



## Important Customer Information

### SCORE 6 software update 6.2.1.0 (RUO)

Product name	Product No.
SCORE 6	SCORE 6.2.1.0

Date: 30 June 2023

Dear Valued Customer,

We are excited to announce that a new SCORE 6 version, **SCORE 6.2.1.0**, has been released and is available for download from our website.

The attached Appendix: 2087-MKT Appendix 1: Rev 02\_SCORE 6.2.1.0 Supplementary information contains an overview of the main changes in SCORE 6.2.1.0 compared to SCORE 6.1.3.1 and other important information regarding installation and migration options.

#### Description

The installer for SCORE 6.2.1.0 and its release notes can be downloaded from <https://labproducts.caredx.com/software/score/score-6/downloads/>

#### Actions required

The required typing kit files differ between SCORE 6.1.3.1 and 6.2.x.x. We will discontinue supporting SCORE 6.1.3.1 after lot E067; therefore, we recommend users to install SCORE 6.2.1.0 as soon as possible. Please see the attached document for further information about recommended upgrade procedures.

Kit file compatibility:

- Typing kit files compatible with SCORE 6.1.3.1 will be provided from lot E061 to lot E067.
- Typing kit files compatible with SCORE 6.2.x.x will be provided from lot E061 moving forward.

Please don't hesitate to contact your local application specialist if you have any questions with regards to this message or the updates.

Should you have any further queries, do not hesitate to contact me.

Kind Regards,

Steve Chang



**Steve Chang**  
Implementation Manager

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Olerup QTYPE 11 and SCORE 6 are available as CE/IVD and research use only products. For local regulatory status, please contact CareDx.

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# SCORE 6.2.1.0 Supplementary information

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**Leslie M**, Kidney Transplant Recipient

*This material has been created for a global audience. Refer to all disclaimers on clinical claims and regulatory status in your region. Olerup QTYPE 11 and the SCORE 6 are available as CE/IVD and research use only products. For local regulatory status, please contact CareDx. Olerup QTYPE 11 is referred to as QTYPE 11*

Appendix 1. 2087-MKT Rev02 SCORE 6.2.1.0 Supplementary information | Steve Chang, Dan Dou, Rebecka Salme |



# **SCORE 6.2.1.0 Software overview**

# Software overview - 1

- New Launch icon:

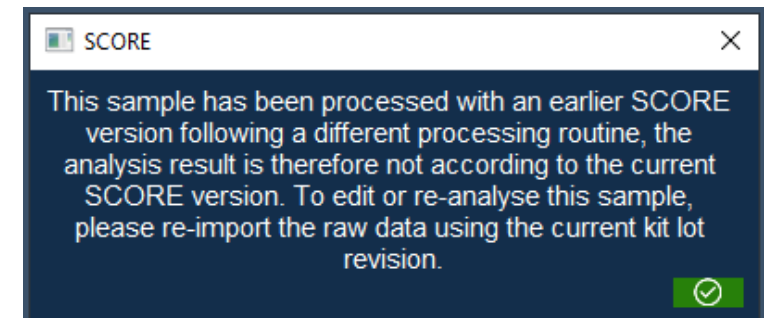


- SCORE 6.2.1.0 (CE/RUO) is a patch for SCORE 6.2.0.1 (which was released as CE only)
  - The same installation procedure as previous SCORE 6 versions
  - Users can have SCORE 6.1.3, SCORE 6.2.0.1 (CE only) and SCORE 6.2.1.0 on the same PC
- Updated support for Windows and SQL server versions

# Software overview - 2

Installation of SCORE 6.2.1.0 and migration options from previous versions

- Option 1: Create a new SQL database for SCORE 6.2.1.0  
(Possible to run different version in parallel - **strongly recommended**)
- Option 2: Upgrade current database to SCORE 6.2.1.0 (**irreversible**; no parallel use)
- NOTE: After a database upgrade, samples previously analysed in SCORE 6.1.3.1 may be viewed in SCORE 6.2.x.x but can only be **re-analysed** by **reimporting** raw data (**E061 and later only**). Samples run on QTYPE lots E060 and older cannot be analysed in SCORE 6.2.x.x.



# Option 1: Create a new SQL database for SCORE 6.2.1.0

SCORE 6.1.3 and 6.2.x.x can be installed and run in parallel on the same PC if the following procedure is followed:

1. Create a **new SQL instance with a different name** to be used by SCORE 6.2.1.0 in order to use several versions in parallel. Do NOT upgrade your current database as it would become inaccessible by any previous version.
2. Install SCORE 6.2.1.0
3. Upon starting SCORE 6.2.1.0, follow the standard procedure to initialize the new instance and have SCORE create the SCORE database structure on it. The procedure is described in the Installation Instructions document.

## Option 2: Upgrade current database to SCORE 6.2.1.0

1. Create a backup copy of your current database before performing the update using the SQL Management Studio software from Microsoft .
  2. Install SCORE 6.2.1.0. Select to upgrade the current software and database. *(Note: This process is **irreversible**, you will not be able to use the database with a previous SCORE version anymore. Old samples can be searched and viewed but not re-analyzed or modified in SCORE 6.2.1.0. Tests from lot E060 and earlier cannot be imported after the update.)*
- Consult the installation manual or your local CareDx representative for instructions/further information



# Software overview - 3

Please upgrade to SCORE 6.2.1.0 ASAP

- The typing kit files differ between SCORE 6.1.3.1 and 6.2.x.x. We will not generate new kit files for SCORE 6.1.3.1 after lot **E067**
- Typing Kit file compatibility:
  - Typing kit files compatible with SCORE 6.1.3.1 will be provided until (and including) lot **E067**.
  - Typing kit files compatible with SCORE 6.2.x.x will be provided **from lot E061 and onward**.

# Software overview - 4

Updated Windows and SQL server support

- Supported Windows versions
  - Windows 10 Pro (64 bit)
  - **Windows 10 Enterprise (64 bit)**
  - **Windows 11 Pro (64 bit)**
- Supported SQL servers
  - Microsoft® SQL Server® 2012
  - Microsoft® SQL Server® 2014
  - Microsoft® SQL Server® 2016
  - Microsoft® SQL Server® 2017
  - **Microsoft® SQL Server® 2019**

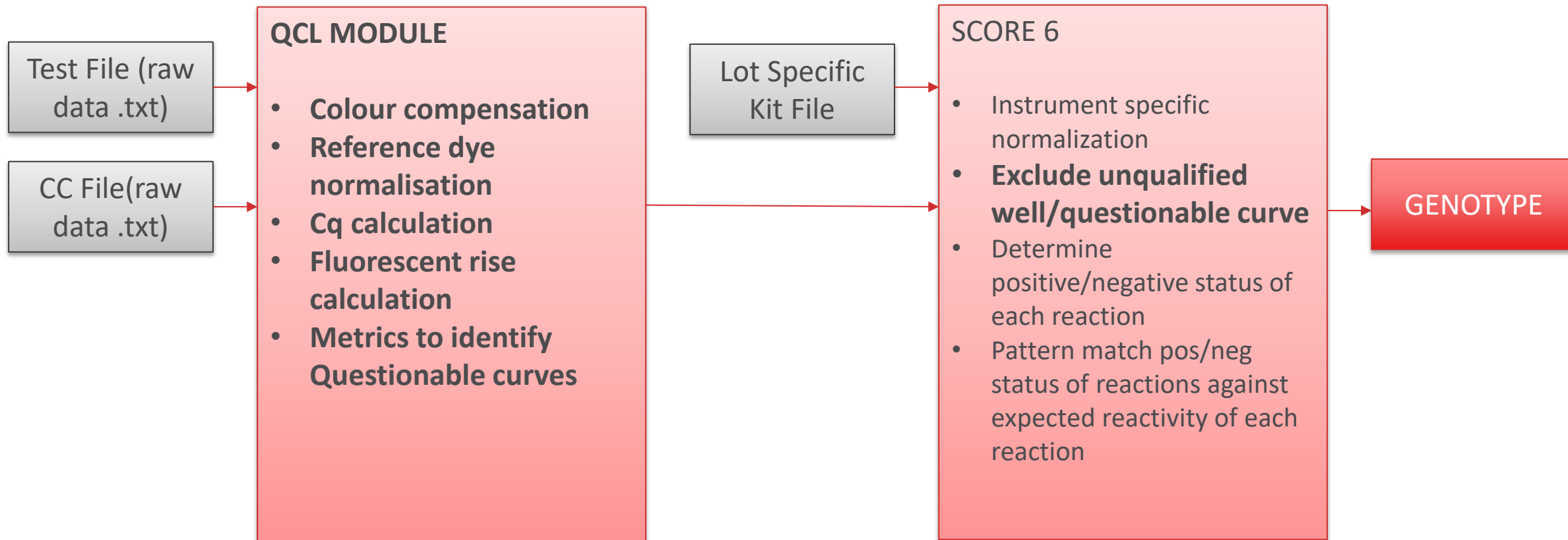
## SCORE 6.2.1.0 Main new features:

1. New raw data processing algorithm (QCL) (SCORE 6.2.x.x)
2. Exclusion of problematic wells
3. Processing high instrument reads (reason for patch)
4. Compatible with QuantStudio 6 Pro and QuantStudio 7 Pro
5. Built-in CC file check (SCORE 6.2)
6. Separated Common and Well documented allele combinations (SCORE 6.2)
7. Other fixes and improvements

# 1. New raw data processing algorithm (QCL) (SCORE 6.2.x.x)

# New features: QCL (QTYPE Calculation Library)

- QCL data process flowchart



# New features: QCL (QTYPE Calculation Library)

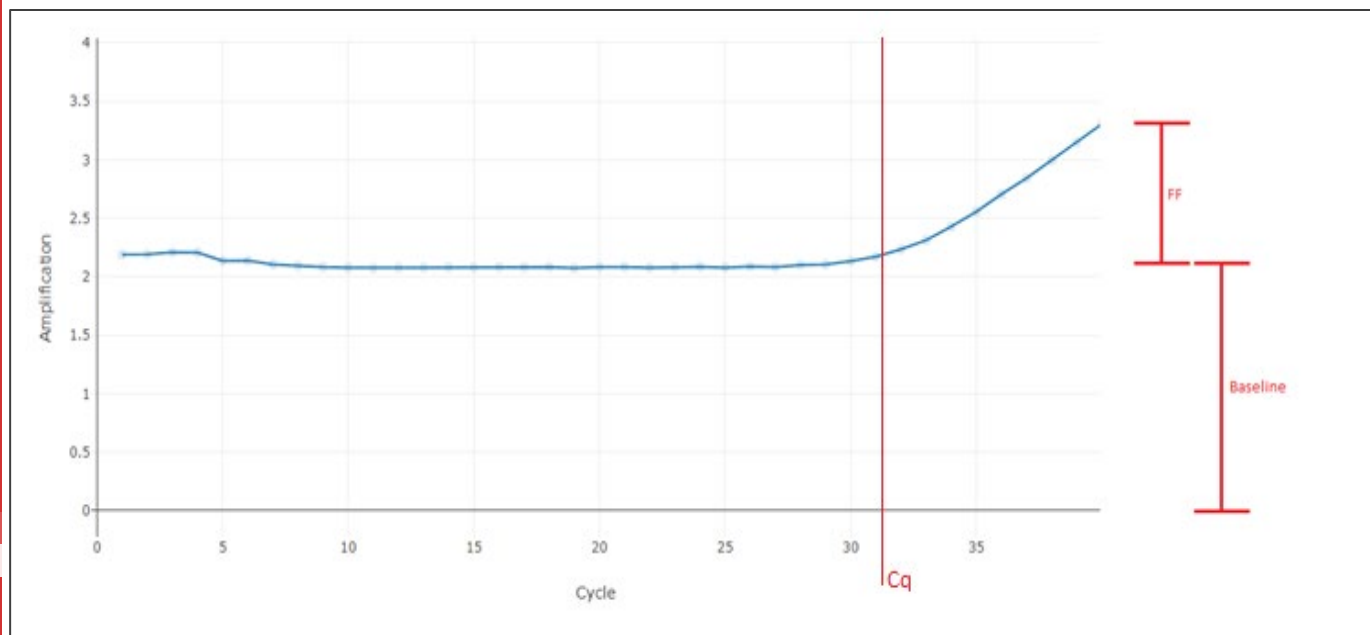
- New Calculation for rFF

Call	+
Well	F1
Channel	O560
Cq	28.50
Rel. Cq	1.08 +
Rel. Range	(0.80-1.25)
Final fl	3.51
Rel. Final fl	2.44 +
Threshold	1.4

$$\text{Rel. Final fl} = \frac{\text{final fluorescence (FF)}}{\text{reference fluorescence (baseline)}}$$

Ex.  $2.44 = \frac{3.51}{\text{reference fluorescence (baseline)}}$

NOTE: Reference fluorescence (baseline) number doesn't show in SCORE 6.2



- Method 1:

- Ratio of the **final fluorescence (FF)** to **reference fluorescence (baseline)** for the same reaction (e.g., FF of FAM to baseline of FAM; rFF is calculated independently from R610 FF)
- this method will be used for most reactions
- For mixes with an inherently high/low baseline, method 2 will be applied

- Method 2 (Same as in SCORE 6.1.3.1, FSCLV):

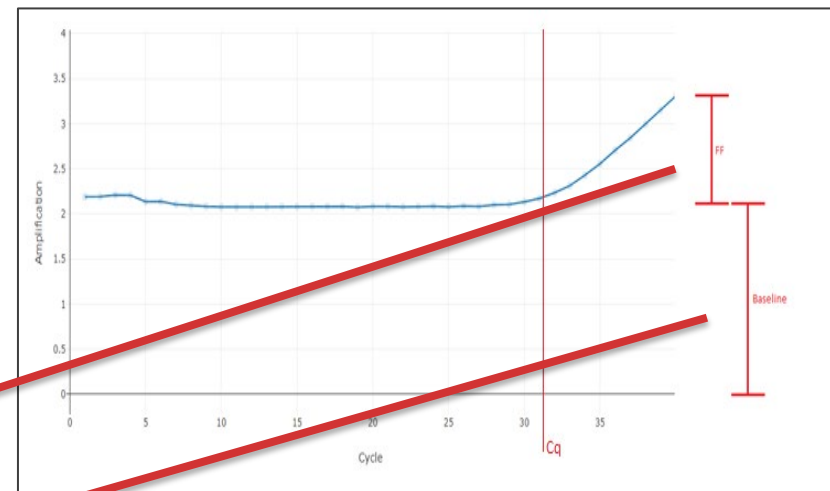
- Ratio of **FF of HLA-specific reaction** to **FF of the internal control**

# QCL Ref Final FI vs. FSCLV Ref Final FI

Both QCL and FSCLV calculations used in SCORE 6.2.x.x  
(determined in the typing kit file)

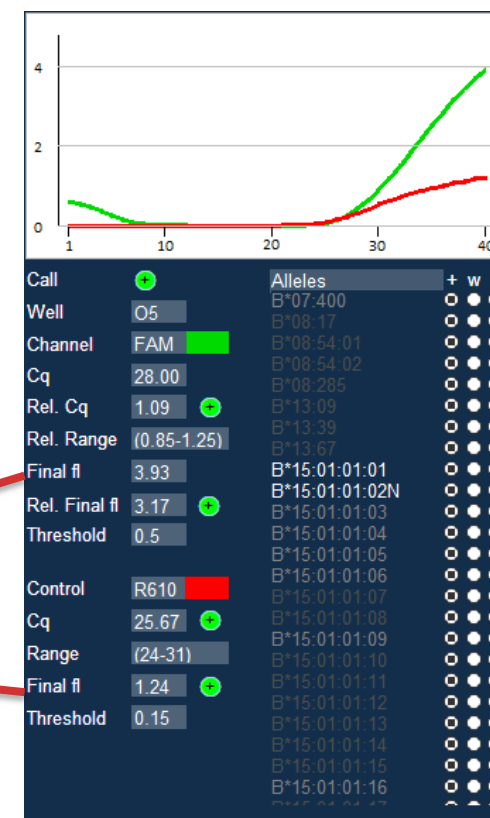
- QCL Ref Final FI :

$$\text{Rel. Final fl} = \frac{\text{final fluorescence (FF)}}{\text{reference fluorescence (baseline)}}$$



- FSCLV Ref Final FI :

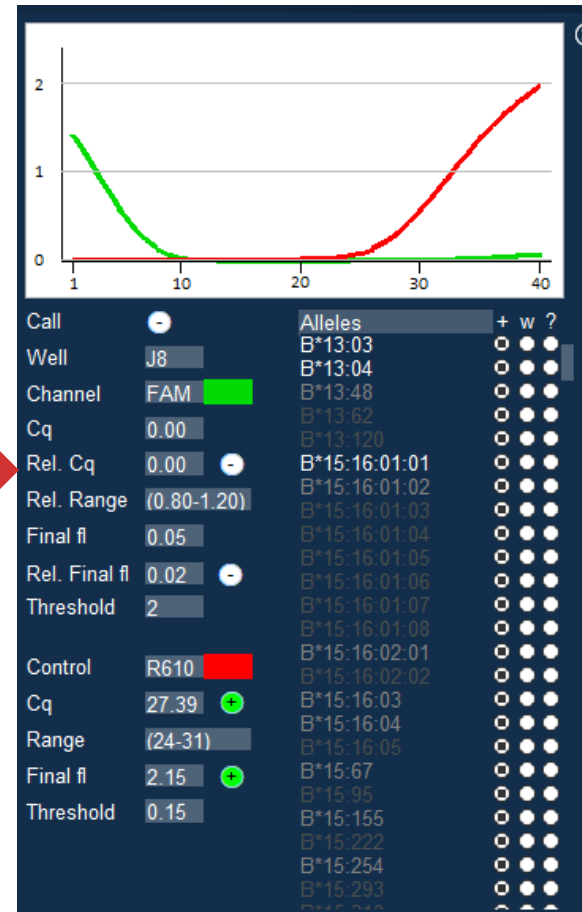
$$\text{Rel. Final fl} = \frac{\text{final fluorescence (FF)}}{\text{internal control (R610) final fluorescence}}$$



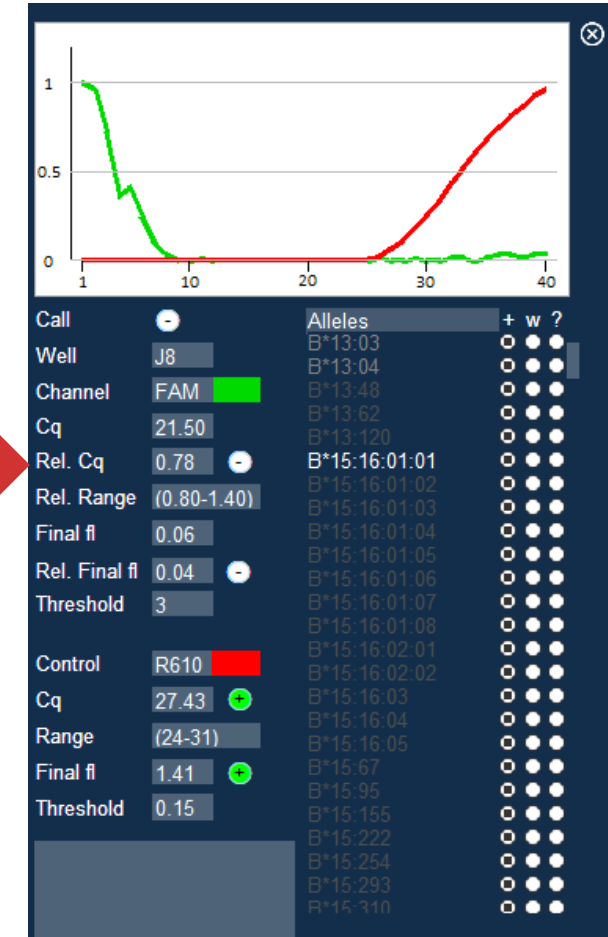
# New features: QCL (QTYPE Calculation Library)

- Benefits of QCL
  - Resolves issue with **Cq = -1**
  - Resolves previous issue with incorrect assignment of **Cq = 0** to wells with an amplification
  - QCL keeps the original Cq calculation without further modification
  - No artificial curve smoothing - SCORE 6.2 shows **actual curve characteristics**, including baseline noise. Not connected to any quality change to the wells/assay
  - Message box stating the reason for well exclusion when applicable

SCORE 6.1.3

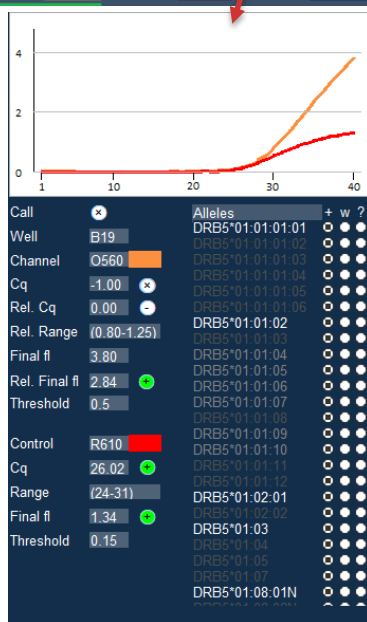
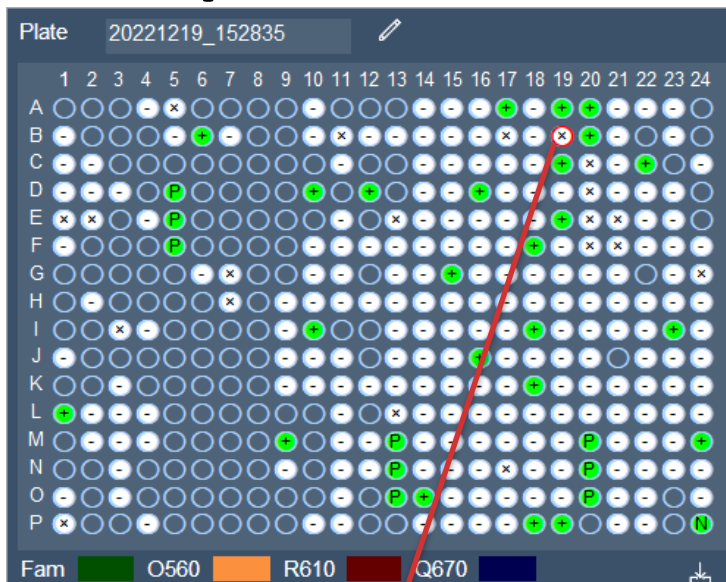


SCORE 6.2.x.x

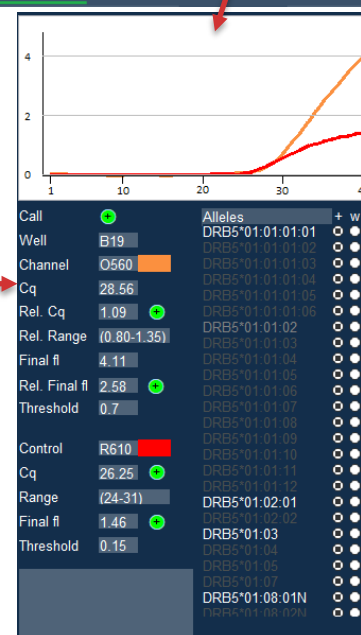
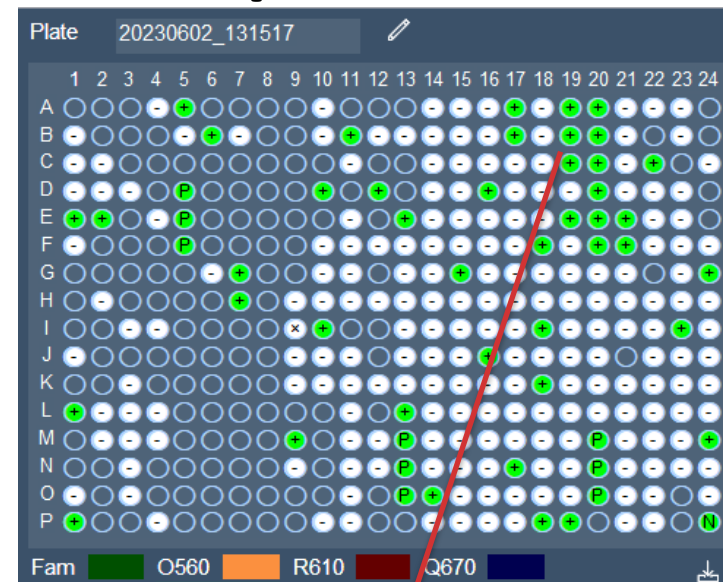




## Example Pictures: Resolves issue with $C_q = -1$



SCORE 6.1.3  
Random Cq= -1



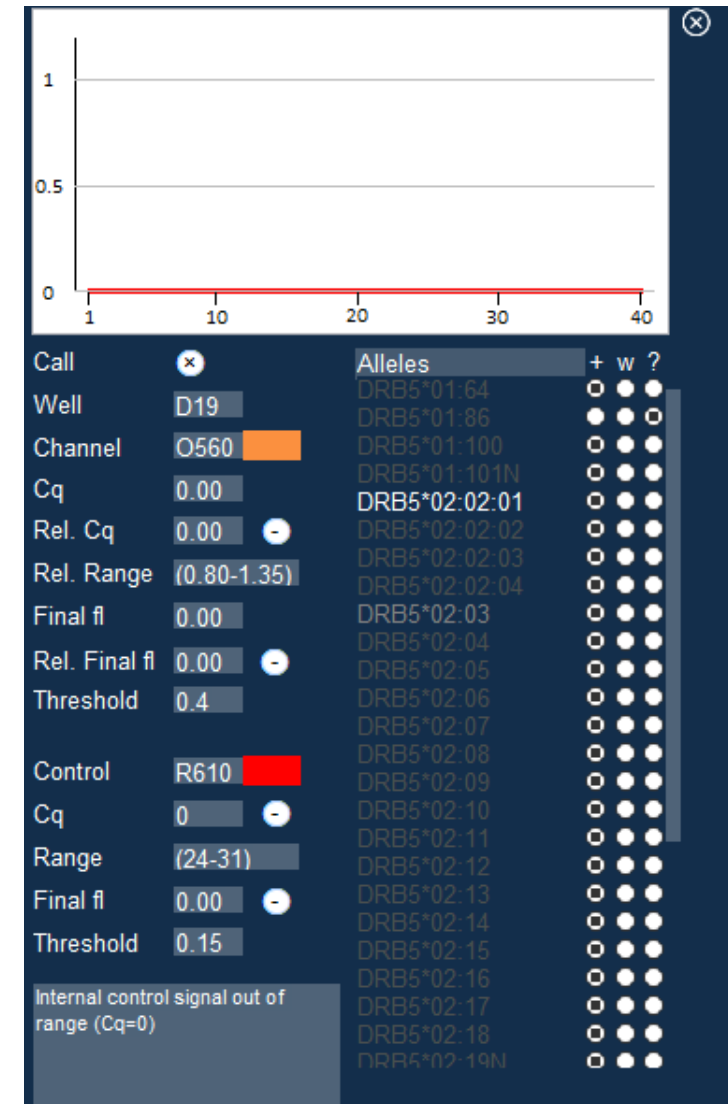
## SCORE 6.2.x.x

### Resolved issues

## 2. Exclusion of problematic wells

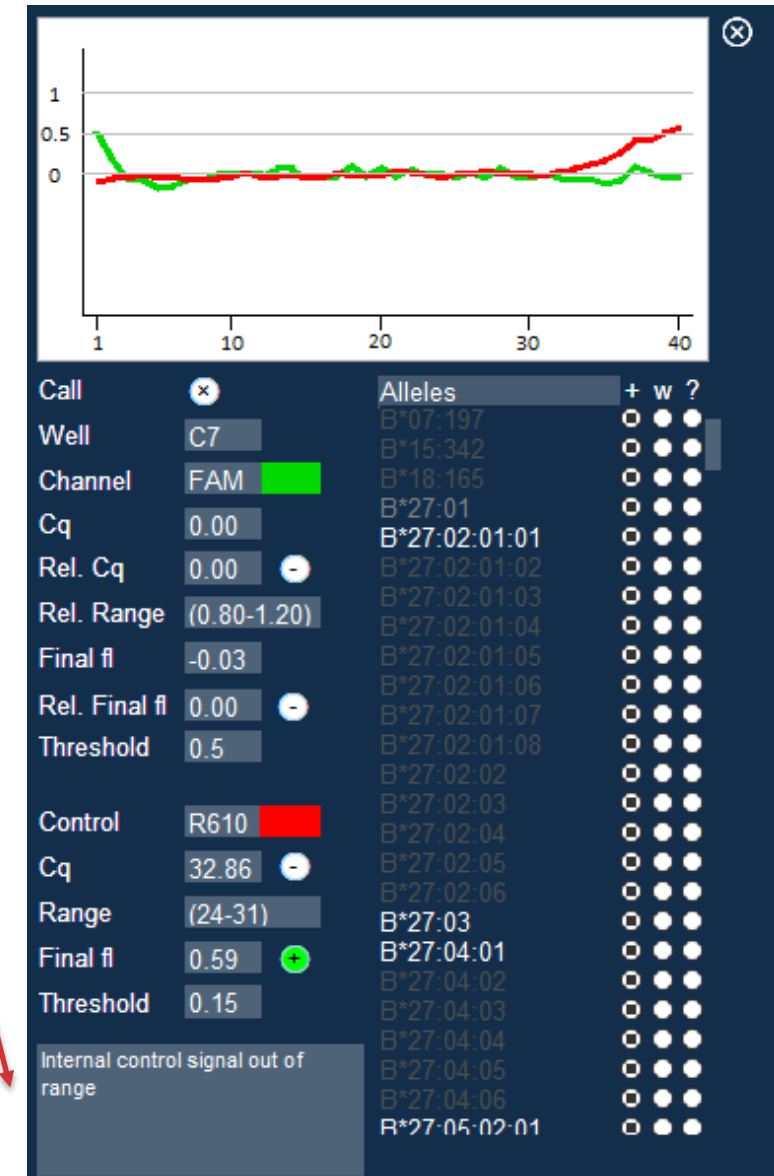
# Exclusion of Questionable Wells (1)

- Well exclusions can be triggered for multiple reasons in SCORE 6.2.x.x (Details in IFU)
- QCL brings improved curve artefact detection and SCORE 6.2.x.x will exclude such wells from analysis
- Users may see a higher number of well exclusions across runs compared to SCORE 6.1.3.1

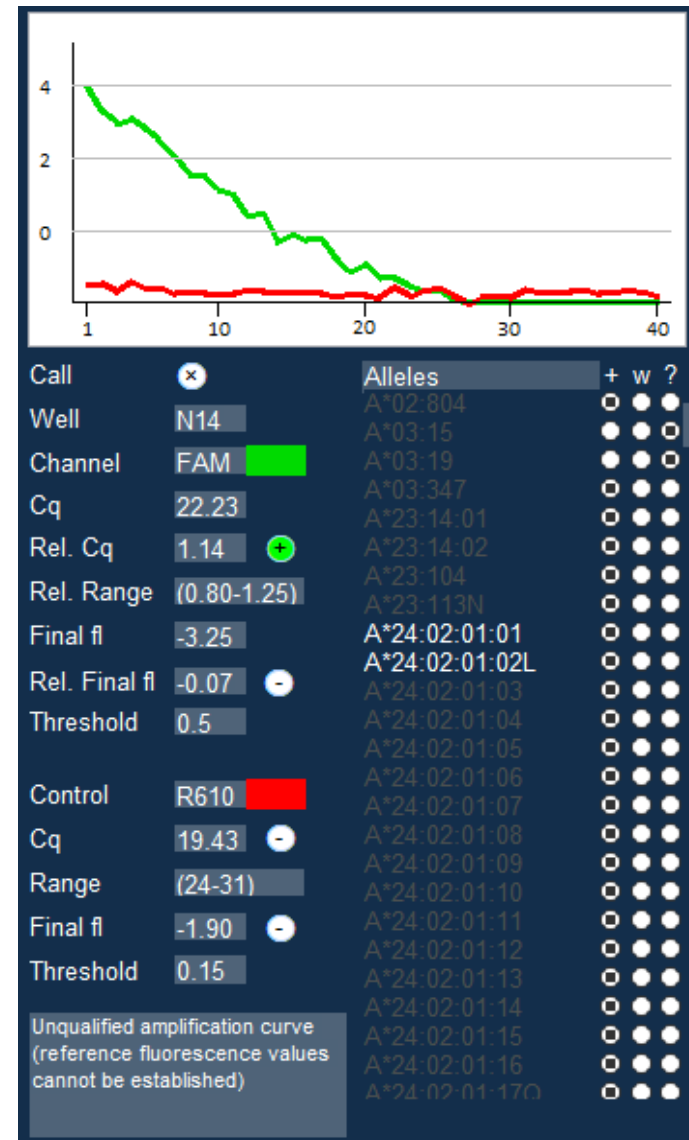
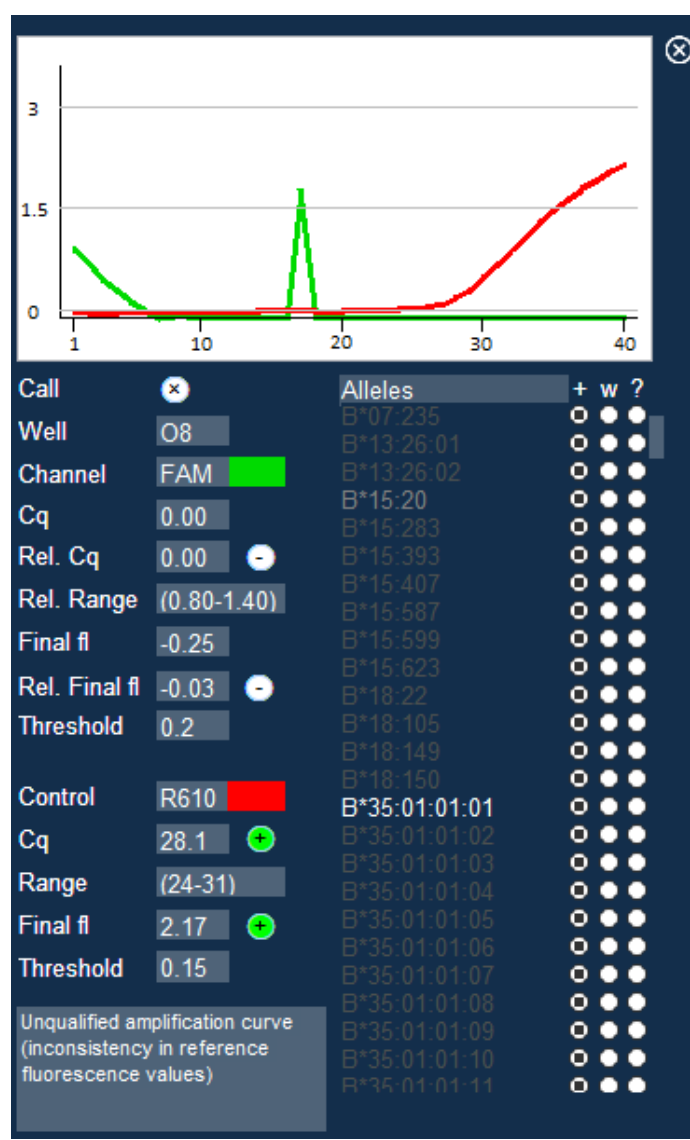
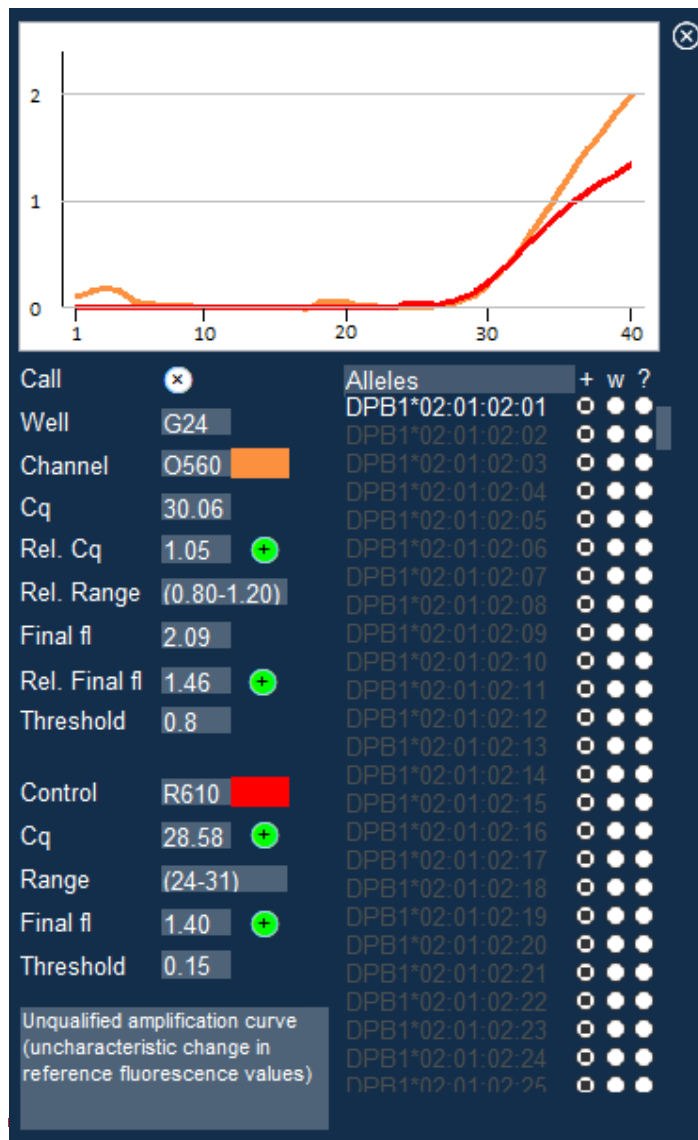


## Exclusion of Questionable Wells (2)

- The change is in the software, is intentional and is not an indication of an issue with the product or assay setup
- The reason for exclusion will be presented in the message box in the reactivity panel
- The well exclusion messages have been modified between SCORE 6.2.0.1 and SCORE 6.2.1.0



# Examples of well exclusions



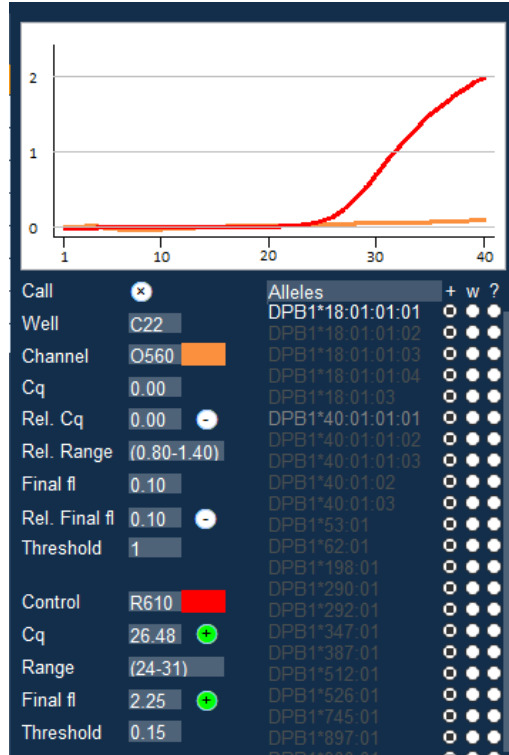
# Auto well exclusion messages tables in IFU

Information in the user interface	Potential issue/possible solution
Internal control signal out of range	Potential setup error, likely due to an insufficient amount of DNA added to the well. If problem consistently occurs in the same well(s), please contact CareDx technical support.
Unqualified amplification curve in the internal control channel	Potential setup error, likely due to an insufficient amount of DNA added to the well. If problem consistently occurs in the same well(s), please contact CareDx technical support.
Internal control signal out of range (Cq=0)	Potential pipetting error or instrument setup error. If problem consistently occurs in the same well(s), please contact CareDx technical support.



Users can find the Potential issue/possible solution for each well exclusion messages in SCORE 6.2 IFU

# NOTE: Occasionally, wells with curves that look normal may be excluded



Unqualified amplification curve  
(uncharacteristic change in reference  
fluorescence values)

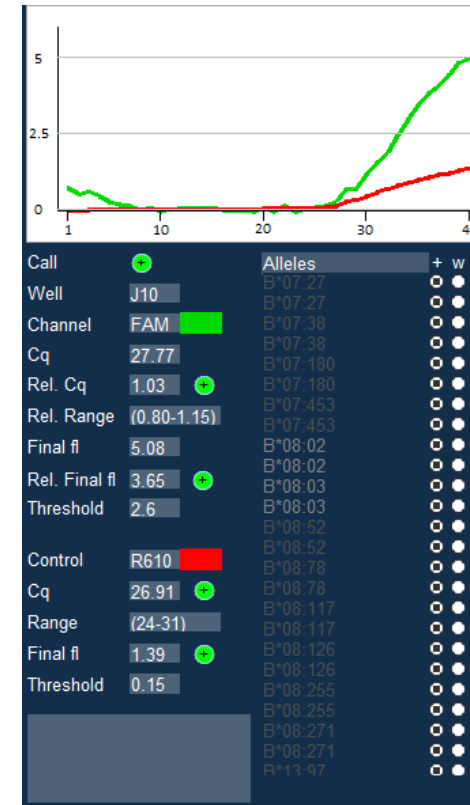
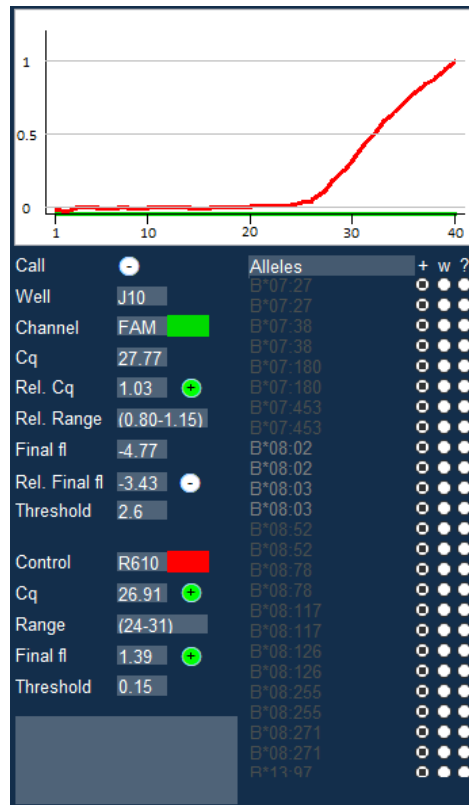
- Metrics had to be set stringent enough to rule out all bad curves
  - Curve jump is there if zoomed in
- Very low prevalence
  - Mix redundancy minimizes negative effect on typing results
  - Manually review the well if needed

### 3. Processing high instrument reads



## Fix the wells that are most likely to be affected by high values

- SCORE 6.2.0.1 was unable to process wells with high values (instrument-related)
- SCORE 6.2.1.0 applies the new scaling system when needed
- Resolved QS6/7 Pro high instrument read issue



## 4. Added instrument compatibility: QuantStudio 6 Pro and QuantStudio 7 Pro

## SCORE 6.2.1.0 can analyze data files from QuantStudio 6 Pro and QuantStudio 7 Pro instruments

- Issues that had to be overcome:
  - Scaling high instrument reads
  - Parsing the data header for QS6 Pro and QS7 Pro (# issue)

```
* Block Type = 384-Well Block
* Calibration Background is expired = No
* Calibration Background performed on = 10
* Calibration Pure Dye ABY is expired = No
* Calibration Pure Dye ABY performed on =
* Calibration Pure Dye CY5 is expired = No
* Calibration Pure Dye CY5 performed on =
* Calibration Pure Dye FAM is expired = No
* Calibration Pure Dye FAM performed on =
* Calibration Pure Dye JUN is expired = No
* Calibration Pure Dye JUN performed on =
* Calibration Pure Dye MUSTANG PURPLE is e
* Calibration Pure Dye MUSTANG PURPLE perf
```

Old ABI instrument data

```
# File Name: D:\HLA\Ruwe-Data\QTYPE\20230502_Repr2_Qtype_SvD_202
# Comment:
# Operator: Admin
# Barcode:
# Instrument Type: QuantStudio™ 7 Pro System
# Block Type: 384-Well Block
# Instrument Name: QS7Pro-2778722070079
# Instrument Serial Number: 2778722070079
# Heated Cover Serial Number: 2779322021758
# Block Serial Number: 2778321121678
# Run Start Date/Time: 2023-05-02 01:09:38 PM CEST
# Run End Date/Time: 2023-05-02 02:00:06 PM CEST
# Run Duration: 50 minutes 27 seconds
# Sample Volume: 10.0
# Cover Temperature: 105.0
# Passive Reference: NONE
# PCR Stage/Step Number: Stage 2 Step 3
# Quantification Cycle Method: CT
```

QuantStudio 6 / 7 Pro raw data

## 5. CC file check in SCORE 6.2.x.x

## SCORE 6.2.1.0 contains a built-in CC file check

The CC file check can now be done in SCORE, generating a report that can be printed and saved

- CC file check procedure:


- 1) Create a new patient/sample
- 2) Create a new test
  - Choose the QTYPE lot that corresponds to the CC lot
- 3) Click the 'CC' button
  - Select CC file to be checked

The screenshot shows the SCORE software interface with the 'Test' tab selected. The 'Patient' field contains 'CC file E053'. Below it, the 'Sample' field also contains 'CC file E053'. The 'Test' table lists several typing kits, with 'QTYPE 11 053QC 00 qPCR' highlighted. A red arrow points from the 'CC' button in the bottom right corner to the 'CC file E053' entry in the 'Patient' field.

Typing kit	Lot	Rev	Test	Locus
QTYPE 11	052QC	00	qPCR	(locus)
QTYPE 11	E052Q	00	qPCR	active typing kits
QTYPE 11	Q045	00	qPCR	
QTYPE 11	Q045b	00	qPCR	
QTYPE 11	053QC	00	qPCR	


# CC file check report

- The CC file check report is auto-generated after clicking CC check
- A minimum of 3 consistent wells per dye is required for the CC to be approved
  - Excluded wells are listed in the report
- The CC file check is **automatically** run with every analysis to prevent users from using an unapproved CC file
- CC files to be used for analysis with SCORE 6.1.3.1 must still be sent to CareDx for approval



6.2.0.0  
For In Vitro Diagnostic use

Olerup SSP AB  
Franségatan 5  
SE-112 51 Stockholm, Sweden



APPROVED

QTYPE color compensation file report

This report confirms that the color compensation file has been approved for use with the QTYPE lot HQ36, provided that the product-specific IPU is followed.  
Please note that CC files are instrument-specific and that a new CC file must be generated and approved after instrument maintenance/calibration

File name

2019-05-29 CC plate No DNA ABI.TXT

Instrument name

Instrument serial number

Tested with lot

revision

ViaA 7

27 888 0637

HQ36

0

Fluorescence rise			
FAM	Q560	R610	Q670
458.864833	2528.972833	5178.841167	15958.331000
1659.572833	2447.270833	4815.808500	1474.889333
-1710.197833	3104.271000	4807.290333	1676.799500
-6865.072833	2812.571333	5867.265833	1813.876333
4599.489500	2915.841000	5387.956667	1192.316500


Excluded wells			
FAM	Q560	R610	Q670
I13			G11
I14			

CC matrix				
Wells / Signal	FAM signal	Q560 signal	R610 signal	Q670 signal
FAM wells	0.993450	-0.141375	-0.132836	-0.261160
Q560 wells	0.106097	0.987557	-0.002536	-0.063408
R610 wells	0.034725	-0.025948	0.991106	0.051032
Q670 wells	-0.024377	-0.063799	-0.007506	0.961858

Report created 2020-11-11 14:22


CE

1 / 1



6.2.0.0  
For In Vitro Diagnostic use

Olerup SSP AB  
Franségatan 5  
SE-112 51 Stockholm, Sweden



NOT APPROVED

QTYPE color compensation file report

This file is not approved.  
Too many wells excluded on the CC plate due to inconsistent spectra.  
Please note that CC files are instrument-specific and that a new CC file must be generated and approved after instrument maintenance/calibration

File name

LCinconsistentCC.txt

Instrument name

Instrument serial number

Tested with lot

revision

LightCycler 480 II

HQ36

0

Fluorescence rise			
FAM	Q560	R610	Q670
4.031667	7.508667	1.980000	0.615000
0.101667	8.206667	1.975000	0.623333
0.033333	8.498333	1.915000	0.593333
0.000000	8.196667	1.975000	0.695000
4.120000	9.113333	1.980000	0.570000

Excluded wells			
FAM	Q560	R610	Q670
I11			
I12			
I13			
I14			
I10			

CC matrix				
Wells / Signal	FAM signal	Q560 signal	R610 signal	Q670 signal
FAM wells	0.000000	0.000000	0.000000	0.000000
Q560 wells	0.000000	0.000000	0.000000	0.000000
R610 wells	0.000000	0.000000	0.000000	0.000000
Q670 wells	0.000000	0.000000	0.000000	0.000000

Report created 2020-11-11 14:23

CE

1 / 1

## 6. Separation of Common and Well documented allele combinations

# Separation of Common and Well Documented allele combinations

HLA-B	B*35	B*58	B35, -; B58(17), -
CWD allele combinations			
	B*35	B*58	B35, -; B58(17), -
CWD/rare allele combinations			
	B*35	B*58	B35, -, Null; B58(17), Null, -
	B*37:67	B*58	-; B58(17), -
Rare allele combinations			
	B*35	B*58	B35, -, Null; B58(17), Null, -
	B*37:67	B*58	-; B58(17), Null, -
Analysed: 12/19/2022 stevechang			
Allele db: HLADB_3.47.0			

SCORE 6.1.3.1

HLA-A	A*01:01:01:01	A*03:01:01:01
Common allele combinations		
	A*01	A*03:01:01:01
Common/Well documented allele combinations		
	A*01	A*03
Well documented allele combinations		
	A*01	A*03
Combinations with rare alleles		
	A*01	A*03

SCORE 6.2.0.1  
(CE only)

Locus	Allele combination	Serology
HLA-A	A*02	A2, -
Common + Common allele combinations		
	A*02	A2, -
	A*02	A2, -
Common + Well Documented allele combinations		
	A*02	A2, -
Well documented + Well Documented allele combinations		
	A*02	A2, -
	A*02	A2, -
Combinations with Rare alleles		
	A*02	A2, Low A2, -, Null
	A*02	Low A2, A2, -, Null; A2, Low A2, -, Null
Analysed: 12/22/2022 stevechang		
Allele db: HLADB_3.49.0		

SCORE 6.2.1.0 (patch)



## Changed the wording of heading titles and default settings (upon installation):

Typing options	These options are set globally and will affect all users connected to the same SQL database	
	Use alleleDb	Kit design version (max 1 year old)
		Use CWD allele version 2
	Nomenclature mode for single results	Group results by allele properties
	Standard nomenclature	Display all alleles in the same way
XML options	Omit silent mutation (display main and subgroups)	Split into Common only and Other allele combinations
HPRIM options	P-nomenclature (same Protein in main binding region)	Add an additional group for Common+Other combinations
Report header	G-nomenclature (same DNA in main binding exons)	Add an additional group for rare alleles
Lab comment	Serological equivalent of HLA dictionary based on	Increased tolerance calculation
	WHO assignment	Increase tolerance until Common results are found
	Expert assignment	Increase tolerance until Common+Other results are found
	Custom serology	Increase tolerance until any results are found
	Designation of serological equivalents is based on:	Limit manual assignment
	R. Holdsworth, C.K. Hurley, S.G.E. Marsh, et al. The HLA Dictionary 2008: Tissue Antigens (2009) 73:95-170	Limit assigned results to main group only
	Omit alleles not tested for by typing kits	Display homozygous results twice
	Omit listing of alleles not tested in the information field	

# Explanation of result allele grouping in SCORE 6.2.1.0

(4) Add an additional group for rare alleles (Default setting)

Typing options

XML options

HPRIM options

Report header

Lab comment

These options are set globally and will affect all users connected to the same SQL database

Use alleleDb Kit design version (max 1 year old) Use CWD allele version 2

Nomenclature mode for single results  
Standard nomenclature

Omit silent mutation (display main and subgroups)

P-nomenclature (same Protein in main binding region)

G-nomenclature (same DNA in main binding exons)

Serological equivalent of HLA dictionary based on  
WHO assignment  
Expert assignment  
Custom serology

Designation of serological equivalents is based on:  
[R. Holdsworth, C.K. Hurley, S.G.E. Marsh, et al. The HLA Dictionary 2008: Tissue Antigens \(2009\) 73:95-170](#)

Omit alleles not tested for by typing kits

Omit listing of alleles not tested in the information field

Export serology list

Group results by allele properties

Display all alleles in the same way

Split into Common only and Other allele combinations

Add an additional group for Common+Other combinations

Add an additional group for rare alleles

Increased tolerance calculation

Increase tolerance until Common results are found

Increase tolerance until Common+Other results are found

Increase tolerance until any results are found

Limit manual assignment

Limit assigned results to main group only

Display homozygous results twice

- Group results by allele properties
- Display all alleles in the same way
  - Split into Common only and Other allele combinations
  - Add an additional group for Common+Other combinations
  - Add an additional group for rare alleles

	Common	WD	Rare
Common			
WD			
Rare			

Four groups total

Locus	Allele combination	Serology
HLA-A	A*02	A2, -
Common + Common allele combinations		
	A*02	A2, -
	A*02 A*02	A2, -
Common + Well Documented allele combinations		
	A*02 A*02	A2, -
Well documented + Well Documented allele combinations		
	A*02 A*02	A2, -
Combinations with Rare alleles		
	A*02	A2, Low A2, -, Null
	A*02 A*02	Low A2, A2, -, Null; A2, Low A2, -, Null

Analysed: 12/22/2022 stevechang  
Allele db: HLADB\_3.49.0

# Explanation of the grouping in SCORE 6.2.1.0

(3) Add an additional group Common + Other combinations

Typing options These options are set globally and will affect all users connected to the same SQL database

Use alleleDb Kit design version (max 1 year old) Use CWD allele version 2

Nomenclature mode for single results  
 Standard nomenclature  
 Omit silent mutation (display main and subgroups)  
 HPRIM options P-nomenclature (same Protein in main binding region)  
 Report header G-nomenclature (same DNA in main binding exons)  
 Lab comment Serological equivalent of HLA dictionary based on  
 WHO assignment  
 Expert assignment  
 Custom serology

Group results by allele properties  
 Display all alleles in the same way  
 Split into Common only and Other allele combinations  
 Add an additional group for Common+Other combinations  
 Add an additional group for rare alleles

Increased tolerance calculation  
 Increase tolerance until Common results are found  
 Increase tolerance until Common+Other results are found  
 Increase tolerance until any results are found

Designation of serological equivalents is based on:  
 R. Holdsworth, C.K. Hurley, S.G.E. Marsh, et al. The HLA Dictionary 2008: Tissue Antigens (2009) 73:95-170

Limit manual assignment  
 Limit assigned results to main group only

Omit alleles not tested for by typing kits  
 Display homozygous results twice

Omit listing of alleles not tested in the information field

Export serology list

	Common	WD	Rare
Common			
WD			
Rare			

Three groups total

- Group results by allele properties
- 1 Display all alleles in the same way
  - 2 Split into Common only and Other allele combinations
  - 3 Add an additional group for Common+Other combinations
  - 4 Add an additional group for rare alleles

HLA-A	A*02	A*11:01:01:01	A2, -, A11
Common + Common allele combinations			
	A*02	A*11:01:01:01	A2, -, A11
Common + Well Documented or Rare allele combinations			
	A*02	A*11	A2, -, Low A2, Null; A11, -, Null
Well Documented and/or Rare allele combinations			
	A*02	A*11	Low A2, A2, -, Null; A11, -, Null

Analysed: 6/1/2023 stevechang  
 Allele db: HLADB\_3.49.0

# Explanation of the grouping in SCORE 6.2.1.0

## (2) Split into Common only and Other allele combinations

Typing options These options are set globally and will affect all users connected to the same SQL database

Use alleleDb Kit design version (max 1 year old) Use CWD allele version 2

Nomenclature mode for single results

Standard nomenclature

Omit silent mutation (display main and subgroups)

XML options

HPRIM options

Report header

Lab comment

P-nomenclature (same Protein in main binding region)

G-nomenclature (same DNA in main binding exons)

Serological equivalent of HLA dictionary based on

WHO assignment

Expert assignment

Custom serology

Export serology list

Designation of serological equivalents is based on:

R. Holdsworth, C.K. Hurley, S.G.E. Marsh, et al. The HLA Dictionary 2008; Tissue Antigens (2009) 73:95-170

Group results by allele properties

Display all alleles in the same way

Split into Common only and Other allele combinations

Add an additional group for Common+Other combinations

Add an additional group for rare alleles

Increased tolerance calculation

Increase tolerance until Common results are found

Increase tolerance until Common+Other results are found

Increase tolerance until any results are found

Limit manual assignment

Limit assigned results to main group only

Omit alleles not tested for by typing kits

Display homozygous results twice

Omit listing of alleles not tested in the information field

	Common	WD	Rare
Common			
WD			
Rare			

- Group results by allele properties
- 1 Display all alleles in the same way
  - 2 Split into Common only and Other allele combinations
  - 3 Add an additional group for Common+Other combinations
  - 4 Add an additional group for rare alleles

Two groups total

▼ HLA-A	A*02	A*11:01:01:01	A2, -, A11
▼	Common + Common allele combinations		
▶	A*02	A*11:01:01:01	A2, -, A11
▼	Other allele combinations		
▶	A*02	A*11	A2, Low A2, -, Null; A11, -, Null
Analysed: 6/1/2023 stevechang			
Allele db: HLADB_3.49.0			

# Explanation of the grouping in SCORE 6.2.1.0

(1) Display all alleles in the same way

Typing options: These options are set globally and will affect all users connected to the same SQL database

Use alleleDb: Kit design version (max 1 year old) | Use CWD allele version: 2

Nomenclature mode for single results: Standard nomenclature | Omit silent mutation (display main and subgroups) | P-nomenclature (same Protein in main binding region) | G-nomenclature (same DNA in main binding exons)

Group results by allele properties: Display all alleles in the same way | Split into Common only and Other allele combinations | Add an additional group for Common+Other combinations | Add an additional group for rare alleles

XML options | HPRIM options | Report header | Lab comment

Serological equivalent of HLA dictionary based on: WHO assignment | Expert assignment | Custom serology | [Export serology list](#)

Designation of serological equivalents is based on: [R. Holdsworth, C.K. Hurley, S.G.E. Marsh, et al., The HLA Dictionary 2008: Tissue Antigens \(2009\) 73:95-100](#)

Increased tolerance calculation: Increase tolerance until Common results are found | Increase tolerance until Common+Other results are found | Increase tolerance until any results are found

Limit manual assignment: Limit assigned results to main group only

Display homozygous results twice

Omit alleles not tested for by typing kits

Omit listing of alleles not tested in the information field

	Common	WD	Rare
Common			
WD			
Rare			

One groups total

- Group results by allele properties
- 1 Display all alleles in the same way
  - 2 Split into Common only and Other allele combinations
  - 3 Add an additional group for Common+Other combinations
  - 4 Add an additional group for rare alleles

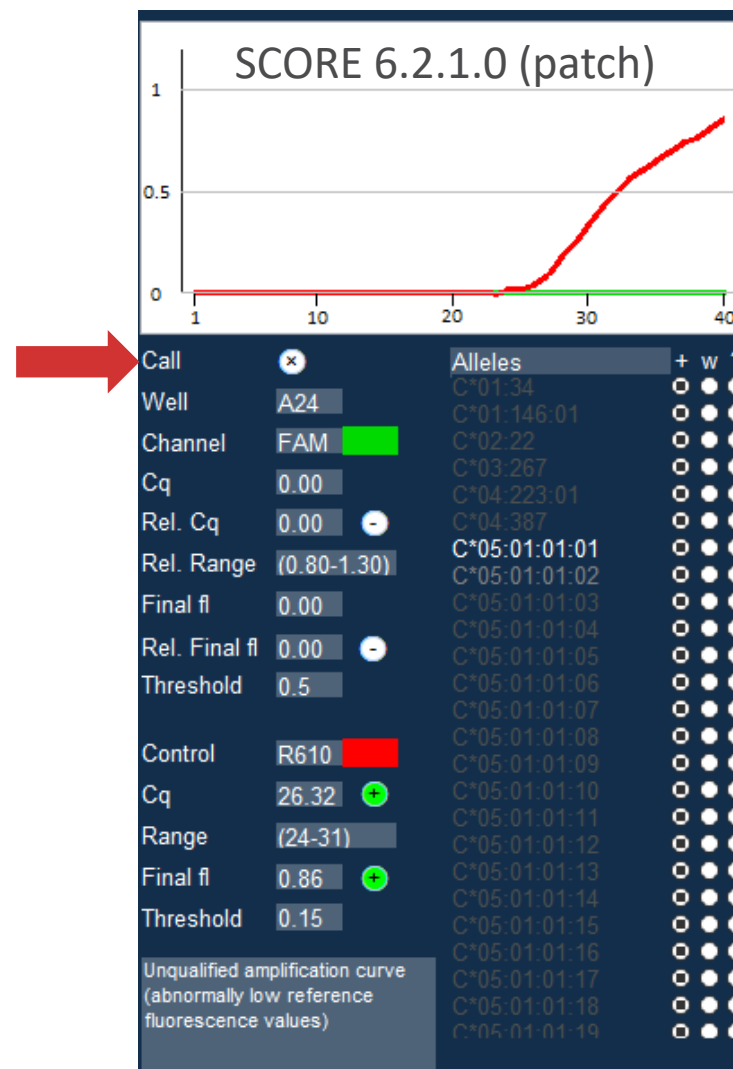
HLA-A	A*02	A*11	A2, Low A2, -, Null; A11, -, Null
Allele combinations			
	A*02	A*11	A2, Low A2, -, Null; A11, -, Null
Analysed:	6/1/2023	stevechang	
Allele db:	HLADB_3.49.0		

## 7. Other Fixes and Improvements



# (1) A24 orange well display corrected

In rare cases, A24 was displayed as an orange symbol with a '+' sign despite the mix being negative in SCORE 6.2.0.1. This has been changed to the correct symbol for an excluded well in SCORE 6.2.1.0.



## (2) SCORE Report Improvements

- Serological Equivalent is cleaner; less “-”
- Empty rows in report removed, signature box on the first page

SCORE 6.1.3.1

Locus	Genotype	Serological eq.	Bw status	E <sup>1</sup> M <sup>2</sup> 3
HLA-A	A*02	A*24	A2, -; A24(9), -, A24, Null, A2403	Bw4 (0)
HLA-B	B*07	B*38	B7, -; B38(16), B16	Bw4/Bw6 (0)
HLA-C	C*07	C*12	Cw7, -; -	(0)
HLA-DRB	DRB1*14:01:01	DRB1*15	DR14(6); DR15(2), -	(0)
	DRB3*02:01	DRB5*01:01	DR52; DR51	(0)
HLA-DQA1	DQA1*01:02	DQA1*01:04:01:01		(0)
HLA-DQB1	DQB1*05:03:01:01	DQB1*06	DQ5(1); DQ6(1), -	(0)
HLA-DPA1	DPA1*01:03:01:01			(0)
HLA-DPB1	DPB1*04:01:01:01			(0)

SCORE 6.2.x.x

Locus	Genotype	Serological eq.	Bw status	E <sup>1</sup> M <sup>2</sup> 3
HLA-A	A*02	A*24	A2, -; A24(9), -	Bw4 (0)
HLA-B	B*07:02:01:01	B*38	B7; B38(16)	Bw4/Bw6 (0)
HLA-C	C*07:02:01:01	C*12:03:01:01	Cw7; -	(0)
HLA-DRB	DRB1*14:01:01	DRB1*15	DR14(6); DR15(2)	(0)
	DRB3*02:01	DRB5*01:01:01:01	DR52; DR51	(0)
HLA-DQA1	DQA1*01:02:01:01	DQA1*01:04:01:01		(0)
HLA-DQB1	DQB1*05:03:01:01	DQB1*06:02:01:01	DQ5(1); DQ6(1)	(0)
HLA-DPA1	DPA1*01:03:01:01			(0)
HLA-DPB1	DPB1*04:01:01:01			(0)

CareDx AB  
Franzégatan 5  
SE-112 51 Stockholm, Sweden

6.2.0.1  
For In Vitro Diagnostic use

IC E061 17164 C39 ABI LUK Sample ID: 2022-07-25 QC E061 17164 C39 ABI LUK

### HLA DNA-typing report

2022-10-11

Patient ID 2022-07-25 QC E061 17164 C39 ABI LUK	Patient name
Sample ID 2022-07-25 QC E061 17164 C39 ABI LUK	Sample received 2022-09-19

**Laboratory assignment**

Locus	Genotype	Serological eq.	Bw status	E <sup>1</sup> M <sup>2</sup> 3
HLA-A	A*01	A*03:01:01:01	A1; A3	(0)
HLA-B	B*08:01:01:01	B*27:05:02:01	B8; B27	(0)
HLA-C	C*02:02:02:01	C*07	Cw2; Cw7, -	(0)
HLA-DRB	DRB1*03:01:01:01	DRB1*04:01:01:01	DR17(3); DR4	(0)
	DRB3*01:01:02:01	DRB4*01	DR52; -, DR53	(0)
HLA-DQA1	DQA1*03:03:01:01	DQA1*05:01:01:01		(0)
HLA-DQB1	DQB1*02:01:01:01	DQB1*03	DQ2; DQ7(3), -	(0)
HLA-DPA1	DPA1*01:03:01:01	DPA1*02:01:01:01		(0)
HLA-DPB1	DPB1*04:01:01:01	DPB1*14:01:01:01		(0)

<sup>1</sup> This locus contains manually edited well calls by the user  
<sup>2</sup> This typing result was assigned manually by the user among one to many potential results. Refer to complete list of results under the respective locus in the report.  
<sup>3</sup> This typing result was edited by the user.

A4 FAM detects Bw4 [negative]  
K7 FAM detects Bw4 [positive]  
P8 FAM, C6 FAM detects Bw6 [positive]

**Analysis details**

Locus	Analyzed by	Manually assigned by	Analyzed with	CWD Serological equivalent	Serology
All loci	dan 2022-09-19		HLADB_3.49.0	2 ExpertWhoSerology_202209	WHO

**Tested QTYPE kits**

Test QTYPE 11	Lot E061	Revision 00	Typing kit update Typingkit_QTYPE_20220919	Updated to Allele db file allele marsh HLADB_3.49.0.vda
Last modification dan 2022-09-19		Data file name 2022-07-25 QC E061 17164 C39 ABI LUK.txt		
Instrument used VIA 7		Colour compensation file name 2022-07-12 C061 C27 R00170 DWP1 ABI LUK.txt		

**Authorise and Review**

Authorised by	Signature	Date
Reviewed by	Signature	Date

Report created 2022-10-11 12:39

CE

1 / 9



### (3) File name of the imported serology file is included in the report

Analysis details		SCORE 6.1.3.1			
Locus	Analysed by	Manually assigned by	Analysed with Allele db	CWD	Serological equivalent
All loci	Carolin 2020-09-24		HLADB_3.40.0	2	WHO assignment

Analysis details		SCORE 6.2.x.x				
Locus	Analysed by	Manually assigned by	Analysed with	CWD	Serological equivalent	Serology
All loci	Rebecka 16/05/2022		HLADB_3.47.0	2	ExpertWhoSerology_202201	WHO

## (4) DRB1 and DRB345 results are no longer grouped as a single locus and are now sorted and presented according to CWD allele status in the Analysis pane

Example 1: A sample with 'Common + Common' DRB1 and DRB3 alleles; both are presented under 'Common + Common allele combinations'

▼ HLA-DRB	DRB1*13	DRB1*15:03:01:01	DR13(6); DR15(2)
	DRB3*02	DRB5*01:01:01:01	DR52; DR51
▼ Common + Common allele combinations			
▶	DRB1*13	DRB1*15:03:01:01	DR13(6); DR15(2)
▶	DRB3*02	DRB5*01:01:01:01	DR52; DR51
▼ Common + Well Documented allele combinations			
▶	DRB1*13	DRB1*15	DR13(6), -; DR15(2), -
▶	DRB3*02	DRB5*01:01	DR52, -; DR51
▼ Well documented + Well Documented allele combinations			
▶	DRB1*13	DRB1*15:23	DR13(6), -; -
▶	DRB3*02	DRB5*01:01:02	-, DR52; DR51
▼ Combinations with Rare alleles			
▶	DRB1*13	DRB1*15	DR13(6), -, Null; DR15(2), -, Null
▶	DRB3*02	DRB5*01	DR52, -, Null; DR51, -, Null
Analysed: 6/2/2023 stevechang			
Allele db: HLADB_3.49.0			

Example 2: A sample with a 'Common + Common' DRB3 allele results; the DRB1 results are listed under the other groupings as there is no 'Common + Common' DRB1 result.

▼ HLA-DRB	No Common + Common results		
	DRB3*02	DR52	
▼ Common + Common allele combinations			
▶	DRB3*02	DR52	
▶	DRB3*02	DRB3*02	DR52
▼ Common + Well Documented allele combinations			
▶	DRB1*08:03:02:01	DRB1*14:14	DR8; DR14(6)
▶	DRB3*02	DRB3*02	DR52, -
▼ Well documented + Well Documented allele combinations			
▶	DRB1*08:19	DRB1*14:14	-; DR14(6)
▶	DRB3*02	-, DR52	
▶	DRB3*02	DRB3*02	DR52, -; -, DR52
▼ Combinations with Rare alleles			
▶	DRB1*08	DRB1*14	DR8, -, Null; -, DR14(6)
▶	DRB3*01	DRB3*02	DR52, -; DR52, -, Null
▶	DRB3*02	DR52, -, Null	
▶	DRB3*02	DRB3*02	DR52, -, Null
Analysed: 6/8/2023 stevechang			
Allele db: HLADB_3.49.0			

## **(5-1) Excluding non-CWD DRB3/4/5 alleles from mixes designed to primarily amplify DRB1 alleles, and vice versa, from SCORE 6.2**

- Allele combination frequency sorting is separated between DRB1 and DRB3/4/5 in SCORE 6.2. Due to this, (non-CWD) DRB3/4/5 alleles amplified in mixes designed to primarily amplify DRB1 alleles – and vice versa – may cause ambiguities in the results.
- To prevent a user from choosing an 'impossible' DRB1/DRB345 allele combination, such non-CWD DRB1 and DRB345 alleles have been removed from analysis in the SCORE 6.2 typing kit files (starting from Typingkit\_QTYPE\_20240126.vda)
- The rejected alleles will be listed in the latest versions of the product inserts for each QTYPE lot

## (5-2) Excluding non-CWD DRB3/4/5 alleles from mixes designed to primarily amplify DRB1 alleles, and vice versa, from SCORE 6.2

Old TKF

HLA-DRB	DRB1*13	DRB1*13	DR13(6)
Common ambiguities			DR52
Common + Common allele combinations			
	DRB1*13	DRB1*13	DR13(6)
	DRB3*01:01:02:01		DR52
	DRB3*01:01:02:01	DRB3*01:01:02:01	DR52
	DRB3*01:01:02:01	DRB3*02	DR52
Common + Well Documented allele combinations			
	DRB1*13	DRB1*13	DR13(6), -
	DRB3*01	DRB3*02	DR52, -; -, DR52
	DRB3*01:01:02:01	DRB3*01	DR52; -
Well documented + Well Documented allele combinations			
	DRB1*13	DRB1*13	DR13(6), -
	DRB3*01		-
	DRB3*01	DRB3*01	-
	DRB3*01	DRB3*02	-; -, DR52
Combinations with Rare alleles			
	DRB1*13	DRB1*13	DR13(6), -, Null
	DRB1*13	DRB1*14:141	DR13(6), -, Null; -
	DRB3*01		DR52, -, Null
	DRB3*01	DRB3*01	DR52, -, Null
	DRB3*01	DRB3*02	DR52, -, Null
	DRB3*02	DRB3*02:42	DR52, -, Null; -
	DRB3*02:42		-



New TKF

(Typingkit\_QTYPE\_20240126.vda and later)

HLA-DRB	DRB1*13	DRB1*13	DR13(6)
	DRB3*01:01:02:01	DRB3*02	DR52
Common + Common allele combinations			
	DRB1*13	DRB1*13	DR13(6)
	DRB3*01:01:02:01	DRB3*02	DR52
Common + Well Documented allele combinations			
	DRB1*13	DRB1*13	DR13(6), -
	DRB3*01	DRB3*02	DR52, -; -, DR52
Well documented + Well Documented allele combinations			
	DRB1*13	DRB1*13	DR13(6), -
	DRB3*01	DRB3*02	-; -, DR52
Combinations with Rare alleles			
	DRB1*13	DRB1*13	DR13(6), -, Null
	DRB1*13	DRB1*14:141	DR13(6), -, Null; -
	DRB3*01	DRB3*02	DR52, -, Null
	DRB3*02	DRB3*02:42	DR52, -, Null; -

- No DRB3/4/5 ambiguity
- Showing the correct result:  
DRB1\*13, DRB1\*13  
DRB3\*01:01, DRB3\*02

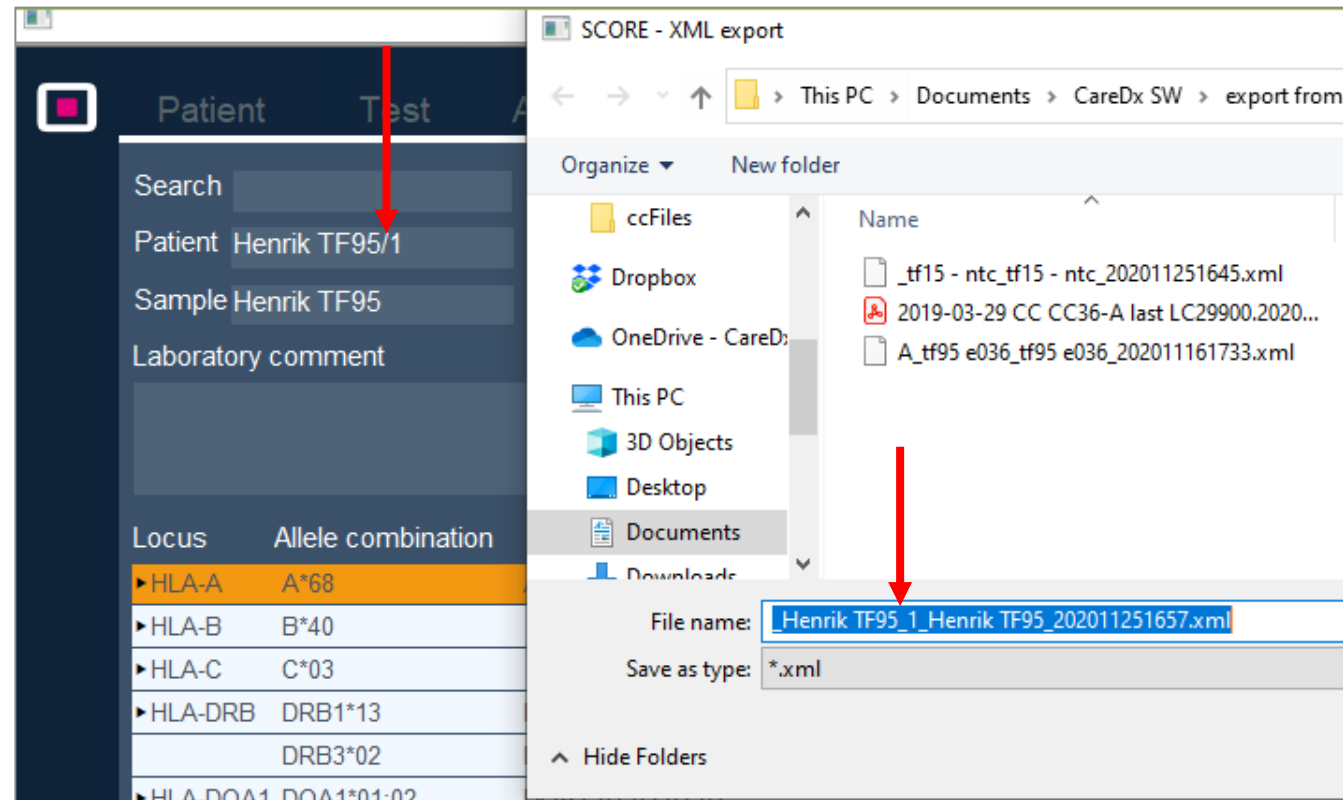
## (5-3) Excluding non-CWD DRB3/4/5 alleles from mixes designed to primarily amplify DRB1 alleles, and vice versa, from SCORE 6.2

- Example of removed non-CWD alleles
- Please refer to lot-specific QTYPE product inserts for full list of rejected alleles

Well	Channel	Main Locus	Alleles that will NOT be included in analysis
E1	O560	DRB345	DRB1*03:17, DRB1*03:27, DRB1*03:35, DRB1*03:81, DRB1*03:167, DRB1*03:188, DRB1*04:140, DRB1*11:136, DRB1*14:141
D1	O560	DRB1	DRB3*01:14
N12	O560	DRB1	DRB3*01:82, DRB3*03:62
O15	O560	DRB1	DRB5*02:31
M15	O560	DRB1	DRB3*03:01:05
N16	O560	DRB1	DRB3*01:42
M16	O560	DRB1	DRB3*02:18, DRB5*01:13, DRB5*01:41
I16	O560	DRB1	DRB5*01:13, DRB5*01:41
E16	O560	DRB1	DRB3*01:71
C16	O560	DRB1	DRB3*02:04
A16	O560	DRB1	DRB4*01:03:26
O17	O560	DRB1	DRB3*01:14
B17	O560	DRB1	DRB3*02:160
P18	O560	DRB1	DRB1*04:245, DRB1*04:352, DRB1*04:357
L18	O560	DRB345	DRB1*12:57, DRB1*13:195, DRB1*14:247
K18	O560	DRB345	DRB1*14:141
I18	O560	DRB345	DRB1*04:20, DRB1*11:30, DRB1*13:67, DRB1*13:195, DRB1*14:46, DRB1*14:141
H18	O560	DRB345	DRB1*03:42, DRB1*03:87, DRB1*11:288, DRB1*12:57, DRB1*14:247
P19	O560	DRB1	DRB3*01:14
O19	O560	DRB1	DRB5*01:22:01, DRB5*01:64, DRB5*01:110, DRB5*01:127N
M19	O560	DRB1	DRB5*01:73
L19	O560	DRB1	DRB3*01:14
G19	O560	DRB1	DRB3*01:23, DRB3*01:46, DRB3*02:146
E19	O560	DRB1	DRB3*03:56, DRB3*03:59

## (6) Xml file exported even if there are unsupported characters in the Patient ID

- In previous versions, the xml export was rejected if the Patient ID or Sample ID contained an unsupported character.
- Any such characters are now replaced with a “\_” (Underscore)



## (7) Corrected rights for Basic user

- Basic users may only change **local settings**, not any **global settings**
  - Basic users can no longer import serological equivalent file
  - Basic users can no longer import XML template

Setup SQL Db  
Update SQL Db

Update SCORE 6 database  
Connected server: .\ScoreBuild

Typing kit database

Current file: Typingkit\_QTYPE\_20220511\_2.07.vda  
Date imported: 2022-05-11

Allele database

Current file: allele\_marsh\_HLADB\_3.35.0.vda  
Date imported: 2022-03-30

Expert and WHO serology

Current file: Expert and WHO Serology list 2019-10-17 (6)  
Date imported: 2022-03-30  
Based on alleleDb: allele\_marsh\_HLADB\_3.35.0

Custom serology

Current file: SEC v4.xml  
Date imported: 2022-03-07  
Based on alleleDb: allele\_marsh\_HLADB\_3.47.0

Typing options  
These options are set globally and will affect all users of the same current user database

Display XML Import shortcut on Home screen

Structure of the XML export file

XML template

Current file: templateStructureCompleteAndSummary.xml  
Date imported: 2022-01-21

HPRIM options

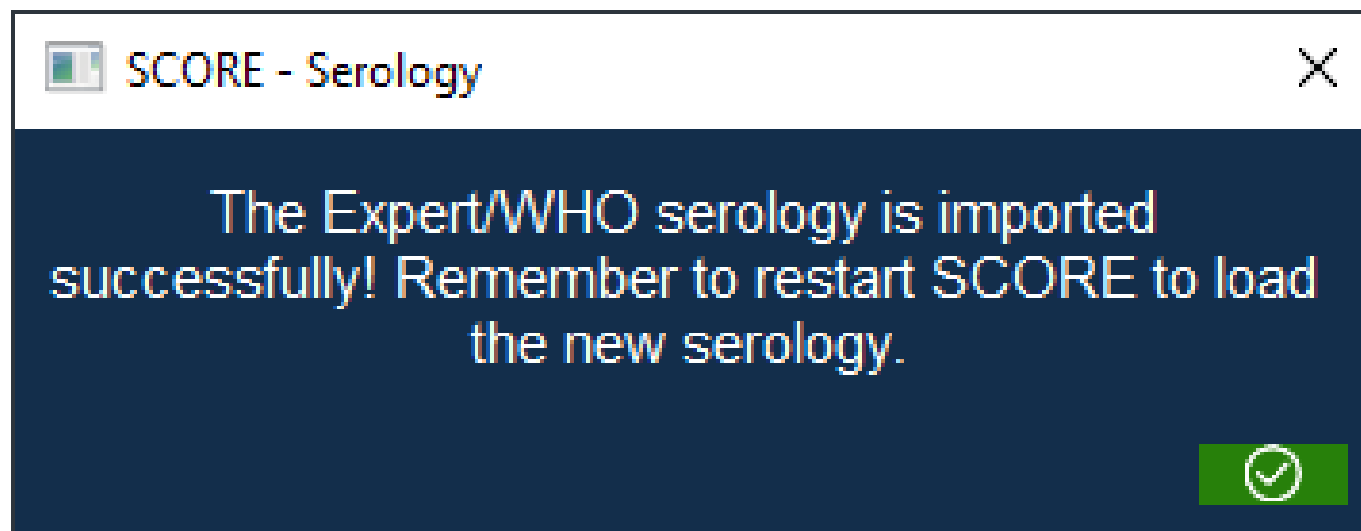
Report header

Lab comment  
These options are set locally and will affect this client installation of SCORE 6 only

Export path: C:\SCORE\Test files

Import path: C:\SCORE\Test files\test request files

## (8) Added a prompt to restart SCORE 6 after import of serology list





## (9) Information about manually excluded wells and/or FN/FP wells in the SCORE 6.2 XML.

Locus	Allele combination		Serology
▶ HLA-A	A*23:04		A23(9)
▼ HLA-B	Check remarks and warnings		
▼ Rare allele combinations			
▶	B*08	B*27	B8, -; -
▼ Remarks and Warnings			
Manually positive:	B9/QTYPE 11/EF42/FAM		
Manually excluded:	B8/QTYPE 11/EF42/FAM		
False negative:	K8/QTYPE 11/EF42/FAM		
False negative:	F24/QTYPE 11/EF42/FAM		
False positive:	B9/QTYPE 11/EF42/FAM		
Analysed: 2020-09-16 Support			
Allele db: HLADB_3.38.0			

- <testSet>  
    <channel>FAM</channel>  
    <positiveWells>P5, M5, L5, 16, K7, G7, D7, C7, P8, D9, B9</positiveWells>  
    <excludedWells>B8</excludedWells>  
    <crossReactiveWells/>  
    <manuallyExcluded>B8</manuallyExcluded>  
    <manuallyPositive>B9</manuallyPositive>  
    <manuallyNegative/>  
    <falsePositive>B9</falsePositive>  
    <falseNegative>K8, F24</falseNegative>  
  </testSet>

## (10) Added a progress bar for xml export functionality

