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.

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.

<table>
<thead>
<tr>
<th></th>
<th>L.pneumophila</th>
<th>L.longbeachae</th>
</tr>
</thead>
<tbody>
<tr>
<td>True positive</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>True negative</td>
<td>20</td>
<td>26</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
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

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)
  37021 CSF (10Plex)
  37024 CSF-E (9Plex)
  37051 CSF (6Plex)
  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 µL 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 and customer support in VIC
Paula Woodbridge for regulatory affairs
Dmitry Kuevda for global marketing and support in QLD