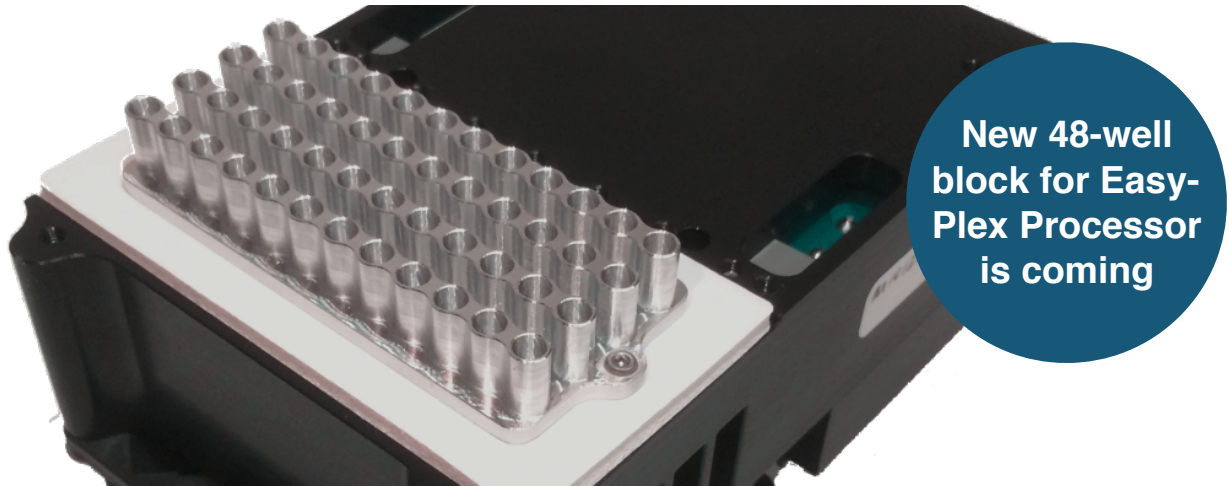


AusDiagnostics TODAY

Valuable and useful
information along with
the most important
company news



New 48-well
block for Easy-
Plex Processor
is coming

REAGENT PANELS

HIGHLIGHTS of the month: improved Enterovirus assay sensitivity, more specific detection of Legionella, and development of a brand-new HPV-test

NEW DEVELOPMENTS

Increased enterovirus sensitivity for CSF and Herpes panels. Following feedback of our customers, we have dramatically improved the amplification conditions for our Enterovirus target. The table below shows Ct value difference between the old and new assay variants.

	OLD	NEW	Δ Ct
EV DNA	12.6	12.2	0.4
EV DNA 1/500	Not detected	20.54	-
EV RNA	24.2	19.1	5.1

Haemophilus influenzae undergoes transformation. A new target gene has been selected for detection of this bacterium. *In-silico* analysis predicts the new gene to be much more specific than the previous one. Laboratory testing showed a more stable signal and less

melting curve noise. Next step - external validation trials - recently started. All CSF panels will be updated with this new target upon trial completion.

High-risk HPV test for cervical cancer screening under development.

Following recommendations of Australian Medical Service Advisory Committee (MSAC) and other international organisations our new HPV test will detect 14 high-risk HPV genotypes with partial genotyping of the most oncogenic 16, 18 and 45 types. With this new test, and the new Easy-Plex 384 ULTRA-Plex System (coming soon) it will be possible to process up to 384 cervical swab samples per 8 hour shift, with a system requiring only 2 m bench space!

Legionella species identification becomes more specific

During our periodic review of assay bioinformatics, the potential of the *L.pneumophila* and *L.longbeachae* assay to cross-react with each other was assessed. Both of these assays were subsequently redesigned against new targets to remove this potential, and to ensure specific detection and identification of these pathogens. Validation results are shown in the table below

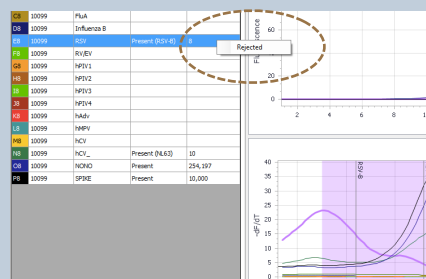
	L.pneumophila	L.longbeachae
True positive	20	15
True negative	20	26
Sensitivity	100%	100%
Specificity	100%	100%

SOFTWARE UPDATES

New versions: *Easy-Plex Assay Setup (1.8.6)* and *Results (1.4.3)* Software were released.

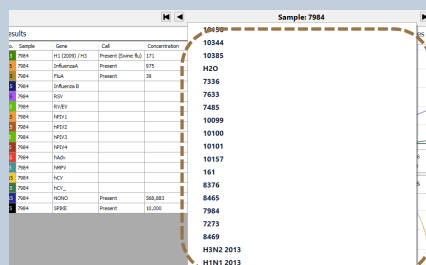
Rejecting calls

If a call seems to be an obvious artefact but is still called by the software, it is now possible to reject it. Just right click on sample result. Then sample will be marked as rejected and you could retest the sample



Simpler navigation

With the new version of the results software it is possible to select genes and samples from dropdown menu



Coming soon: 96-well cyclers support

The next 1.4.4 software version will analyse data generated by 96-well real-time PCR machines such as Roche LC480 and ABI7500. A new AusDiagnostics *Easy-Plex 96 Analyser* is also coming soon. That will complete the *Easy-Plex 96 System* for low throughput labs allowing single sample runs to be performed with no extra costs.

RECENTLY LAUNCHED

A brand-new panel **Respiratory Pathogens with Bordetella (8Plex)**

Influenza A	Includes H1, H3, H5 and H7
Influenza B	Includes Yamagata and Victoria lineages
RSV	Respiratory Syncytial Virus all type A and B strains
PIV 1	Human Parainfluenza virus 1
Rhinovirus and enterovirus	Includes rhinovirus (types A, B and C) and enterovirus (types A, B, C and D)
Bordetella spp.	Includes B. pertussis, B. holmesii and a small subset of B. bronchiseptica
Human ref. gene for sample adequacy control	
Artificial sequence for assay control	

COMING SOON

CSF and Herpes panels with updated cycling conditions optimised for better EV performance. *Scheduled changes to be implemented in November 2015*

Easy-Plex 384 v.High-Plex

27050 CSF (16Plex)
27091 Herpes, Entero and Adenovirus (8Plex)
27092 Viral CSF (8Plex)
27093 Viral (8Plex)

Easy-Plex 72

67060 CSF (14Plex) 37050 CSF-D (14Plex)
37021 CSF (10Plex) 37024 CSF-E (9Plex)
37051 CSF (6Plex) 37022 CSF B (10Plex)
37023 CSF C(14Plex) 37025 CSF Hobart

New generation of Respiratory pathogens and Pneumonia panels with updated Legionella assay

Easy-Plex 384 v.High-Plex

20612 Respiratory Pathogens B (16Plex)
20631 Pneumonia (16Plex)
20731 Pneumonia EU (16Plex)
20632 Atypical Pneumonia (8Plex)

Easy-Plex 72

60631 Atypical Pneumonia A (12Plex)
30780 Bordetella and Atypical Pneumonia (12Plex)
30870 Atypical Pneumonia (8Plex)
30682 Legionella (4Plex)
31081 Chlamydia and Atypical Pneumonia (10Plex)
30833 WDP Atypical Pneumonia (7Plex)

Production start – December 2015.

ROBOTIC SYSTEMS

We continue working on a brand new generation of Sample Processor – *Easy-Plex* generation ULTRA-Plex. With this system it will be possible to process up to 48 samples per run. With a new 48 well thermocycler block the processor will remain in its original size, meaning doubling of the throughput in the same bench space.

SAMPLE EXCHANGE PROGRAM

AusDiagnostics's Sample Exchange Program (ASEP) 2015 Q4

is due to start! All AusDiagnostics faecal panel users (*Easy-Plex 72* or *Easy-Plex 384 High-Plex*) are welcome to participate. Participating labs must send ~1 mL of pre-treated faecal sample in a transport buffer (such as Roche S.T.A.R. buffer). We will expect two positive and one negative sample from each participant. Submitting samples with uncommon pathogens is highly encouraged. The protocol for this Exchange Quarter has been altered to distribute 1 mL blind aliquots instead of 220 uL to comply with extraction protocols. Samples for the exchange must be received by November 4th. Participants will receive their blind aliquots by November 13th, and results should be submitted by November 27th. For more information about ASEP, please send your queries to jeanne.zhang@ausdx.com. We look forward to receiving your samples!

COMPANY NEWS

New NSW customers support team

Emma McCabe and Lauren Gilbert

Hiring new staff

James Habel - field service engineer and customer support in VIC

Paula Woodbridge for regulatory affairs

Dmitry Kuevda for global marketing and support in QLD

AusDiagnostics

Multiplexed diagnostics Affordable healthcare