September 2017

COMPANY NEWSLETTER

AusDiagnostics TODAY

Latest Research and Company News

PROCESSOR "MARK3"

MEET THE NEW MT-PROCESSOR

Production of the first batch of the updated MARK3 Processors is nearly complete

The production of the first 12 Processors of the new MARK3 generation has commenced. Along with engineering improvements such as easier assembly, simplifying the replacement of the thermocycler, improved tip ejection, and improved connection of the pipettor head, the new version also provides some great user benefits:

- embedded computer. No stand alone computer needed any more, meaning significant savings in bench space and fewer cables on the bench
- embedded monitor and keyboard. For space limited facilities these features provide significant benefits

Also, as a part of a company rebranding we have changed the name of the our processors. Now they are called MT-Processor reflecting the Multiplex-Tandem (MT) PCR process which is automated by the liquid handling robot. To distinguish from previous generations the new processor is called MARK3 while the current one is MARK2.

ROTOR-GENE PHASING OUT

AusDiagnostics will cease production of all products for the Rotor-Gene by the end of 2017.

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 flexible throughput panels. "Mini-Plex" products run of the 96 well cycler offer high complexity 24 well kits in addition to the 8 and 16-well kits available on High-Plex. ***If you are still using Rotor-Gene products please contact your sales representative to plan a switch.***

PRODUCT DEVELOPMENTS: UPDATED CAMPYLOBACTER ASSAYS

Campylobacter is a wide genus of bacteria some of which are well known for high pathogenicity to humans causing acute gastrointestinal disease while the pathogenic properties of the other genus members remain uncertain. Recent studies have shown that some Campylobacter species like *C.hominis* are unlikely to be pathogenic and could be persistent in a healthy population. Due to these findings and based on the results of customer surveys it was decided to change the *Campylobacter spp.* assay in faecal panels to a more specific primer set detecting only proven pathogenic species. Updated faecal panels will detect the following Campylobacter species: *C.jejuni, C.coli, C.lari, C.doylei*. During the next few months all enteric pathogen panels will be updated with these new assays.

CRE (16-WELL) REF.21098 CARBAPENEM-RESISTANT ENTEROBACTERIACEAE PANEL

Carbapenemase-resistant Enterobacteriaceae (CRE), are a major public health threat. Fast and reliable molecular testing of resistance genes is increasingly demanded. Australian National Alert System for Critical Antimicrobial Resistances recommends performing monitoring of certain sets of genes all of which have been included in the AusDiagnostics CRE-panel (REF. 21098).

The clinical performance of the targets in the CRE panel was assessed in multiple clinical laboratories across Australia and Europe. Eight sites including laboratories in Melbourne (Victoria) , Adelaide (South Australia), Sydney (NSW), London (UK), Norwich (UK), Monza (Italy) participated in the validation studies. Specimen types used in the validation trials include pure bacterial colonies harvested directly from culture plates and extracted rectal swabs. Alternate methods for confirmation of data included whole genome sequencing (WGS) and/or Sanger sequencing or with published in-house PCR methods. In some studies GeneXpert Carb-R (Cepheid) or Ingenius-CRE ELIte MGB kit (ElitechGroup) were used for comparison. Species identification was performed with Vitek MS or chromID® CARBA (Biomeriux).

The combined assay validation results from the clinical sites are in the tables below

Target	Sensitivity % (95% CI)	Specificity % (95% CI)
pan-VIM	98.6 (91.3-99.9)	99.5 (98.5-99.8)
pan-IMP	100 (94.8-100.0)	99.7 (98.7-99.9)
KPC	98 (93.7-99.5)	99.8 (99.0-100.0)
NDM	98.1 (92.8-99.7)	100 (99.2-100.0)
IMI	100 (62.9-100.0)	99.7 (98.1-100.0)
SME	100 (31.0-100.0)	100 (98.6-100.0)
GES	100 (82.2-100.0)	100 (98.5-100.0)
GES (ESBL)	100 (19.8-100.0)	100 (98.6-100.0)
OXA-23 like	100 (83.4-100.0)	100 (97.3-100.0)
OXA-48 like	100 (94.2-100.0)	99.8 (98.4-100.0)
OXA-51 like	100 (78.1-100.0)	100 (96.1-100.0)
OXA-58	100 (5.5-100.0)	100 (96.6-100.0)
pan-CMY	96.9 (82.0-99.8)	100 (96.8-100.0)
CTX-M group1	99.1 (94.6-100.0)	99.6 (97.3-100.0)
CTX-M group9	100 (90.0-100.0)	100 (98.5-100.0)
MCR1	94.1 (69.2-99.7)	99.5 (96.7-100.0)

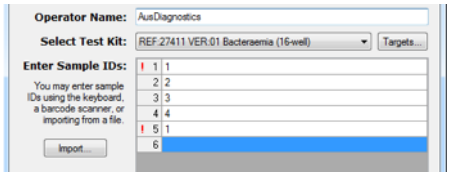
NEW SOFTWARE RELEASE

The new versions of the Assay Setup and Analyser software have been released The most important features are highlighted below. T**he names of the software have been changed as a part of a company re-branding.**

Multiplex-Tandem Assay Setup ver. 1.11.3

Sample name duplicates in setup table are now flagged with a red '!'

Sample duplicates are now flagged with a red '!' in the sample entry table for increased noticeability.



Pause/continue alert now more noticeable, both visually and audibly.

The pause/continue alert has been made more noticeable in an effort to reduce accidental pausing of runs. Visually, the paused message is now in bold red type. If the pause button is pressed during a run, the second line of the run status changes to 'Paused. Press "Continue" to resume operation.'

Additionally, the pause button will now beep once when pressed as a confirmation/alert of this event.

Support for faster pipetting

New products will use a multi-dispense pipetting feature. This will allow faster pipetting of Step 1 products into the Step 2 plate. For Ultra-Plex users, this multi-dispense feature will save up to 10 minutes of run time.

Multiplex-Tandem Analysis ver. 1.7.2

Opened .384 files and associated source files are now automatically archived as exchange files (.epx)

Opening a .384 file will now activate automatic archiving. This will replace the opened .384 file with an exchange file (.epx) of the same name and location. This exchange file will contain the original .384 file and the associated source files. This feature saves about 2 Mbytes for every run file on your computer drive!

Addition of message on exported Summary file if High Sensitivity was used in the analysis

A warning message will be displayed on the exported Summary file if High Sensitivity was used in the analysis.

"Check" call values will no longer display on exported Analysis Summary

The software will no longer display "Check" call values when exporting an Analysis Summary, they will instead show as blank cells with no value.

See more in the software advisory notice from 17 Aug 2017 in the regulatory section of our website.

EXTERNAL ISO 13485 AND IVDD AUDIT

AusDiagnostics has successfully passed the one year external surveillance audit by the Notified Body TUV SUD to ISO 13485 and the 98/79/EC Directive on In Vitro Diagnostic Medical Devices (IVDD). During the audit no non-conformances were found.

RECENTLY UPDATED

- **Melt temperature range for NORO-1 assay**
- **Temperature range for RSV in 8-well panels**
- **Melt temperature range for H3 in a flu typing assays**
- **HSV-1 range temperature melt update**
- **Updated Campylobacter assays in faecal panels**

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

COMING SOON

Bacterial Drug Resistance Panels update:

- **CRE (16-well) VER.2, REF. 21098** will be ARTG listed and CE IVD marked
- **CRE Colindale (16-well) ver.1, REF. 21099** will be ARTG listed and CE IVD marked

STI (16-well) VER.2, REF. 27112

Phasing out of the whole set of Rotor- Gene IVD products.

PRICE LIST UPDATED FROM W.E.F. 1 JULY 2017

Please note, that some prices have been changed with effect from the beginning of the financial year starting 1st of July 2017. Whilst the prices of standard products increased slightly, the prices for the CORE products remain unchanged making them even more cost effective.

COMPANY NEWS

A new Company address from 1st November:
290-292 Coward Street, Mascot, NSW, 2020

AusDiagnostics commences direct operations in New Zealand

A new company was opened in August in Auckland enabling AusDiagnostics to work directly with New Zealand customers.

AusDiagnostics branch starts in the US

In the 4th quoter of 2017 we are opening our first USA office emphasising our commitment to develop this market.

Re-branding of systems names

To simplify and clarify the names, our systems now called ***Mini*-Plex 12**, ***High*-Plex 24** and ***Ultra*-Plex 48**. The number reflect the maximum number of samples tested in a run

AusDiagnostics
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