

31st October 2016

Software Update Advisory Notice

Dear Valued Customer,

AusDiagnostics has validated and released new software versions. These updates could affect your use of the System. Please review this Software Advisory Notice closely to determine whether these changes may have an adverse effect on your lab environment. A qualified AusDiagnostics representative may proceed to install these software releases if you have no concerns with the described changes. Updated system IFUs, with software updates incorporated, will be available on the AusDiagnostics website or ask your AusDiagnostics representative (DOC ID for *Easy-Plex™* 384 (High-Plex) System IFU: 9150r06, and *Easy-Plex™* 72 System IFU: 9050r16).

For more comprehensive information about what is included in these software updates, and how to use the new features, please refer to your AusDiagnostics customer care specialist, or refer to the attached Software Release Notes.

AusDiagnostics Software Updates

Software Type	Version	Changes
Easy-Plex™ Assay Setup	1.9.6	<ol style="list-style-type: none"> 1. Fix for creating EP96 24-well import files 2. Fix for creating Ultra-Plex import files 3. Fix for creating import files for interleaved 8-well templates with less than 24 samples 4. Fix for lot entry of EP96 5. Improved Processor handling conditions for Ultra-Plex 6. Addition of Step 1 cycle count to .esetup files 7. Fix for unexpected Processor errors, including changes to UV dialog and splash screen 8. Addition of timer at completion of Step 1 9. Change of the format of kit names 10. Addition of warning message if sensitivity option is not the default setting

AusDiagnostics Software Updates

Easy-Plex™ Results	1.6.6	<ol style="list-style-type: none"> 1. Fix for reading Rotor-Gene (.rex) files with very low take-off values and clipped maximum readings 2. Fix for the DTprime data transposition detection in the case where there is only one sample 3. Fix to prevent wide peaks with a missing 50% peak height from being classed as valid 4. Addition of Calculated Ct and Corrected Melt Temperature columns to the results CSV export 5. Fix sample sorting for Ultra-Plex files 6. Fix well sorting on EP96 files or cyclers other than DTprime 7. Addition of Calculated Ct column to Advanced view table 8. Addition of genotype call to historical data 9. Addition of complete run info (batch numbers, user and PC names, etc.) to historical data 10. Addition of positive controls filter to History viewer 11. Addition of Cartridge and Reaction Strip batch info to Reports 12. Removal of 1000's comma separator from concentration values in CSV exports. This change might affect integration in LIMS. 13. Fix for reading data values from History that are not a number (NaN) 14. Recognition of file types that cannot be determined
RealTime_PCR	7.7.5.42	<ol style="list-style-type: none"> 1. Updated user interface 2. Internal hardware diagnostics check before each run 3. Cross talk with Easy-Plex™ Results after each run

SOFTWARE RELEASE NOTES

Easy-Plex™ Assay Setup Software version 1.9.6

Update #1-3:

- 1. Fix for creating EP96 24-well import files**
- 2. Fix for creating Ultra-Plex import files**
- 3. Fix for creating import files for interleaved 8-well templates with less than 24 samples**

With these three updates the Step 1 output files for Analyser import were optimised across all various platforms (Easy-Plex™ 384 System (High-Plex), Easy-Plex™ 96, and Ultra-Plex).

Update #4

Fix for lot entry of EP96 (for Easy-Plex™ 96 products)

Only Step 2 Strip products with a lot number commencing with the letter “E” will be accepted by this software release.

Update #5

Improved Processor handling conditions for Ultra-Plex

The Step 2 dilution set-up for Ultra-Plex templates by the liquid handling Processor commences 12 cycles before the end cycle number, in order to save time in the overall process.

Update #6

Addition of Step 1 cycle count to .esetup files

In order to determine the Calculated Ct (i.e. the take-off value for a positive call based on the combined Step 1 and Step 2 PCR cycles, while taking the dilution factor into account), a record of the amount of cycles used during Step 1 will be stored in the output .esetup files.

Update #7

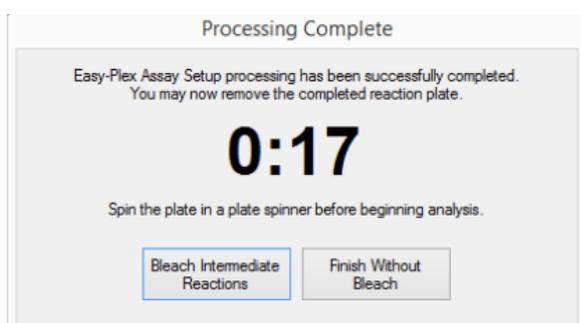
Fix for unexpected Processor errors, including changes to UV dialog and splash screen

Support has been added for unexpected Processor errors, with popup dialogue messages appearing instead of the software crashing.

Update #8

Addition of timer at completion of Step 1

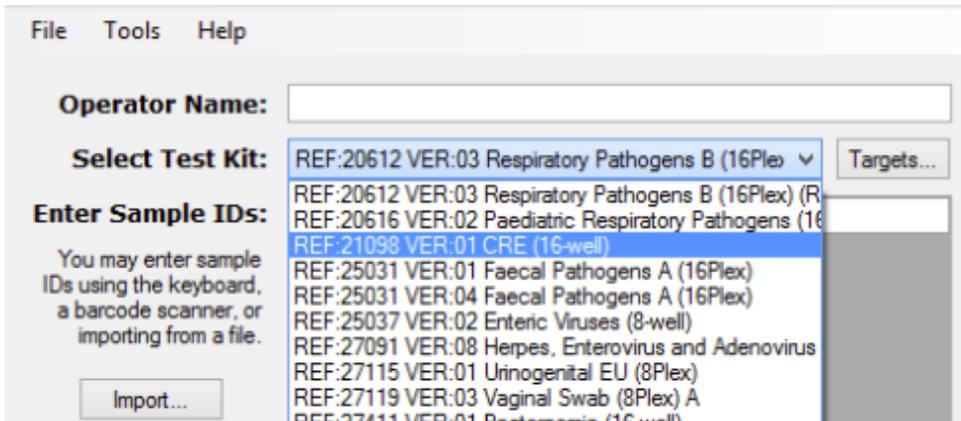
Once the Step 1 has completed, a timer will start ticking so that operator can assess the time since Step 1 completion.



Update #9

Change of the format of kit names

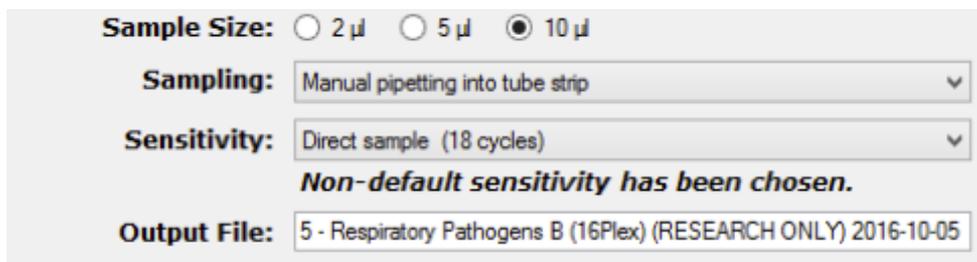
The pull down Select Test Kit menu now separates catalogue number and version. This is to comply with AusDiagnostics' new labels and IFUs. The format should be REF:XXXXX VER:XX



Update #10

Addition of warning message if sensitivity option is not the default setting

A warning message will be displayed if a Sensitivity other than the default setting has been selected.



Easy-Plex™ Results Software version 1.6.6

Update #1

Fix for reading Rotor-Gene (.rex) files with very low take-off values and clipped maximum readings

Rotor-Gene files containing wells with very low take-off values and/or clipped maximum fluorescence readings can now be opened in the Results software.

Update #2

Fix for the DTprime data transposition detection in the case where there is only one sample

This software release can correctly read one sample High-Plex results files where the output Step 1 information had been accidentally transposed during import in the RealTime_PCR software.

Update #3

Fix to prevent wide peaks with a missing 50% peak height from being classed as valid

This feature prevents non-specific fluorescence readings with a melt peak within the target melting window from being called positive.

Update #4

Addition of Calculated Ct and Corrected Melt Temperature columns to the results CSV export

The Calculated Ct is the take-off value for a positive call based on the combined Step 1 and Step 2 PCR cycles, while taking the dilution factor into account. The values for Calculated Ct and Corrected Melt Temperature columns have been added to the Results CSV export. This might affect the integration in LIMS. Please consult your local IT department.

Well	Sample	Gene	Call	Concentration	Calculated Ct	Corrected Melt
A1	XXXX	Influenza A				
B1	XXXX	Influenza B				
C1	XXXX	RSV				
D1	XXXX	RV/EV	Present (100%)	67121	19.42	86.13

Update #5

Fix sample sorting for Ultra-Plex files

Samples from Ultra-Plex Results files are now correctly listed in a correct sequence while toggling through Samples and Genes.

Update #6

Fix well sorting on EP96 files or cyclers other than DTprime

When exporting CSV data from the result files from the Easy-Plex™ 96, LC480, BioRad or ABI7500 instruments, all values are displayed in the correct columns.

Update #7

Addition of Calculated Ct column to Advanced view table

Calculated Ct values (see Update #4) have now also been added to the Advanced View table in the Results home page.

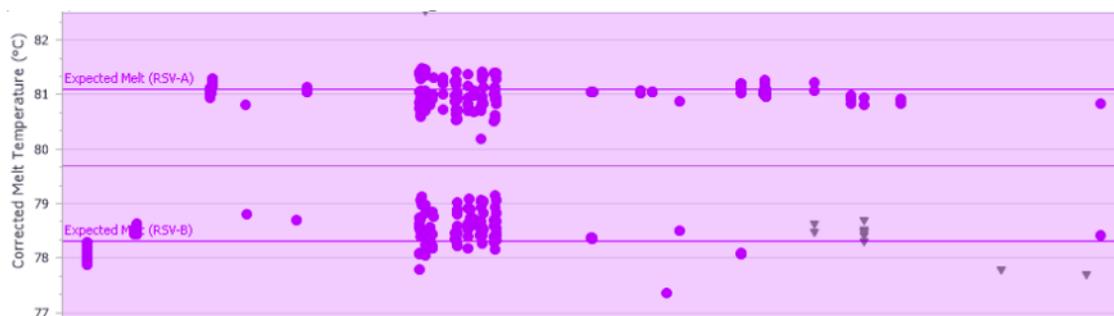
Results

No.	Sample	Gene	Call	Corrected Melt	Take-Off	Calculated Ct
A4	8882 1	Influenza A	Present (16%)	85.3	12.62	21.27
C4	8882 1	Influenza B	Present (28%)	81.02	11.76	20.41
E4	8882 1	RSV	Present (27%) (...)	81.06	11.77	20.41
G4	8882 1	hPIV1	Present (12%)	81.68	13.07	21.72
I4	8882 1	RV/EV	Present (14%)	85.84	12.8	21.44
K4	8882 1	hAdv	Present (3%)	84.23	15.12	23.76
M4	8882 1	Sample Adequacy	Present	81.52	11.61	20.26
O4	8882 1	SPIKE	Present	81.8	14.84	23.49

Update #8

Addition of genotype call to historical data

A Genotype call for targets has now been added to History.



Update #9

Addition of complete run info (batch numbers, user and PC names, etc.) to historical data

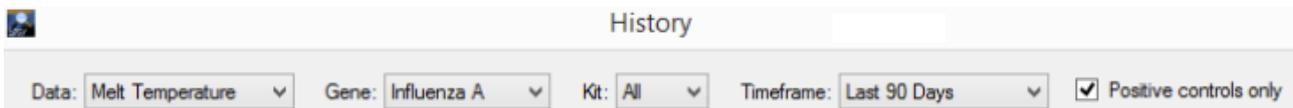
The following fields have been added to Melt History. This will enable comprehensive data analysis of results acquired from multiple sites.

- Genotyping result
- Concentration value
- Serial no. of Processor
- Assay Setup run info
- Serial Number of analyser
- Lot no. of plates
- Lot no. of strips
- Lot no. of Mastermix A
- Lot no. of Mastermix B
- User and PC names

Update #10

Addition of positive controls filter to History viewer

By ticking the “Positive controls only” box in History, the graphs will only plot the data from samples starting with “Pos”, hence filtering the positive control results from any other data.



Update #11

Addition of Cartridge and Reaction Strip batch info to Reports

Step 2 Strip (for Easy-Plex™ 96 products), and Mastermix cartridge lot number information has now been included in Reports > Analysis.

Operator: j Experiment Start Date: 06 Sep 2016

Sample ID	Gene Target	Call	Intensity
te1	Camelostrongylus		
	Haemonchus		
	Trichostrongylus spp		
	T. circumcincta		
	O.ostertagi		
	Oesophagostomum		
	Cooperia		
	SPIKE	Present	★★★★

Step 1 MM batch: A30672DD, Step 1 reaction tube batch: S950129, Step 2 MM batch: B30841D, Step 2 reaction strip batch: E950022

Sample ID	Gene Target	Call	Intensity
3% Who8 2	Influenza A	Present	★★★★
	Influenza B		
	RSV		
	RWEV	Present	★
	Sample Adequacy		
	SPIKE	Present	★★★★

MasterMix cartridge batch: C100056RL Step 1 reaction tube batch: S100056

Update #12

Removal of 1000's comma separator from concentration values in CSV exports

The format of Export Results and Summary now has integers rather than formatted numbers (as an example, see Concentration column in Update #4).

Update #13

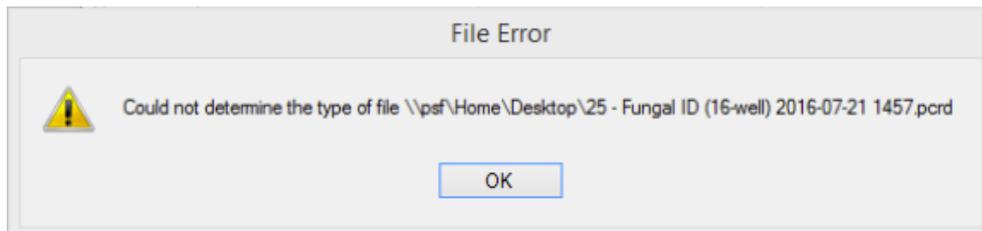
Fix for reading data values from History that are not a number (NaN)

The History viewer filters out data values that can cause the chart to throw an exception/error.

Update #14

Recognition of file types that cannot be determined

An informative message will now appear when a non-results file type that can not be recognised by the software is opened.



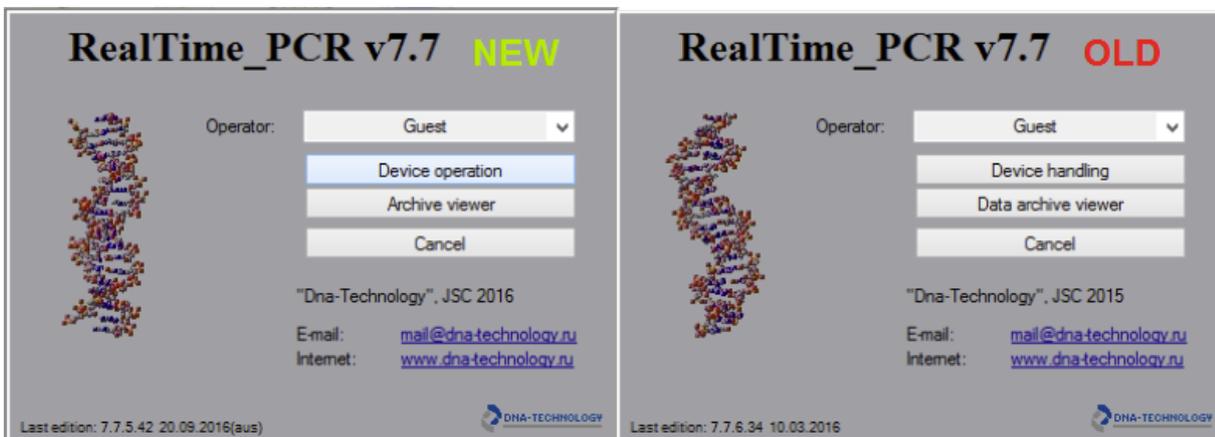
RealTime_PCR Software version 7.7.5.42

The RealTime_PCR v7.7.5.42_au accommodates the latest firmware update, and in turn has an updated user interface. With this, the description of certain buttons has been renamed, without having their actual function altered. Another update allows the device to perform an internal diagnostics test before commencing the run, to ensure all hardware components are working correctly. Another important new feature allows .384 and .r96 files to be opened in the Easy-Plex™ Results software after the run has completed.

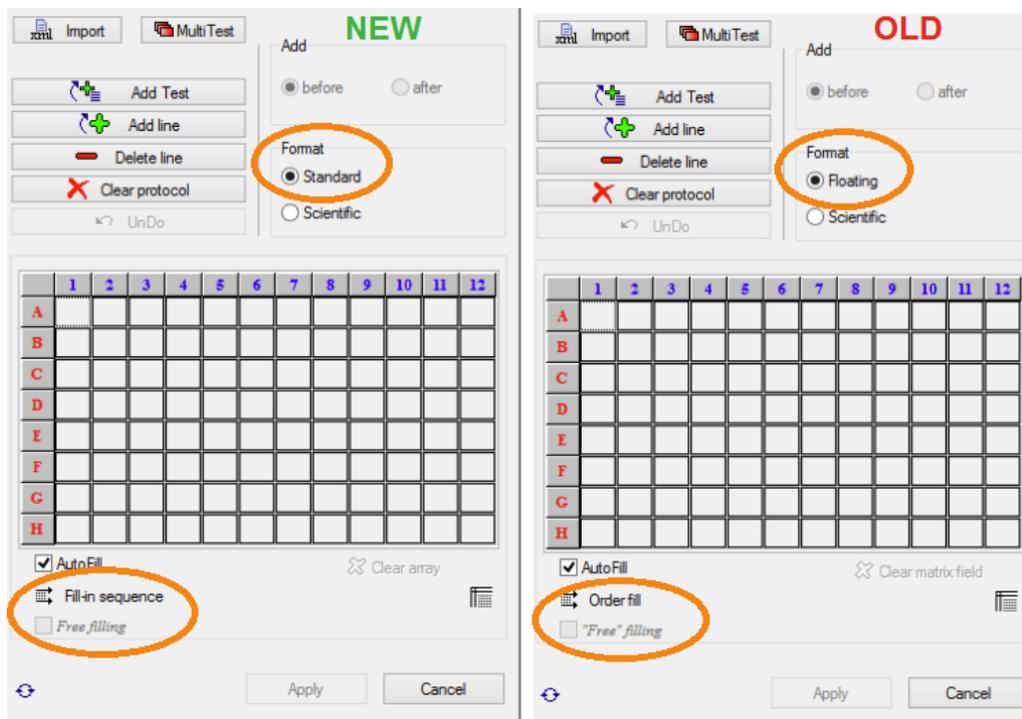
Update #1

Updated user interface

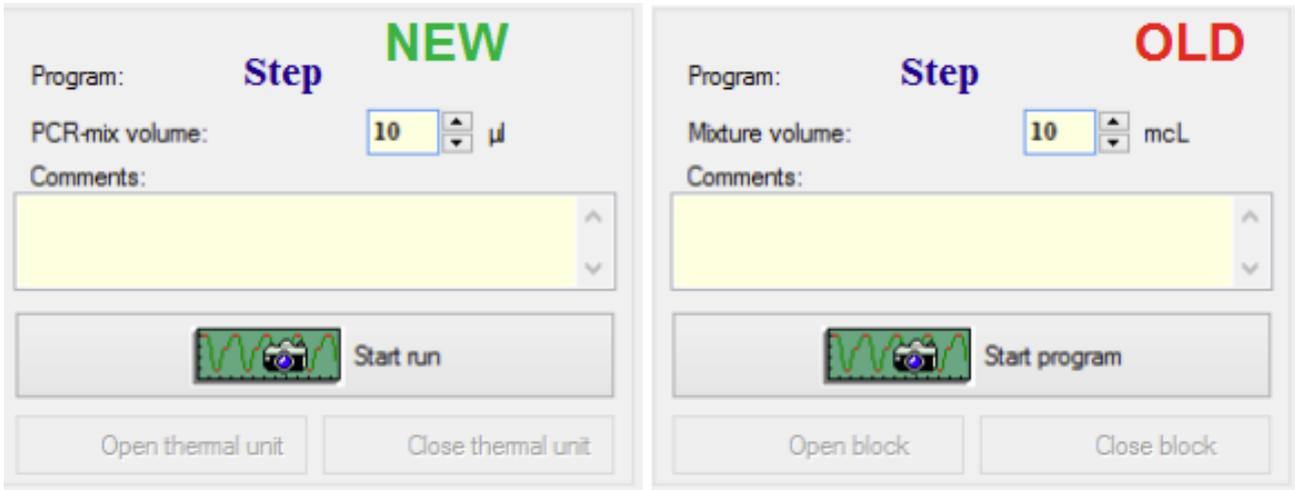
1. "Device Operation" (new) vs "Device Handling" (previous versions)
"Archive Viewer" (new) vs "Data Archive Viewer" (previous versions)



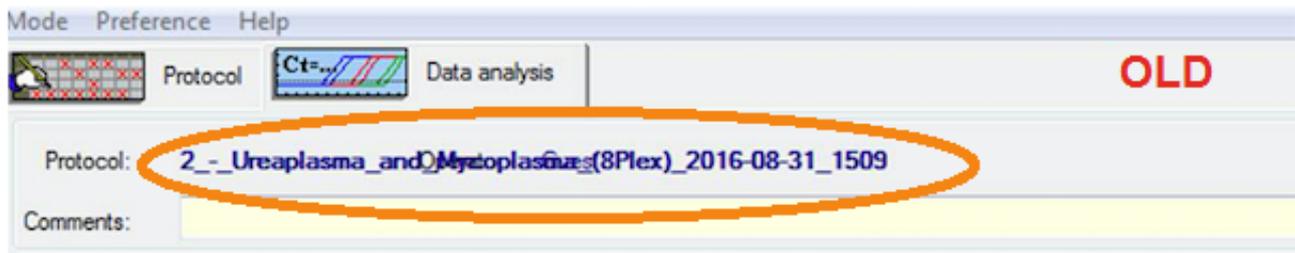
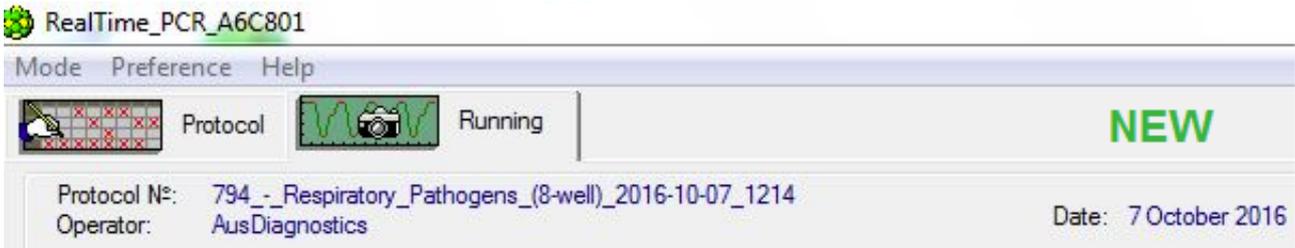
2. "Standard Format" (new) vs "Floating Format" (previous versions)
"Fill-in sequence" (new) vs "Order-fill" (previous versions)



- 3. "PCR-mix volume" (new) vs "Mixture volume" (previous versions)
- "Start run" (new) vs "Start Program" (previous versions)
- "Open/close thermal unit" (new) vs "Open/close block" (previous versions)



- 4. While the run is in progress, the Protocol Number, Date, and Operator information will be displayed in a clearer way than on previous versions.



Update #2

Internal hardware diagnostics check before each run

When the run is started (by clicking "Start Run"), a camera shutter sound will be heard accompanied by the following on-screen message. This indicates that the internal hardware diagnostics is being performed to ensure everything is working accordingly.



Update #3

Cross talk with Easy-Plex™ Results after each run

After the run has finished, an Attention message box will prompt the user whether they: “Would you like to open the file in Easy-Plex™ results software?”. If YES is clicked on this message, the run file will be opened in the Easy-Plex™ Results software. If NO is clicked, the standard DNA-Technology “loading parameters” post-run screen will be displayed.

