December 2017

COMPANY NEWSLETTER

AusDiagnostics TODAY

AUSDIAGNOSTICS IS MOVING FORWARD

AusDiagnostics has moved into new facilities with offices and production area twice as big reflecting the company's substantial growth and providing space for further development

New facilities at 290-292 Coward St Mascot

The new development in Sydney (290-292 Coward Street, Mascot NSW 2020, Australia) has approximately doubled the space for the company. The new production facility has seven bays for liquid handling robots - twice what was present in the old building and there is increased space for manufacturing and servicing of instruments, research and development laboratories, and administration. The premises will be shared with our new sister company, Confidential Pathology, which is being set up as a validation trials centre and molecular pathology laboratory.

The engineering area is capable of manufacturing up to 60 robots per month, tripling our previous manufacturing output, while the kit production facility should be able to grow to 5 million tests per year (about 8 x our current output).

Engineering production area

IVD RELEASE IN Q1 2018

- **Staphylococcus typing (8-well), REF. 21341**
- **Staphylococcus + VRE (8-well), REF.21341**
- **CRE EU (16-well) ver.1, REF. 21099**
- **STI (16-well), REF. 27112**
- **Haemochromatosis (8-well), REF.22156**

will be ARTG listed and CE IVD marked

ROTOR-GENE PHASING OUT

AusDiagnostics will cease production of almost all *Easy*-Plex 72 (Rotor-Gene) products by the end of 2017 with the remaining products phased out during 2018.

Now with a full range of High-plex, Ultra-plex and Mini-plex products based on 96- or 384-well cyclers all existing Rotor-Gene products can be successfully substituted with more cost effective and higher throughput panels. ***Contact your sales representative to finalise the switch.***

INTRODUCING HAEMOCHROMATOSIS (8-WELL) PANEL (REF. 22156)

Panel targets. Hereditary Haemochromatosis (HH) is one of the most frequently occurring genetic disorders in populations of Northern European decent. It is an autosomal recessive disorder of iron metabolism that results in excessive intestinal iron absorption and the accumulation of iron in major organs. It can subsequently lead to liver cirrhosis (which may lead to hepatocellular carcinoma), diabetes, cardiomyopathy and in some cases, early death.

Sequence variants in the *HFE* gene account for approximately 80% of HH cases and there have been several such variants identified. The **C282Y** variant of the *HFE* gene is the principal variant associated with the development of haemochromatosis. It is a G-to-A mis-sense nucleotide substitution that results in a change of tyrosine (Y) for cysteine (C) at amino acid position 282 in the HFE protein. Approximately 85%-90% of HH patients are homozygotes for this variant[5] and the carrier frequency of this allele is approximately 9.5-14.1%. The **H63D** variant is more frequently associated with iron overload when it is present as a compound heterozygote with the C282Y mutant and 5-7% of HH patients present with this genotype. The **S65C** is another identified HFE variant the clinical importance of which is yet to be confirmed however iron loading has been established in C282Y/S65C compound heterozygotes.

Diagnostic algorithm. The Haemochromatosis (8-well) panel detects both wild and mutated types for all three HFE variants and uses a quantitative diagnostic algorithm in order to determine the genotype. The amplification curves of each target are analysed and the ratio of the concentrations of each variant and its wild type are compared. If the ratio is less than 0.4, no variant (i.e. wild type) is indicated. If the ratio is 0.4-2, a heterozygous is suggested. A ratio greater than 2 suggests the presence of a homozygote.

The clinical performance for the targets used in this product were assessed by multiple clinical laboratories in Australia. Each institution's alternative method was considered the reference method for this assessment.

Assay	SENSITIVITY % (95% CI)	SPECIFICITY % (95% CI)
Wildtype 282	100.0 (97.0-100.0)	100.0 (92.7-100.0)
Heterozygous C282Y	100.0 (89.1-100.0)	100.0 (97.3-100.0)
Homozygous C282Y	100.0 (81.5-100.0)	100.0 (97.6-100.0)
Wildtype 63	100.0 (96.3-100.0)	100.0 (93.4-100.0)
Heterozygous H63D	100.0 (90.8-100.0)	100.0 (97.2-100.0)
Homozygous H63D	100.0 (80.8-100.0)	100.0 (97.6-100.0)
Wildtype 65	100.0 (97.6-100.0)	100.0 (80.8-100.0)
Heterozygous S65C	95.2 (74.1-99.8)	100.0 (97.6-100.0)
Homozygous S65C	ongoing	99.5 (96.7-100.0)

NEW GENERATION OF PANELS IN 12-WELLS

'***Extended multiplexing in economy format***' - is the idea behind the design of our new generation of products. These products will utilise 12-wells of the PCR plate per sample, with the intention of replacing a selection of existing 8-well products.

Initially, the 8-well products, which utilise just half of the PCR plate, were designed to cover a limited number of essential targets needed by labs at a low cost. However it has become increasingly difficult in some areas of pathology to find a set of "essential" targets that satisfies the needs of all customers, resulting in numerous panels consisting of similar targets. The new 12-well panels have been created by merging similar 8-well panels. By doing this, production is simplified and customers will be offered an increased range of multiplexed targets at a similar price point. The Step 1 tubes and Step 2 plates will remain the same price as 8-well products, however the Mastermix will cost slightly more as the Low, rather than Demi master mix is required.

The first 12-well products scheduled to be released in 2018 are:

- **Viral (12-well)**, this is a combination of the Viral (8-well), Viral CSF (8-well) and HEA (8-well) products.
- **Faecal Bacteria and Parasites (12-well)**, this is a combination of two Faecal Bacteria and Parasites (8-well) panels with the addition of *Yersinia*.

A third 12-well panel is planned for release later in 2018 which will merge together the Urinogenital (8-well) panel (which detects *Chlamydia trachomatis*, *Neisseria gonorrhoea*, *Mycoplasma genitalium*, *Trichomonas vaginalis* etc.) with *Neisseria* resistance gene detection assays for macrocolides and cephtriaxones.

Viral Panel (12-well), REF.27095

Well	Target
1	HSV1
2	HSV2
3	VZV
4	EBV
5	CMV
6	HHV6
7	HHV7
8	EV
9	Parechovirus
10	Adenovirus
11	Human DNA control
12	SPIKE - Artificial sequence for assay control

Faecal bacteria & parasites, REF.25041

Well	Target
1	Shigella spp. and Salmonella spp.
2	Campylobacter jejuni & C. coli
3	Shigatoxin 1 & 2
4	E.coli O157
5	Yersinia enterocolitica & Y. pseudotuberculosis
6	Clostridium difficile toxin A
7	Clostridium difficile toxin B
8	Cryptosporidium spp.
9	Giardia lamblia
10	Entamoeba histolytica
11	Human reference gene
12	SPIKE - Artificial sequence for assay control

AUSDIAGNOSTICS MOVING FORWARD *(cont.)*

New research and development area

The spacious research and development area has expanded from the original PCR lab to include nucleic acid extraction, protein bioengineering and sequencing zones. This facilitates the company's growth strategy for commercialising our own DNA/RNA extraction methods and provision of sequencing services. Upon relocation, AusDiagnostics successfully passed the Australian Therapeutic Goods Administration (TGA) surveillance audit to ISO 13485 standard.

SOFTWARE UPDATE

- **Shigatoxin 1 and 2 discrimination in mixtures**
- **RSV A and RSV B discrimination in mixtures**
- **RV detection when two serotypes present together**

If your product includes one of these targets please download and install the new template.

RECENTLY RELEASED

Bacterial Drug Resistance Panels update:

- **CRE (16-well) VER.2, REF. 21098** is ARTG listed and CE IVD marked

COMPANY NEWS

We wish you a great holiday season and a Happy New Year 2018!

AusDiagnostics
Multiplexed Diagnostics | Affordable Healthcare