason/s for change(s):

- New campylobacter assay – Increased specificity for pathogenic campylobacter species (*C. jejuni*, *C. coli*, *C. lari*, and *C. doylei*)
- Updated noro-2 assay – increased inclusivity.

Faecal Pathogens C (16-well)

Catalogue number of product: REF 25036 (VER 06)

New Document ID of IFU: 25036r02

Reason/s for change(s):

- New campylobacter assay – Increased specificity for pathogenic campylobacter species (*C. jejuni*, *C. coli*, *C. lari*, and *C. doylei*)
- Updated noro-2 assay – increased inclusivity.

Enteric Viruses (8-well)

Catalogue number of product: REF 25037 (VER 06)

New Document ID of IFU: 25037r02

Reason/s for change(s):

- Updated noro-2 assay - increased inclusivity.

Faecal Pathogens M (16-well)

Catalogue number of product: REF 25039 (VER 06)

New Document ID of IFU: 25039r03

Reason/s for change(s):

- New campylobacter assay - Increased specificity for pathogenic campylobacter species (*C. jejuni*, *C. coli*, *C. lari*, and *C. doylei*)
- Updated noro-2 assay - increased inclusivity
- Sapovirus target added

Parasites (8-well)

Catalogue number of product: REF 25021 (VER 07)

New Document ID of IFU: 25021r01

Reason/s for change(s):

- Now available for IVD use. CE-IVD marked in Europe and included on the ARTG in Australia.
- The cyclospora assay has minimal validation data. Therefore, this assay will remain for performance evaluation only (i.e. RUO) until sufficient clinical performance data has been obtained.

The performance data for the following targets has been updated for all relevant panels;

- Enterovirus
- Shigella
- Cryptosporidium
- D.fragilis
- E.histolytica
- G18S (Giardia lamblia)
- Giardin

Effective date of change: 28th of June 2017

Please don't hesitate to contact us at support@ausdiagnostics.com or through the details below, if you have any further enquiries or require any assistance.

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