

# AusDiagnostics TODAY

COMPANY  
NEWSLETTER

Latest Research  
and Company News



Celebrating  
Anniversary  
Launching New  
Products

## WE ARE TEN YEARS OLD!

And we are ready to launch new generations of products. For high sample numbers: low cost panels for essential pathogens; and at the other extreme: large 24-well panels for single sample diagnostics

### FIRST ULTRA-PLEX KITS ARE AT PRE-LAUNCH STAGE

The Easy-plex™ 384 ULTRA-Plex System was designed to cover the needs of high throughput customers. This means a big number of samples required to be tested in one go for a relatively small number of targets, but still in multiplex format. Hence an 8-well panel format capable of supporting up to 48 samples per run is the main ULTRA-plex feature. Diagnosis of STIs, HPV, herpes viruses, enteric viruses etc. usually requires a large number of patients to be tested for a limited number of targets, so some of these were selected for the first generation of ULTRA-plex products.

#### High-risk HPV panel (REF 83201)

1	HPV 18 or 58
2	HPV 35 or 59
3	HPV 39 or 68
4	HPV 16 or 56
5	HPV 45 or 66
6	HPV 31 or 52
7	HPV 33 or 51
8	Human DNA & Artificial assay control

This panel was designed to screen for HPV infection for cervical cancer screening needs with simultaneous genotyping. Alternatively, this panel is quite convenient for reflex genotyping of HPV positive samples detected by other systems.

#### Urogenital panel (REF 87113)

1	Chlamydia trachomatis
2	Neisseria gonorrhoeae
3	Trichomonas vaginalis
4	Mycoplasma genitalium
5	Ureaplasma urealyticum
6	Mycoplasma.hominis & Ureaplasma parvum
7	Human RNA control Gene
8	Artificial sequence for assay control

#### Herpes,Enterovirus,Adenovirus (REF 87091)

1	Herpes simplex virus 1
2	Herpes simplex virus 2
3	Varicella zoster virus
4	Cytomegalovirus
5	Enterovirus
6	Adenovirus group B C and E
7	Human RNA control Gene
8	Artificial sequence for assay control

### NEW ZIKA VIRUS FEATURING ARBOVIRAL (8-WELL)

In response to urgent demand of Zika virus diagnostics we have released an Arboviral Panel featuring this and some other important Flaviviruses.

1	Zika Virus
2	Dengue Virus types 1-3
3	Dengue Virus Type 4
4	Chikungunya Virus
5	Ross River Virus
6	Barmah Forest Virus
7	Human RNA control Gene
8	Artificial sequence for assay control

- The Zika assay is designed to pick up both African and Asian lineages including isolates from Brazil and Central America.
- The Zika assay has been successfully tested on QAP samples and a few patient samples
- Other targets are crucial for differential diagnosis

## FIRST ULTRA-PLEX KITS ARE AT PRE-LAUNCH STAGE (cont.)

Some respiratory and enteric pathogens panels are also available in a high-throughput ULTRA-plex format

### Atypical Pneumonia panel (REF 80632)

1	Mycoplasma pneumoniae
2	Chlamydomphila pneumoniae
3	Chlamydomphila psittaci
4	Legionella longbeachei and pneumophila
5	Pneumocystis jirovecii
6	Cryptococcus neoformans
7	Human RNA control Gene
8	Artificial sequence for assay control

This panel is now featuring PCP as well

### Enteric Viruses panel (REF 85037)

1	Rotavirus A
2	Norovirus genogroup I
3	Norovirus genogroup II
4	Adenovirus group F and G
5	Sapovirus
6	Astrovirus
7	Enterovirus
8	Artificial sequence for assay control

## REGULATORY STATUS UPDATES

### Products Recently Released as IVDs

- The Parechovirus assay was finally listed as an IVD, making the whole Viral (8-well) panel, REF 27093 the IVD product.
- All assays in Enteric Bacteria and Parasites (8-well) panel, REF 25035 have been validated and the product listed as an IVD.

### Products Pending Release as IVDs

The following products are planned to be released soon as IVDs

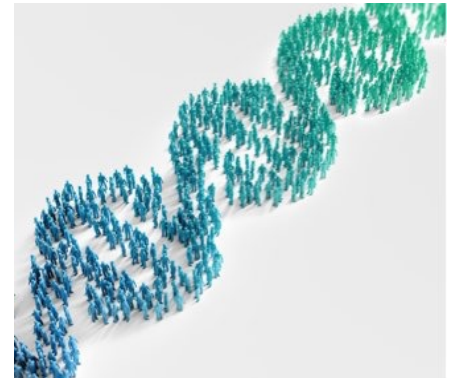
- Urinogenital (8-well), REF 27113 and Urinogenital (UltraPlex), REF 87113
- Gastrointestinal Parasites (8-well), REF25023
- Atypical Pneumonia (8-well), REF 20632, Atypical Pneumonia (UltraPlex), REF 80632
- CRE (16-well), REF 21098
- Bacteremia (16-well), REF 22411

# FIRST GENETIC DISEASES PANELS ARE COMING SOON

The first panel from the list is designed to detect genetic variants associated with Hemochromatosis – inherited disorder of iron metabolism.

### Hemochromatosis (8-well), REF 22156

This panel detects the HFE gene along with wild and mutant variants of H63D, S65C and C282Y single nucleotide polymorphisms.



## NEW 24-WELL PANELS FOR ENHANCED TESTING OF INDIVIDUAL SAMPLES

Addressing different needs to the ULTRA-Plex system, the recently launched Easy-Plex™ 96 features the ability to test for a broad range of relevant target on single samples.

Expanding this approach further we have launched 24-well panels for such conditions like Bacteraemia, Bacterial resistance testing and CSF testing.

### Comprehensive CSF (EP96), REF 77024

1	Herpes simplex virus 1
2	Herpes simplex virus 2
3	Varicella zoster virus
4	Cytomegalovirus
5	Epstein Barr virus
6	Human herpesvirus 6
7	Enterovirus
8	Human parechovirus
9	Pan-bacteria 16S RNA
10	Neisseria meningitidis (ctrA)
11	Neisseria meningitidis (sod)
12	Haemophilus influenzae
13	Streptococcus pneumoniae
14	Streptococcus agalactiae
15	Staphylococcus spp.
16	Methicillin-resistance gene (mecA)
17	Staphylococcus aureus femA
18	E.coli (beta-glucuronidase gene)
19	Listeria monocytogenes
20	MTB (IS6110 and MPT64)
21	Leptospira interrogans
22	Cryptococcus neoformans
23	Human RNA control Gene
24	Artificial sequence for assay control

### Sepsis (EP96), REF 72411

1	Staphylococcus spp.
2	Staphylococcus aureus
3	Methicillin-resistance gene mecA
4	Streptococcus spp.
5	Streptococcus pneumoniae
6	Streptococcus pyogenes
7	Streptococcus agalactiae (GBS)
8	Enterococcus spp.
9	Enterococcus faecium
10	Enterococcus faecalis
11	Enterobacteriaceae
12	E.coli (beta-glucuronidase gene)
13	Klebsiella spp
14	Proteus mirabilis
15	Serratia marcescens
16	Citrobacter freundii
17	Burkholderia cepacia
18	Pseudomonas aeruginosa
19	Acinetobacter baumannii
20	Listeria monocytogenes
21	Aspergillus fumigatus
22	Candida spp.
23	Human RNA control Gene
24	Artificial sequence for assay control

## COMPANY NEWS

The 30th of August 2016 is the company's birthday. We would like to say thank you to all our valued customers for the great support and much help, which has enabled us to grow up and make better and better products. Over the next decade, in

accordance with our 'Blue Ocean' strategy, we plan to deliver more informative, more automated and easier to use diagnostic products whilst, contrary to expectations, continuing to decrease the costs per detected target! So, watch out for our imminent developments and innovations.

