

## Advisory Notice – Respiratory Products Updated

Dear Valued Customer,

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

As part of these changes we will be adding a new panel and renaming three existing products; they will still have the same catalogue numbers. The name changes are as follows:

Old Product Name	New Product Name	Cat. No.
Paediatric Respiratory Pathogens (16-well)	Upper Respiratory Pathogens (16-well)	REF 20616
Respiratory Pathogens (UltraPlex)	Respiratory Viruses (UltraPlex)	REF 80614
Respiratory Pathogens with Bordetella (8-well)	Influenza, RSV and Bordetella (8-well)	REF 20615

In addition to these name changes we will also be updating some of the assays included in the Respiratory products, please find the products included in the update, and details of the changes listed below:

### Respiratory Pathogens B (16-well)

**Catalogue number of product:** REF 20612 VER 08

**New Document ID of IFU:** 20612r06

**Reason/s for change(s):**

- New Influenza A assay – this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- New HA-H3 assay – this assay was redesigned to increase differentiation from H1(2009).

### Upper Respiratory Pathogens (16-well)

**Formerly Paediatric Respiratory Pathogens (16-well)**

**Catalogue number of product:** REF 20616 VER 03

**New Document ID of IFU:** 20616r05

**Reason/s for change(s):**

- Updated Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- Updated HA-H3 assay - this assay was redesigned to increase differentiation from H1(2009).
- The hPIV1 assay has been redesigned to allow combination with assays hPIV2 and hPIV3. The Human Parainfluenza virus (hPIV) assays 1, 2 and 3 have been combined into one well in order to free up space for additional targets in the panel. These combined assays still allow for reporting of each subtype individually.
- Addition of hPIV4 - this assay was introduced to the Paediatric Respiratory Pathogens (16-well) panel in response to customer requests.
- Addition of a combined pan-Coronavirus assay. The combined pan-coronavirus assay amplifies alphacoronaviruses and subgroup A betacoronaviruses from humans. The combined pan-coronavirus assay does NOT allow for differentiation between subtypes.

## Respiratory Pathogens C (16-well)

**Catalogue number of product:** REF 20613 VER 06

**New Document ID of IFU:** 20613r07

### Reason/s for change(s):

- New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- New HA-H3 assay - this assay was redesigned to increase differentiation from H1(2009).Respiratory Viruses (UltraPlex)

## Respiratory Viruses (UltraPlex)

### Formerly Respiratory Pathogens (UltraPlex)

**Catalogue number of product:** REF 80614 VER 06

**New Document ID of IFU:** 80614r04

### Reason/s for change(s):

- New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- The hPIV1 assay has been redesigned to allow combination with assays hPIV2 and hPIV3. The Human Parainfluenza virus (hPIV) assays 1, 2 and 3 have been combined into one well in order to free up space for additional targets in the panel. These combined assays still allow for reporting of each subtype individually.
- Addition of Human Metapneumovirus A and B, these assays detect all type A and B strains.
- Sample Adequacy Control "NONO" removed.

## Respiratory Viruses (16-well)

**Catalogue number of product:** REF 20602 VER 16

**New Document ID of IFU:** 20602r07

### Reason/s for change(s):

- New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- New HA-H3 assay - this assay was redesigned to increase differentiation from H1(2009).
- The hPIV1 assay has been redesigned to allow combination with assays hPIV2 and hPIV3. The Human Parainfluenza virus (hPIV) assays 1, 2 and 3 have been combined into one well in order to free up space for additional targets in the panel. These combined assays still allow for reporting of each subtype individually.
- Update of Coronaviruses assays - the assay for 229E remains the same, but the other coronaviruses are targeted by the new assays. The Coronavirus assays have been combined into one well in order to free up space for additional targets in the panel. The combined pan-coronavirus assay amplifies alphacoronaviruses and subgroup A betacoronaviruses from humans. The combined pan-coronavirus assay does NOT allow for differentiation between subtypes.
- Addition of Human Bocavirus assay.
- Addition of Parechovirus assay which detected types 1-8.
- Addition of EV specific assay

### New Panel:

## Respiratory Viruses (12-well)

**Catalogue number of product:** REF 20618 VER 01

**New IFU:** 20618r01

### Assays:

Influenza virus A (includes H1, H3, H5 and H7)

Influenza B virus B (Yamagata and Victoria lineages)

Respiratory Syncytial Virus (includes and differentiates types A and B)

RV/EV Rhinovirus (types A, B and C) and Enterovirus (types A, B, C and D)

Human Parainfluenza virus 1

Human Parainfluenza virus 2

Human Parainfluenza virus 3

Human Parainfluenza virus 4

Human Adenovirus (includes groups B, C, E and some A, D; excludes hAdv21)

Human Metapneumovirus (type A and B are differentiated)

NONO: Human reference gene for sample adequacy control

SPIKE: Artificial sequence for assay control

## **Influenza, RSV and Bordetella (8-well)**

### **Formerly Respiratory Pathogens with Bordetella (8-well)**

**Catalogue number of product:** REF 20615 VER 03

**New Document ID of IFU:** 20615r06

#### **Reason/s for change(s):**

- New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- The hPIV1 assay has been removed in response to customer requests.
- The RV/EV assay has been removed in response to customer requests.
- Addition of the new HA-H3 and H1(2009) assays in response to customer requests.
- Addition of the Bordetella parapertussis assay which detects both Bordetella parapertussis and Bordetella bronchiseptica. This assay was included in this panel in response to customer requests.

## **Influenza + RSV (8-well)**

**Catalogue number of product:** REF 20081 VER 07

**New Document ID of IFU:** 20081r05

#### **Reason/s for change(s):**

- New Influenza A assay - this assay was designed to target an alternative segment of the Influenza A genome, in order to increase assay sensitivity and to negate the effects of recent mutations in the matrix gene.
- New HA-H3 assay - this assay was redesigned to increase differentiation from H1(2009).

## **Effective date of change: Friday 22nd June 2018**

Please don't hesitate to contact us at [info@ausdiagnostics.com](mailto:info@ausdiagnostics.com) or through the details below, if you have any further enquiries or require any assistance.

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