

15 December 2016

Advisory Notice – Respiratory Pathogens & Atypical Pneumonia Panel changes

New Product Versions to be released:

There will be a future update to a product/s you order, new IFUs will be released to reflect these changes. Please find the products affected, and details of the change below:

Respiratory Pathogens B (16-well)

Previous catalogue number of product: REF 20612 VER 02

New catalogue number of product: REF 20612 VER 04

New Document ID of IFU: 20612r04

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

Reason/s for change:

- L.pneumophila and L.longbeachae assays have been updated (see below*)
- Now available for IVD use in Europe.

Atypical Pneumonia (8-well)

Previous catalogue number of product: REF 20632 VER 02

New catalogue number of product: REF 20632 VER 04

New Document ID of IFU: 20632r02

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

Reason/s for change:

- L.pneumophila and L.longbeachae assays have been updated (see below*)
- Now available for IVD use in Europe.

New Instructions for Use to be released:

There will be a new version of the Instructions for Use (IFU) released for a product/s you order. Please find the products affected, and details of the change below:

Paediatric Respiratory Pathogens (16-well) REF 20616 VER 01

New Document ID of IFU: 20616r01

Reason/s for release of new IFU: This product is now available for IVD use in Australia and Europe.

Child Cough (8-well) REF 20691 VER 01

New Document ID of IFU: 20691r01

Reason/s for release of new IFU: This product is now available for IVD use in Australia and Europe.

Respiratory Pathogens (8-well) REF 20614 VER 02

Previous Document ID of IFU: 20614r01

New Document ID of IFU: 20614r02

Reason/s for release of new IFU: Update of description of software capabilities.

Respiratory Pathogens C (16-well) REF 20613 VER 03

Previous Document ID of IFU: 20613r02

New Document ID of IFU: 20613r03

Reason/s for release of new IFU: Update of description of software capabilities.

Respiratory Pathogens with Bordetella (8-well) REF 20615 VER 01

Previous Document ID of IFU: 20615r01

New Document ID of IFU: 20615r02

Reason/s for release of new IFU: Update of description of software capabilities.

* Details on updated Legionella assays

New assays for *L. longbeachae* and *L. pneumophila* have been designed based on predicted issues with specificity and inclusivity for each assay. Several samples were run in the panels with the new assays and sequencing results were obtained confirming the new panels give the correct results. See Table 1 for the Sensitivity and Specificity of these new assays.

Table 1. Sensitivity and Specificity for the updated *L.pneumophila* and *L.longbeachae* assays, including 95% Confidence Interval (CI).

| Assay | <i>L.pneumophila</i> | <i>L.longbeachae</i> (dotLK) |
|---------------------------|-----------------------|------------------------------|
| True Positive | 30 | 22 |
| True Negative | 22 | 32 |
| False Positive | 0 | 0 |
| False Negative | 0 | 0 |
| Sensitivity % (95% CI) | 100.0 (85.9-100.0) | 100.0 (81.5-100.0) |
| Specificity % (95% CI) | 100.0 (81.5-100.0) | 100.0 (86.7-100.0) |

Date effective of change: 3rd January 2017

Please don't hesitate to contact us in Australia on +61 (0) 2 96988030 (Australia, New Zealand, Oceania & Asia) or in the UK on +44 (0) 1494 300121 if you have any further queries or require any assistance with the updated products.