



Important Customer Information

SCORE 6 software update 6.2.1.0

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 6.2 version, **SCORE 6.2.1.0**, has been released and is available for download from our website. Please note that SCORE 6.2.1.0 is a patch for SCORE 6.2.0.1.

The attached Appendix: 2086-MKT Appendix 1: Rev01_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 SCORE 6.2.0.1 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 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:

- Kit files compatible with SCORE 6.1.3.1 will be provided up until lot **E067**.
- Kit files compatible with SCORE 6.2.x.x are available from lot **E061**.
- QTYPE lots **E061-E067** will be available in kit files for SCORE 6.1.3.1 and SCORE 6.2.x.x.
- The kit file for lot **E068** and onwards may only be used with SCORE 6.2.x.x

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

Lab Products
CareDx AB
Franzégatan 5,
SE-112 51 Stockholm, Sweden
Tel: +1 210-478-1039
Email: stchang@caredx.com

Manufacturer:

CareDx AB
Franzégatan 5,
SE-112 51 Stockholm, Sweden
Tel: +46-8-508 939 00
Fax: +46-8-717 88 18

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

©2023 CareDx, Inc. All rights reserved.

All service marks and trademarks are owned or licensed by CareDx, Inc. or its affiliates.



SCORE 6.2.1.0 Supplementary information

Steve Chang (Implementation Manager)

Dan Dou (R&D)

Rebecka Salme (Tech Support)

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

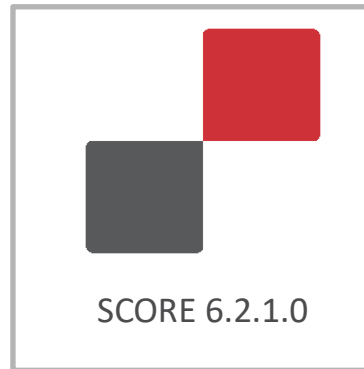
Appendix 1. 2086-MKT Rev01 SCORE 6.2.1.0 Supplementary information | Steve Chang, Dan Dou, Rebecka Salme |



SCORE 6.2.1.0 Software overview

Software overview - 1

- New Launch icon:

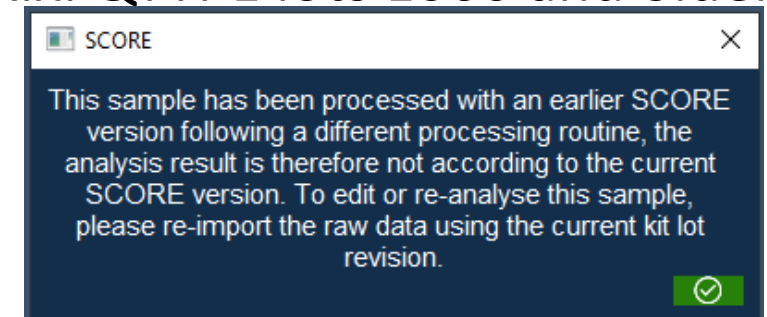


- SCORE 6.2.1.0 (CE/RUO) is a patch for SCORE 6.2.0.1 (which was released as CE only)
 - The same installation procedure as previous SCORE 6 versions
 - Users can have SCORE 6.1.3, SCORE 6.2.0.1 (CE only) and SCORE 6.2.1.0 on the same PC
- Updated support for Windows and SQL server versions

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 (no parallel use)
- NOTE: Users can *re-analyse* old samples in SCORE 6.2.x.x only by **Reimporting** raw data (**E061 above only**) as new samples in SCORE 6.2.x.x. QTYPE lots E060 and older won't be able to analyse in SCORE 6.2.x.x



Option 1: Create a new SQL database for SCORE 6.2.1.0

SCORE 6.1.3 or 6.2.0.1 and SCORE 6.2.1.0 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 start of 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 SQL Management Studio software from Microsoft.
 2. Install SCORE 6.2.1.0. If prompted, 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 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 from lot **E061 to lot E067**.
 - Typing kit files compatible with SCORE 6.2.x.x will be provided **from lot E061 moving forward**.

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**

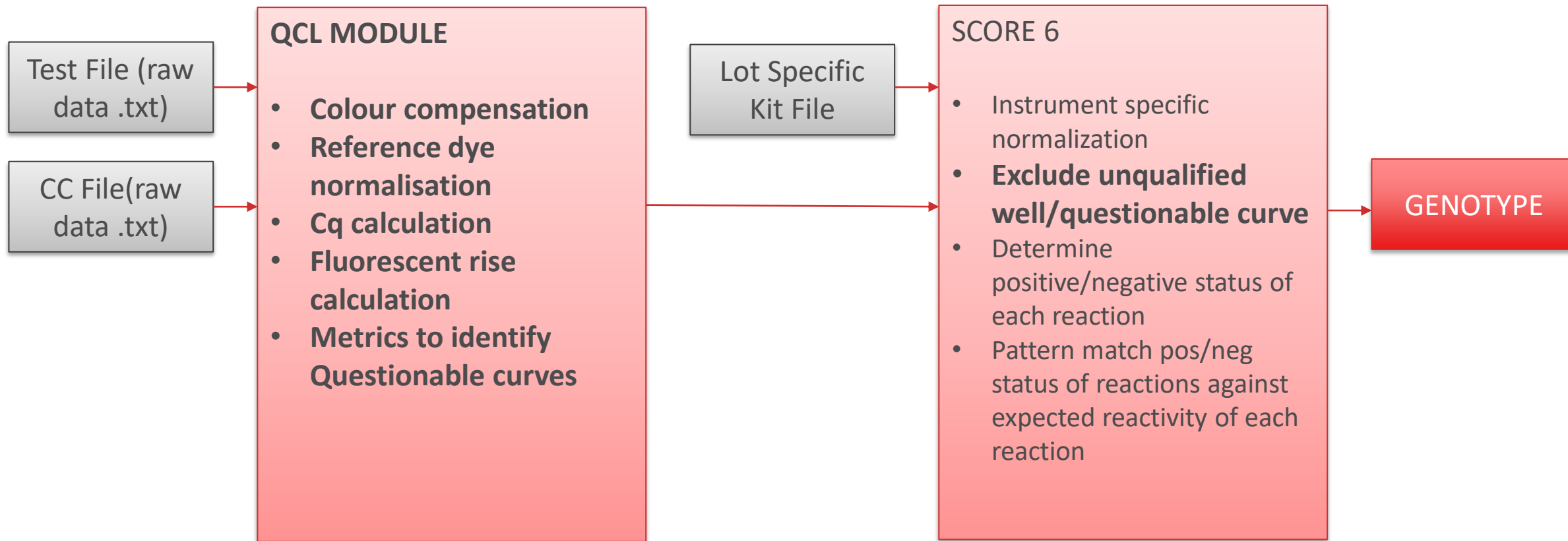
SCORE 6.2.1.0 Main new features:

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 (**Q**TYPE **C**alculation **L**ibrary)

- QCL data process flowchart



New features: QCL (QTYPE Calculation Library)

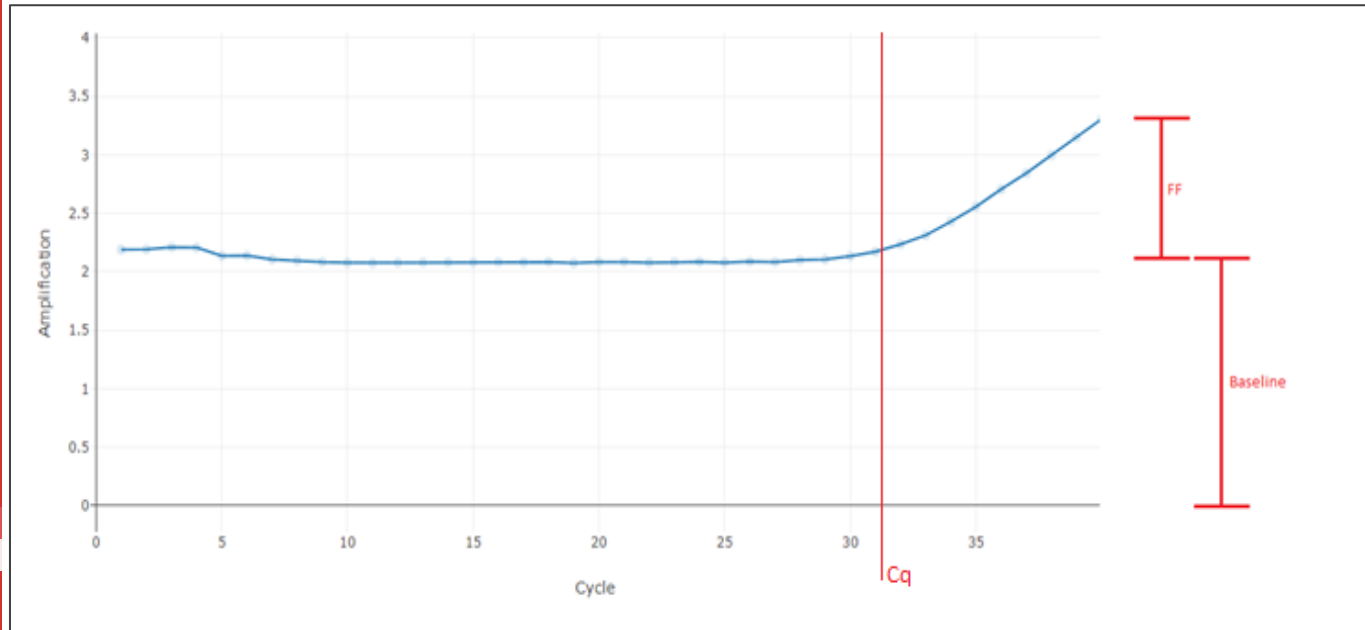
- New Calculation for rFF

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):

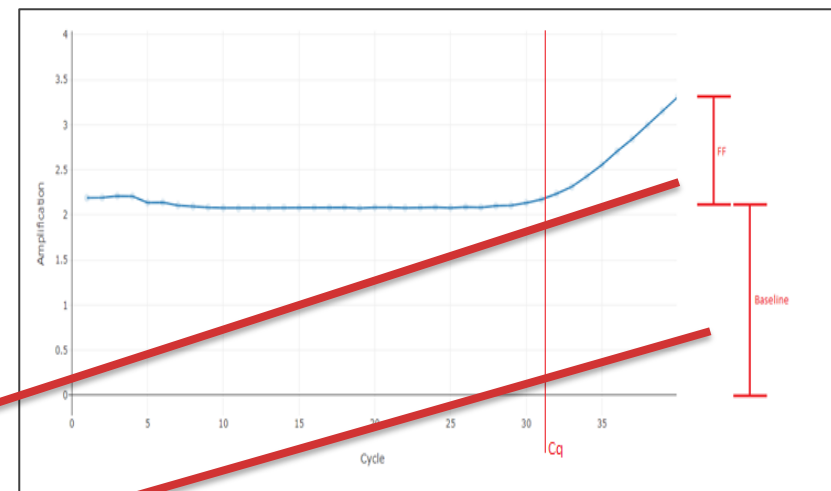
- Ratio of **FF of HLA-specific reaction** to **FF of the internal control**

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)

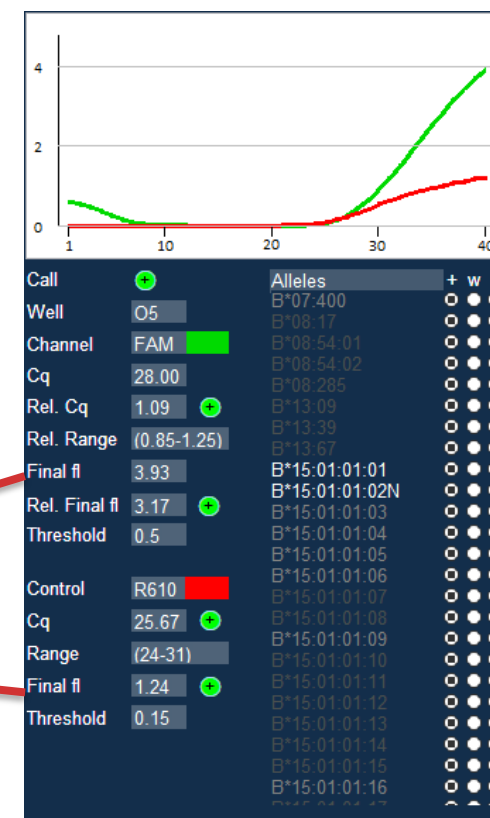
- QCL Ref Final FI :

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



- FSCLV Ref Final FI :

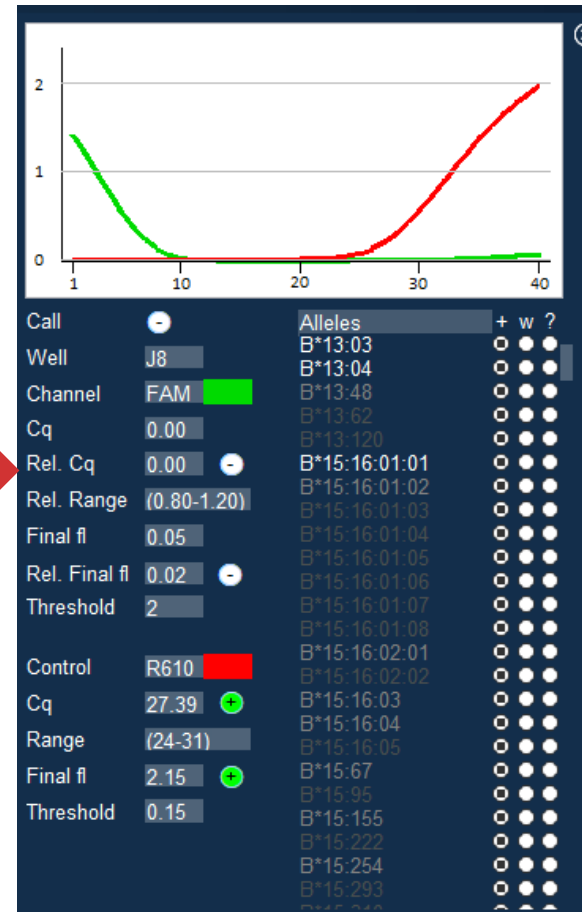
$$\text{Rel. Final fl} = \frac{\text{final fluorescence (FF)}}{\text{internal control (R610) final fluorescence}}$$



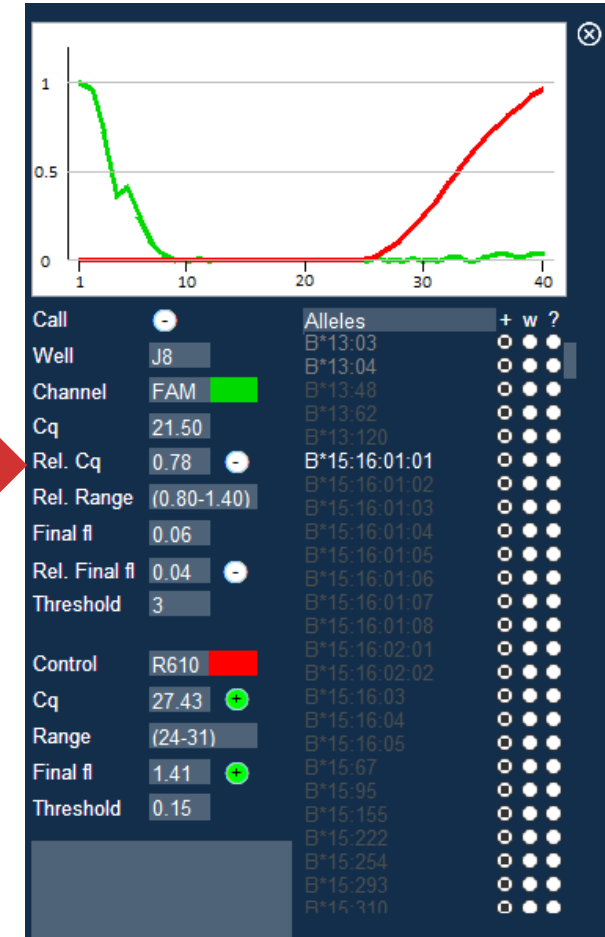
New features: QCL (QTYPE Calculation Library)

- 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

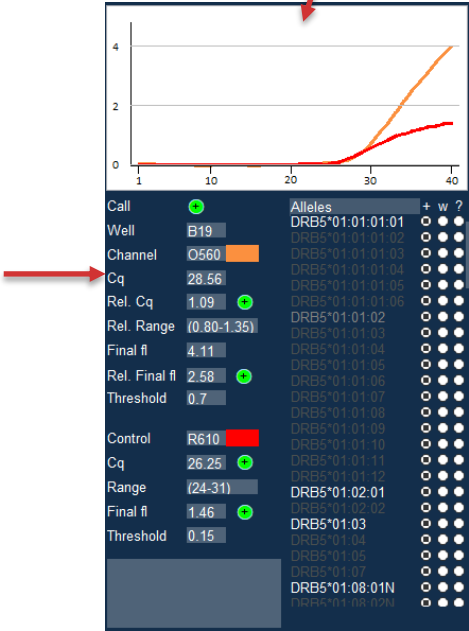
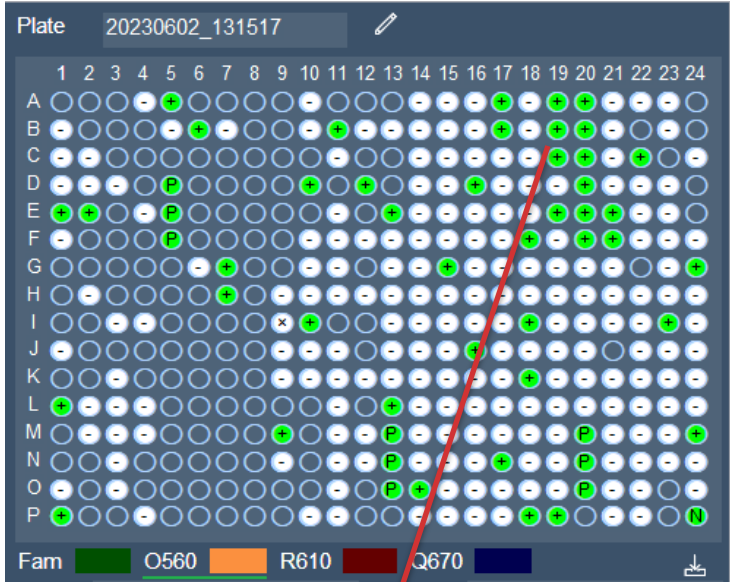
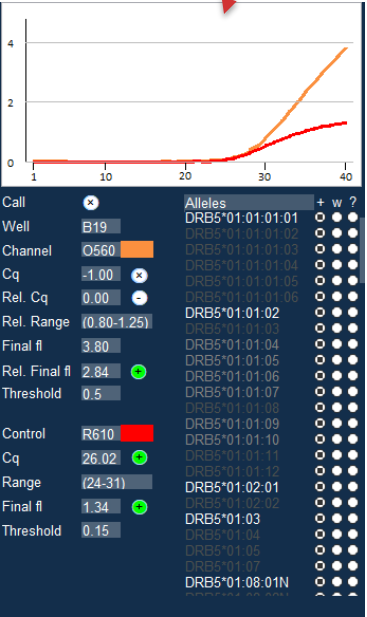
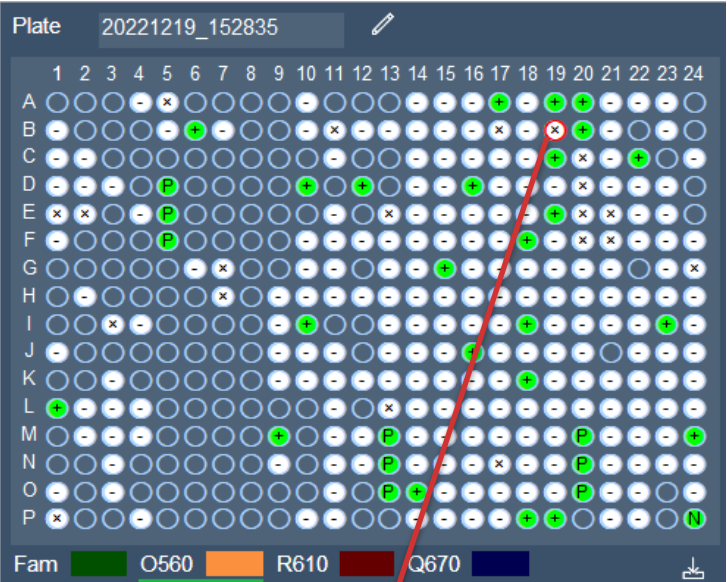
SCORE 6.1.3



SCORE 6.2.x.x



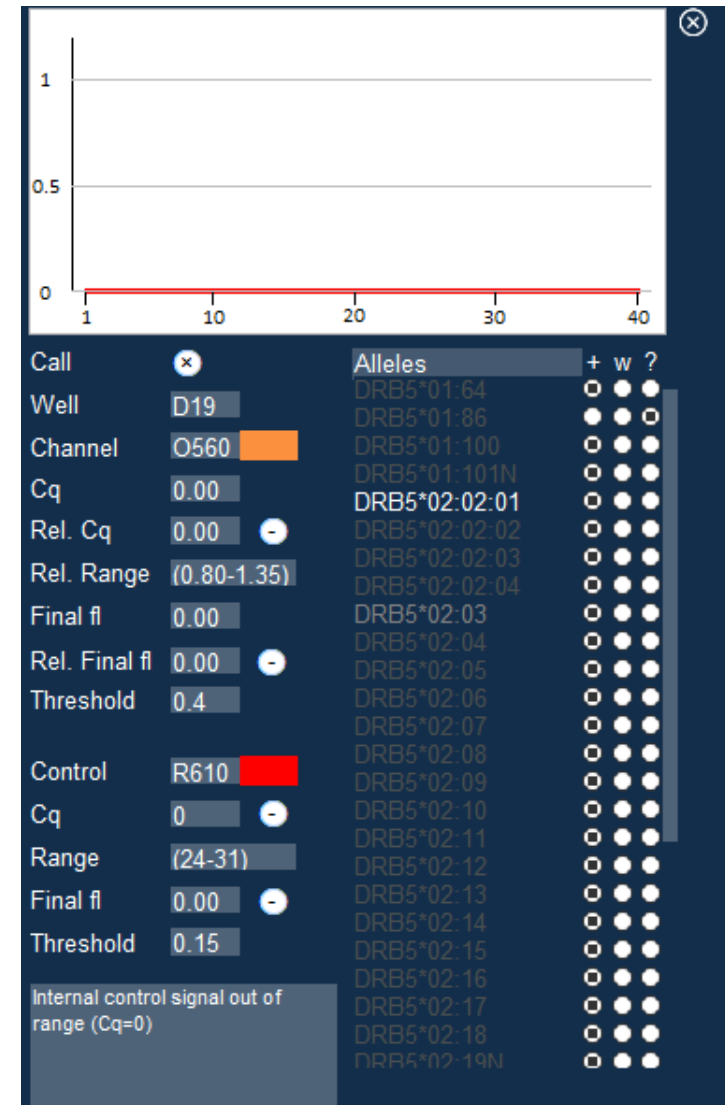
Example Pictures: Resolves issue with Cq = -1



2. Exclusion of problematic wells

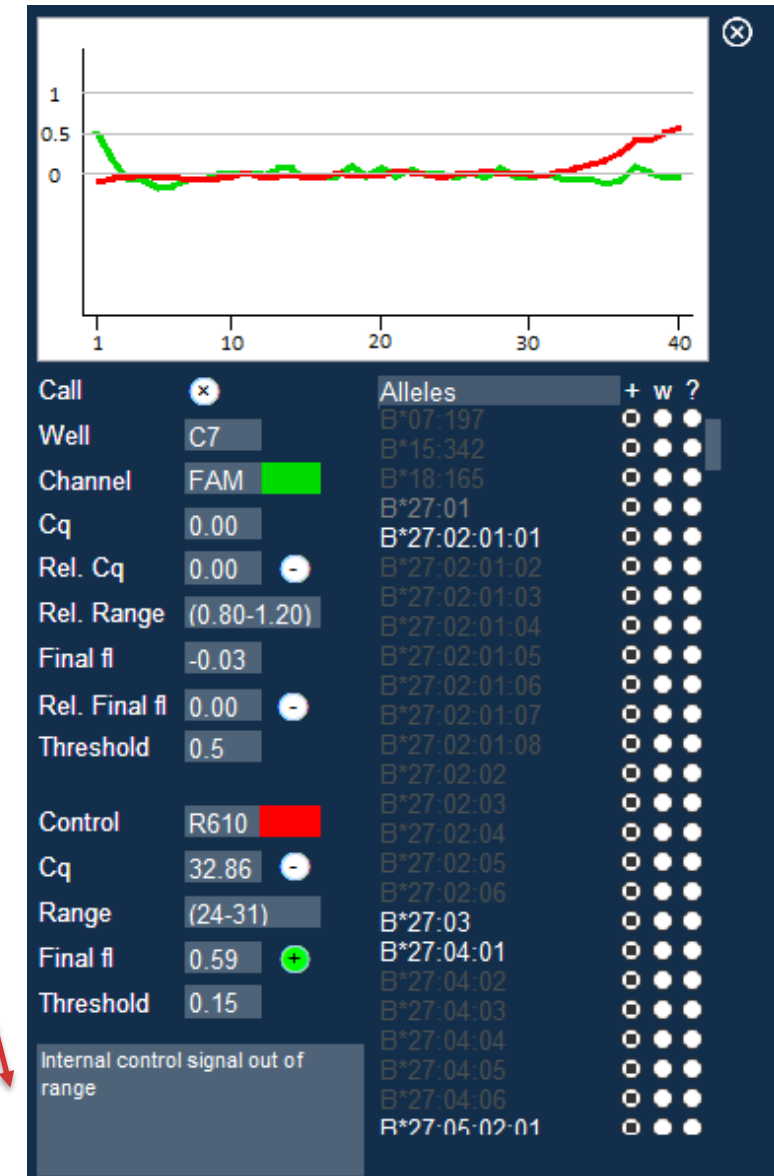
Exclusion of Questionable Wells (1)

- 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 SCORE6.1.3

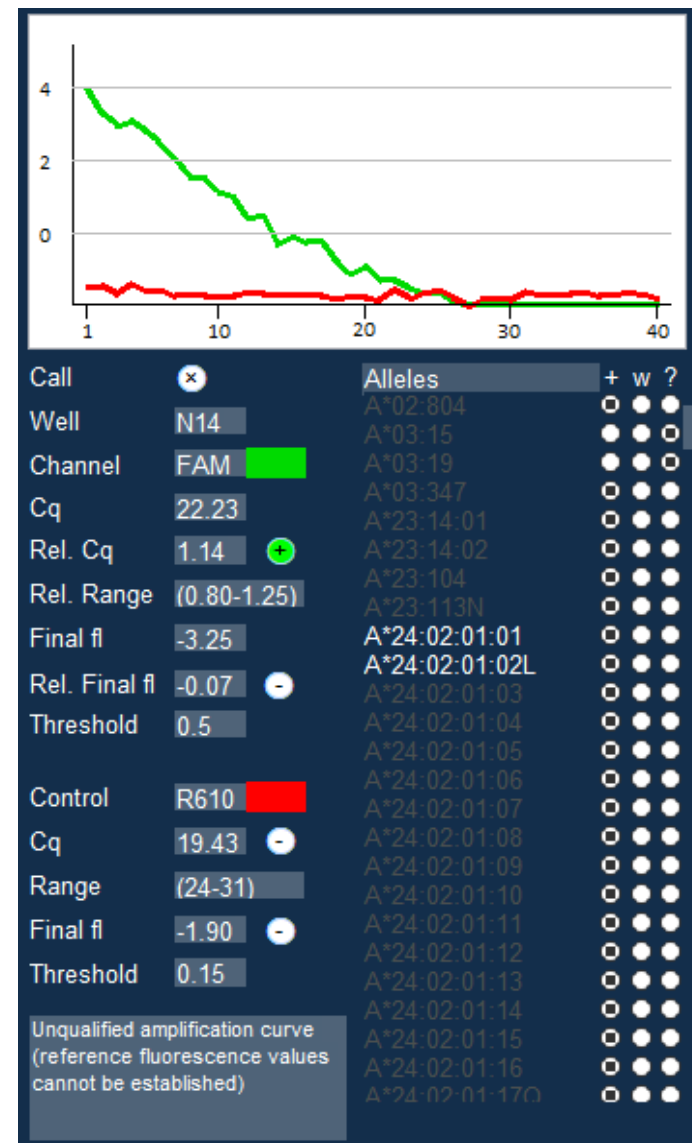
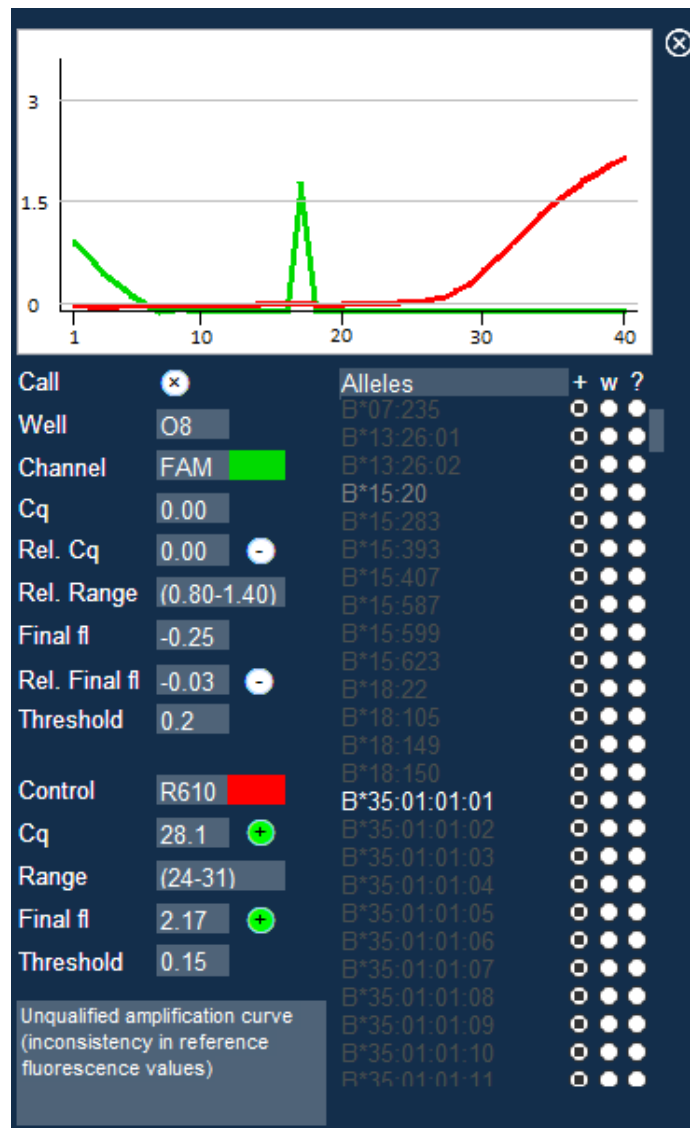
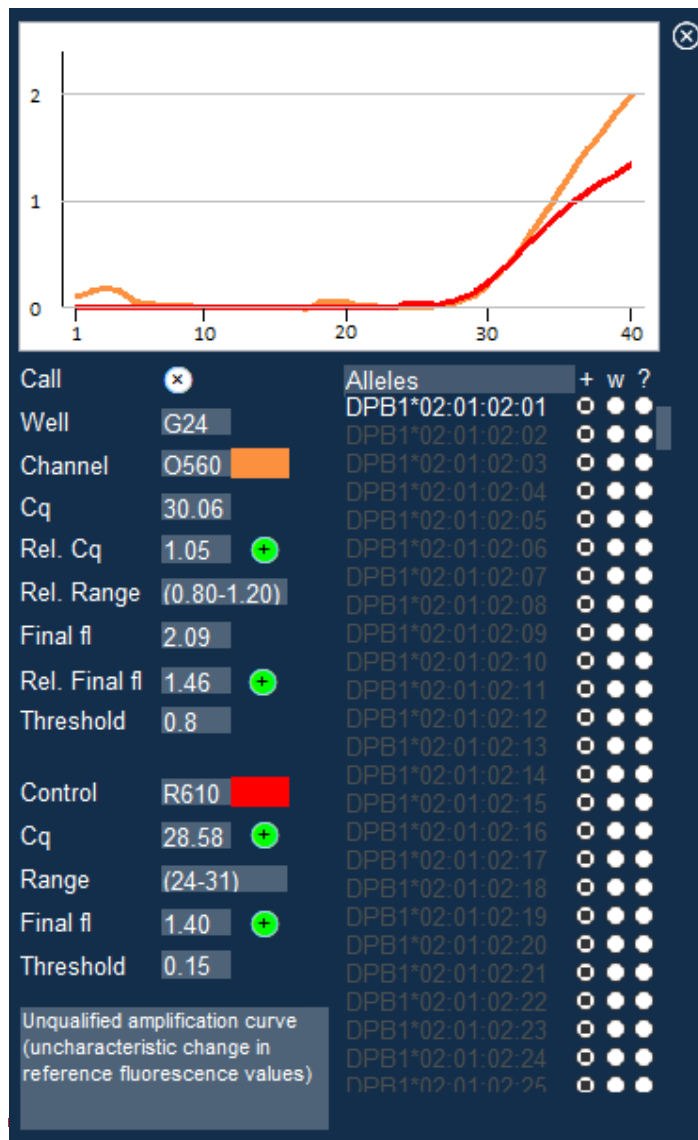


Exclusion of Questionable Wells (2)

- The change is in the software, is intentional and is not an indication of an issue with the product or assay setup
- The reason of exclusion will be present 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



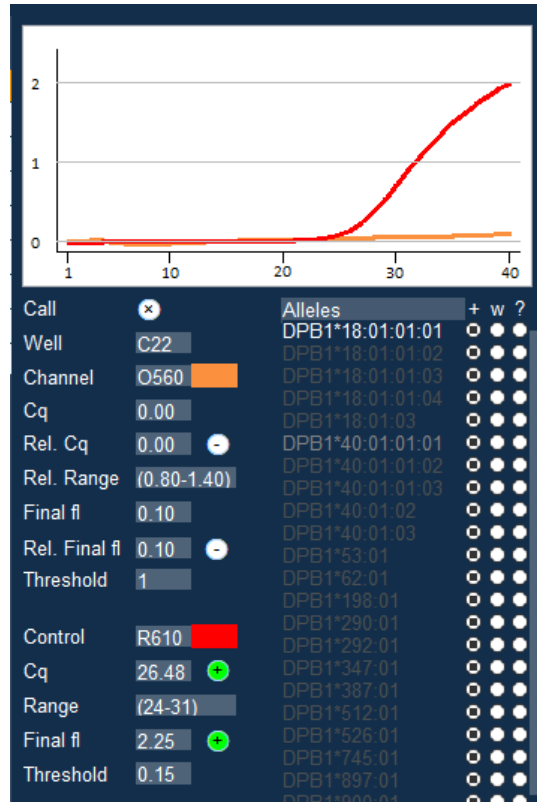
Auto well exclusion messages tables in IFU

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 IFU

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



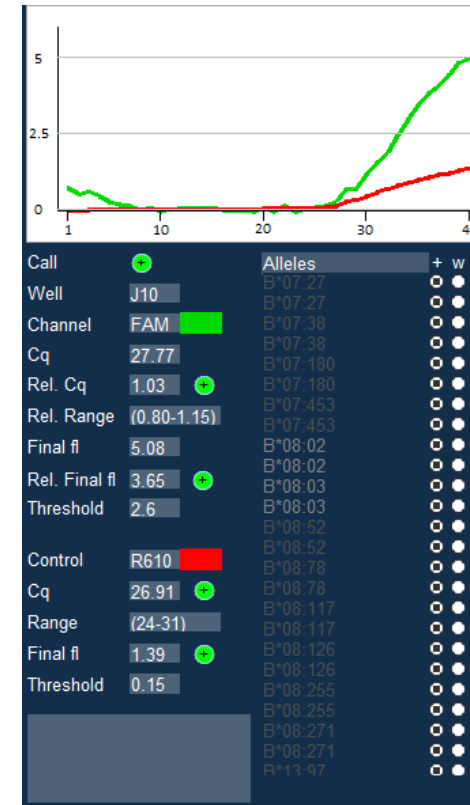
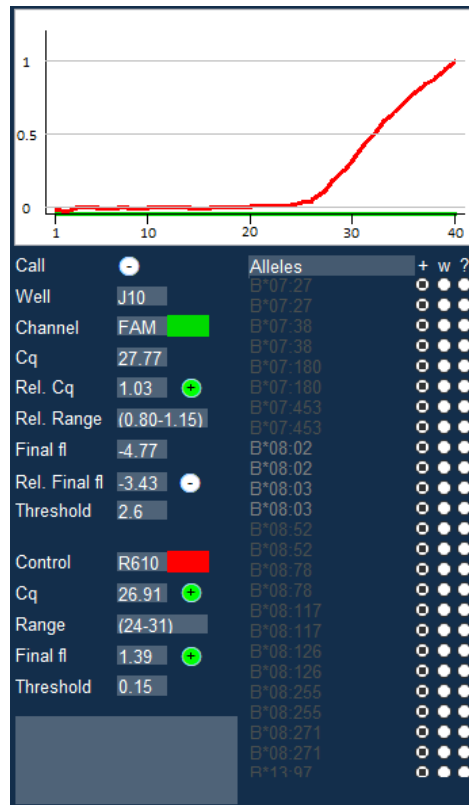
Unqualified amplification curve
(uncharacteristic change in reference
fluorescence values)

- 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_20
# 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
# Acquisition Date/Time: 2023-05-02 02:00:15 PM CEST
```

QuantStudio 6 / 7 Pro raw data

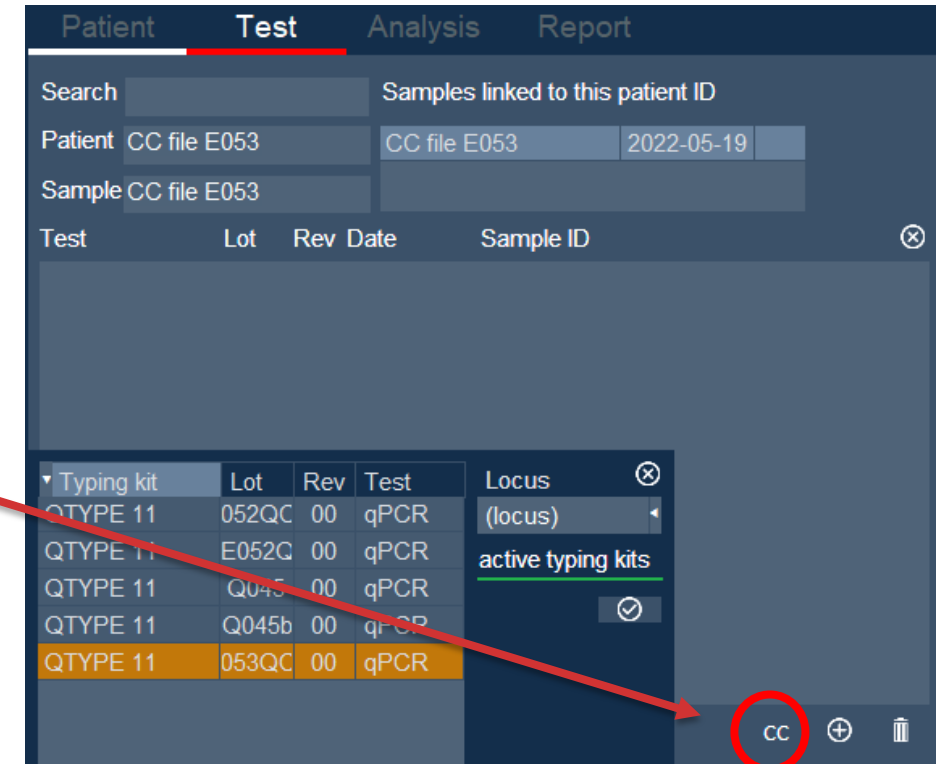
5. CC file check in SCORE 6.2.x.x

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 (see picture)
 - Select CC file to be checked



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

6.2.0.0
For In Vitro Diagnostic use

Olerup SSP AB
Franzénsgatan 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

VIA 7

Instrument serial number

27 888 0637

Tested with lot revision

HQ36 0

Fluorescence rise

FAM	Q550	R510	Q570
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	Q550	R510	Q570
I13			G11
I14			

CC matrix

Wells / Signal	FAM signal	Q550 signal	R510 signal	Q570 signal
FAM wells	0.993450	-0.141375	-0.132836	-0.261160
Q550 wells	0.106097	0.987557	-0.002536	-0.063408
R510 wells	0.034725	-0.025948	0.991106	0.051032
Q570 wells	-0.024377	-0.063799	-0.007506	0.961858


Report created 2020-11-11 14:22

1 / 1

SCORE⁶

6.2.0.0
For In Vitro Diagnostic use

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

 CareDx[®]

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

LightCycler 480 II

Tested with lot

HQ36

revision

0

Fluorescence rise

FAM	Q550	R510	Q570
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	8.198667	1.975000	0.695000
4.120000	9.113333	1.980000	0.570000

Excluded wells

FAM	Q550	R510	Q570
I11			
I12			
I13			
I14			
I10			

CC matrix

Wells / Signal	FAM signal	Q550 signal	R510 signal	Q570 signal
FAM wells	0.000000	0.000000	0.000000	0.000000
Q550 wells	0.000000	0.000000	0.000000	0.000000
R510 wells	0.000000	0.000000	0.000000	0.000000
Q570 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 labels title and default settings:

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 the 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 for rare alleles (Default setting)

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

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

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

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

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

XML options 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

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

Omit alleles not tested for by typing kits

Omit listing of alleles not tested in the information field

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

	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 ¹ M ² 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 ¹ M ² 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 ¹ M ² 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)

¹ This locus contains manually edited well calls by the user
² 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.
³ 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	Analysed by	Manually assigned by	Analysed 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

(4-1) DRB1 and DRB345 results are no longer grouped as a single locus and are now grouped 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	

(4-2) DRB1 and DRB345 results are still assigning in association by double clicking one of the alleles

Double Click DRB3 Common + Common result

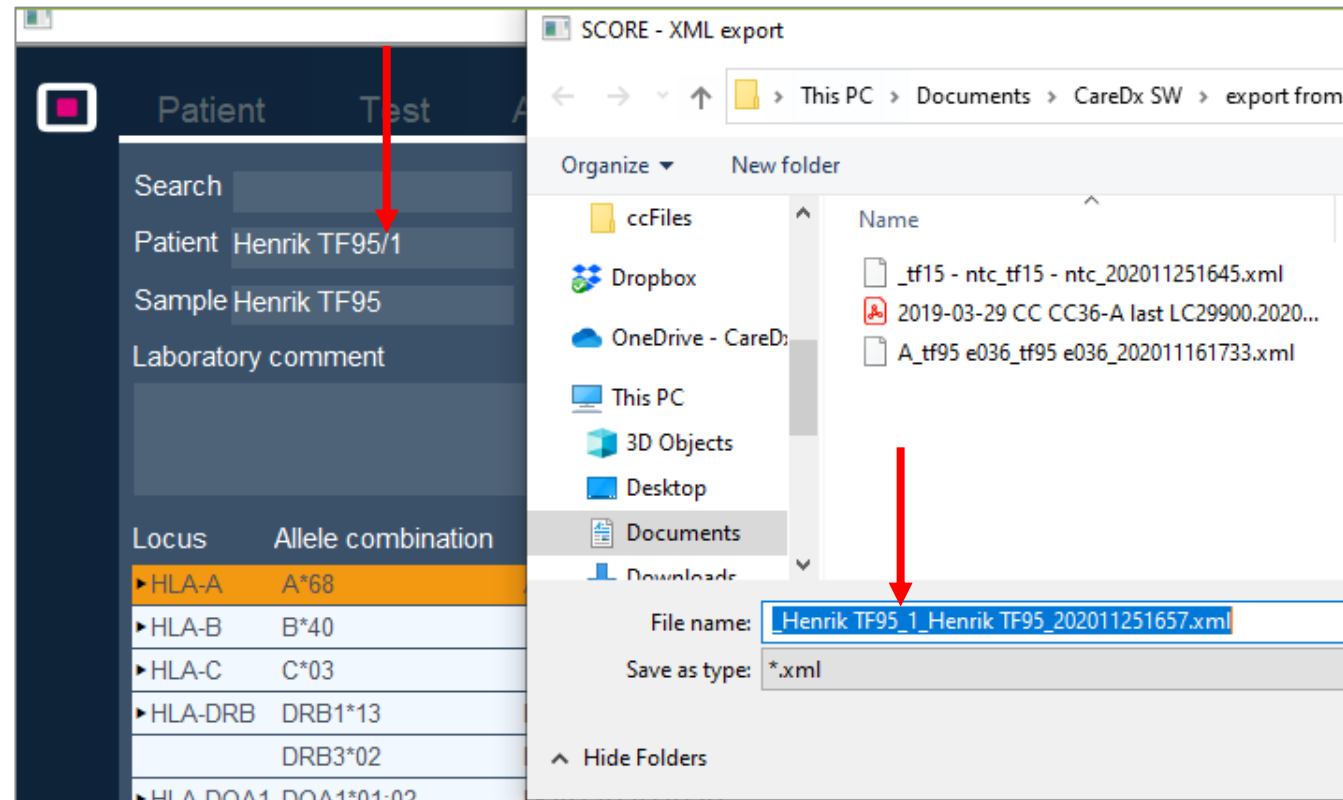
▼HLA-DRB No Common + Common results			
DRB3*02		DR52	
▼ Common + Common allele combinations			
DRB3*02		DR52	
DRB3*02	DRB3*02	DR52	
▼ Common + Well Documented allele combinations			
DRB1*08:03:02:01	DRB1*14:14	DR8; DR14(6)	
DRB3*02	DRB3*02	DR52, -	
▼ Well documented + Well Documented allele combinations			
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: 6/23/2023 stevechang			
Allele db: HLADB_3.49.0			
▼ Assigned interpretation			
▼ Assigned serology			

Associated DRB1 (Common + Well Document) results shown in Assigned results

▼ HLA-DRB	DRB1*08:03:02:01	DRB1*14:14	DR8; DR14(6)
	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			
▼ Assigned interpretation			
	DRB1*08:03:02:01 DRB3*02	DRB1*14:14	
▼ Assigned serology			
	DR8 DR52	DR14(6)	

(5) 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)



(6) 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

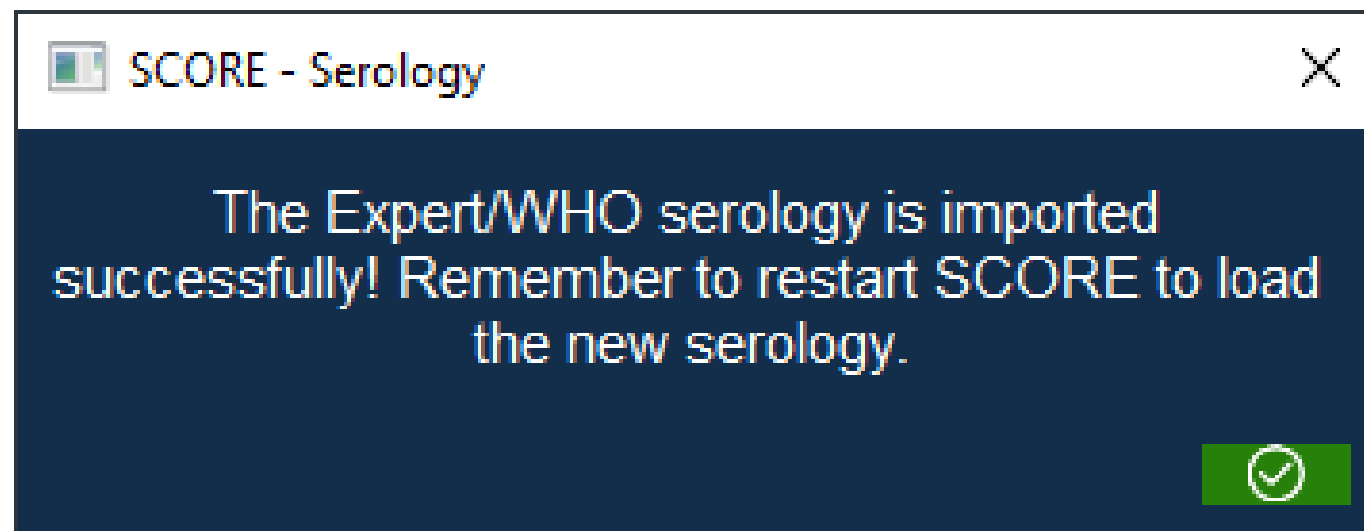
Report header

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

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



(8) 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>

(9) Added a progress bar for xml export functionality

