AusDiagnostics
TODAY

**ISO 13485 &
98/79/EC IVDD
Certified**

NEW LEVEL OF CERTIFICATION

A new milestone in the delivery of better products and services to our customers

We are proud to inform you that AusDiagnostics is now certified by the Notified Body TUV SUD to ISO 13485 and the Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), which allows us to CE mark IVDs listed in Annex II, list B (i.e. Chlamydia and CMV) and establish our presence in the international markets. It also represents a new level of quality assurance and control implemented by the company in the recent years. Many months of intensive work have gone into restructuring the quality management system, and implementing additional process controls and traceability features. Combined with the positive feedback from several audits this has culminated in a new level of company certification along with the previously obtained Australian TGA recognition of the company's QMS system.

ASEP PLANS FOR 2017

AusDiagnostics Sample Exchange Program (ASEP) is a complimentary sample exchange program hosted by AusDiagnostics. There will be two distributions for each sample type. AusDiagnostics will receive, process, and distribute all samples, and then compare all results in an anonymous report.

Faecal Pathogens Exchange

The program will aim to include as many diarrhoea causing viruses and bacteria as possible

Atypical Pneumonia Exchange

The exchange will focus on pathogens found in the lower respiratory tract

Enquiries?

For more information and details on how to enter please contact *asep@ausdx.com*

PRODUCT DEVELOPMENTS

New packaging of synthetic positive controls commencing 15th December 2016

- The product will be packed in 2mL screw-cap tubes so that tubes can be used directly on the Processor auto-sampling block *(please check with your customer care rep.)*
- The volume for each aliquot will be increased from 12µL to 50µL . This new format will allow the same tube of control to be reused throughout multiple runs on the same day.

AusDiagnostics' Nucleic Acid Extractor

We have started the development of the extraction robot along with its extraction chemistry. The prototype will be available for trials in 2017.

27th ECCMID Vienna, Austria 22 – 25 April 2017

AusDiagnostics invites everybody to visit our booth at 27th ECCMID in Vienna, Austria, 22–25 April 2017

Sample type	Distribution	Registration	Specimen Collection	Specimen testing
Faecal Pathogens	1	January	January	February
	2		June	July
Atypical Pneumonia Pathogens	1	April	April	May
	2		October	November

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BACTERIAL VAGINOSIS AND VAGINITIS PANEL, REF. 27117

This kit (**REF. 27117**) detects *Candida* (*albicans, crusei, glabrata, parapsilosis*) infection or *Trichomonas vaginalis* invasion which can cause **vaginitis** and the imbalance of normal vaginal flora which can be indicative of **bacterial vaginosis**. For the diagnosis of bacterial vaginosis the kit relies on an algorithm that compares bacterial loads relative to human cell markers (which acts as a surrogate for the presence of clue cells), and examines the relative proportion of bacteria associated with normal flora (*Lactobacillus*) and with bacterial vaginosis (*Gardnerella vaginalis* and *Atopobium vaginae*). The validation of the algorithm was done against the subjective call of an expert microbiologist examining a Gram stain of the swab by high power light microscopy considering the Nugent or Ison/Hay score and other factors.

A recent study carried out in Melbourne, showed the following clinical performance:

Target	BV or intermediate*	Candida**
Sensitivity % (95% CI)	95.3 (82.9–99.2)	95.1* (82.2–99.2)
Specificity % (95% CI)	94.0 (85.9–97.8)	95.3 (87.7–98.5)

* – compared to Nugent or Ison/Hay score
** – compared to microbiology assay

NEW SOFTWARE RELEASE

We have just released the new versions of the Assay Setup, Results and Analyser software. The most important features are highlighted below.

Easy-Plex™ Assay Setup version 1.9.6

Addition of timer at completion of Step 1
Once the Step 1 has completed, a timer will start ticking so that operator can asses the time from Step 1 completion

Change of the format of kit names
The pull down Select Test Kit menu now separates catalogue number and version. This is to comply with AusDiagnostics' new labels and IFUs. The format should be REF:XXXXX VER:XX

Easy-Plex™ Results version 1.6.6

Addition of Calculated Ct added to the Advanced view table and to the results CSV export
The Calculated Ct is the take-off value for a positive call based on the combined Step 1 and Step 2 PCR cycles, while taking the dilution factor into account. The values for the Calculated Ct (along with Corrected Melt Temperature) have been added to the Results CSV export. Also Calculated Ct can now be seen in the advanced view table in the 'Results' home screen - see the picture below

Addition of positive controls filter to History viewer
By ticking the "Positive controls only" box in History, the graphs will only plot the data from samples starting with "Pos", hence filtering the positive control results from any other data.

Easy-Plex™ Analyser (DT Prime) Software version 7.7.5.42 with a new firmware.

Hardware diagnostics check before each run
When the run is started (by clicking "Start Run"), a camera shutter sound will be heard indicating that the internal hardware diagnostics is being performed to confirm everything is working correctly.
Automatic opening of *Easy*-Plex™ Results Software after the run is over

See more in the software advisory notice from 31 Oct 2016 in the regulatory section of our web site.

NEW REGULATORY SECTION ON THE WEB SITE

We have recently launched a new web site section where all product advisory notices, certificates, SDS and any other relevant regulatory documents are available for downloading. See more:
www.ausdiagnostics.com/regulatory.html

RECENTLY RELEASED

New versions of Faecal Pathogens M (REF. 25031) and Faecal Pathogens A (REF.25039) have been released in November

- The Salmonella assay has been updated to reduce the occurrence of false positives. The gene target is unchanged.
- Noro 1 and Noro 2 assays have been updated in order to remove background. The gene target is unchanged.

COMING SOON

Respiratory Pathogens panels update:

- **Respiratory Pathogens B (16-well) ver.4, REF. 20612** will be CE IVD marked
- **Atypical Pneumonia (8-well) ver. 4, REF. 20632** will be listed as IVD and CE-IVD
- **Paediatric Respiratory Pathogens (16-well) ver.1, REF.20616** will be listed as IVD and CE-IVD
- **Child cough (8-well) ver.4, REF.20691** will be listed as IVD and CE-IVD

Phasing out of the following *Easy*-Plex™ 72 (Rotor- Gene) IVD products.

- Herpes (4-well) REF 67040,
- Faecal Bacteria (6-well) REF 65090,
- Bordetella (3-well) REF 60690,
- Vancomycin Resistance (5-well) REF 61120,

They may be ordered up until June 30th 2017

We Wish You a Great Festive Season and a Happy New Year!

COMPANY NEWS

Christmas Closure

We will be closing for our end of year holidays on Friday afternoon the 23rd of December 2016 and re-opening on Tuesday the 3rd of January 2017. The mail box support@ausdiagnostics.com will still be monitored for urgent enquiries.

New staff

Peter French has joined the company as a General Manager in November. Other professionals who joined us recently are:

Kelly Berger – production assistant, started in June
James Grant - mechatronic engineer, started in August
Vicky Kobylski - customer support, started in September
Stefan Venter - field service engineer, started in October
Jake Napper - production assistant in the UK Office, August
Phil Summers - territory manager in the UK Office, December

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