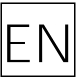

INSTRUCTIONS FOR USE

HISTO TYPE Rainbow QS6

Test kit for the determination of HLA alleles on a molecular genetic basis

CE 0123

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BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
A BAG Group company

T. +49 (0) 6404/925-100
F. +49 (0) 6404/925-460
M. info@bag-diagnostics.com
W. www.bag-diagnostics.com

Ordering:
T. +49 (0) 6404 / 925 - 450
F. +49 (0) 6404 / 925 - 460
M. order@bag-diagnostics.com

Customer Service:
T. +49 (0) 6404 / 925 - 125
F. +49 (0) 6404 / 925 - 421
M. service@bag-diagnostics.com

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1. INTENDED USE

The intended use of the HISTO TYPE Rainbow QS6 kit is the identification of HLA Class I and II alleles using the QuantStudio™ 6 Flex System for PCR amplification. HISTO TYPE Rainbow QS6 is an in vitro diagnostic test for tissue typing on a molecular genetic basis (see Product Description).

The HISTO TYPE Rainbow QS6 kit is intended to be used by health care professionals with experience in molecular genetic techniques at:

- transplantation centers
- hospital laboratories
- bone marrow registries

HLA typing for transplanation purposes must follow guidelines issued by professional societies like the European Federation for Immunognetics (EFI), the American Society for Histocompatibility and Immunogenetics (ASHI) or national societies like the Deutsche Gesellschaft für Immungenetik (DGI).

2. PRODUCT DESCRIPTION

HISTO TYPE Rainbow QS6 kits are used for the molecular genetic determination of HLA Class I and II alleles at 11 loci: HLA-A, B, C, DRB1/3/4/5, DQA1, DQB1, DPA1 & DPB1. Kits are designed to generally detect all alleles at the 11 loci; if any rare alleles are not detected the alleles are listed in Kit Specific Information documents (KSI) which are available from the download section of the BAG website. The primer and probe binding sites are listed there as well. The kit provides low to medium resolution typing results of the common and well documented alleles using CWD list 2.1.0 which is largely based on CWD 2.0.0 list[1]. The CWD list 2.1.0 used is available from the document download section of the BAG website. Confirmed diagnostic results of HLA alleles are a prerequisite for a successful organ transplantation.

3. TEST PRINCIPLE

The test is performed with genomic DNA as starting material. The DNA is amplified in a real-time PCR with sequence-specific primers (SSP). The primers were specially developed for the selective amplification of segments of specific HLA alleles or allele groups. The amplicons are detected using sequence-specific fluorescence dye-labelled hydrolysis probes (TaqMan®-probes), which increases the sensitivity and specificity of the test compared to the classical SSP.

If amplicons are present, the probes are hydrolysed by the Taq polymerase and a fluorescence signal is generated to enable detection of the amplicon. Five different wavelength ranges of fluorescence signals are measured by the optical detection unit of the real time PCR cycler. The presence of a positive reaction is determined primarily by the Cq point, which is the point where fluorescence signal increases beyond the baseline threshold. For amplification to be valid the amplification must also achieve a certain threshold of fluorescence at the end of the PCR process. This is to prevent false positive reactions.

Each PCR reaction also contains an internal amplification control (Human Growth Hormone gene (HGH)) which is detected in a specific fluorescent channel.

To distinguish positive reactions from negative or irrelevant amplifications the ratio of the Cq of the specific reaction compared to the Cq of the internal amplification is calculated. The thresholds for these Cq ratios (CqR) vary from reaction to reaction and hence the PlexTyper® software is required for the analysis of amplification data.

4. MATERIAL

4.1 Contents of the HISTO TYPE Rainbow QS6 kit

- **10x 230 µl Plex Mix**, ready to use, contains dNTPs, Taq Polymerase, reaction buffer. (contains the hazardous substance 2-methylisothiazol-3(2H)-one at a concentration of < 0.05%, see chapter 7 and 13)
- **10x HISTO TYPE Rainbow QS6 plates** for HLA-typing. The pre-pipetted and dried reaction mixtures in each well contain HLA-specific primers and probes as well as HGH-specific internal amplification control primers and probes (oligomixes).
- **10x qPCR Seal**

4.2 Additionally required reagents and devices

- Reagents for DNA isolation (validated extraction kits see 6.2)
- Real time-PCR Cycler (validated cycler see 4.3)
- Plate holder QS6 (REF 726321)
- Variable pipettes (0.5 – 1000 µl) and pipette tips
- Application spatula for qPCR Seal
- Molecular grade DNAse free water
- Suitable plate centrifuge
- For QuantStudio™ 6 calibration please use BAG RT-PCR Universal Custom Dye Calibration Kit REF 728260

4.3 Validated real time-PCR Cycler

Real time-PCR Cycler
QuantStudio™ 6 Flex System, Applied Biosystems / Thermo Fisher Scientific (QS6)

The following fluorophores are used in the HISTO TYPE Rainbow QS6 kits.

Fluorophore	At the cycler / software	Wavelength in nm
TAMRA	TAMRA	Excitation: 557 Emission: 583
FAM	FAM	Excitation: 495 Emission: 520
O560 (CAL Fluor® Orange 560)	O560	Excitation: 538 Emission: 559
R610 (CAL Fluor® Red 610)	R610	Excitation: 590 Emission: 610
Q670 (Quasar® 670)	Q670	Excitation 647 Emission: 670

5. STORAGE AND STABILITY

~~The kits are shipped on dry ice.~~ All reagents must be stored at ≤ -20°C in temperature-controlled devices. The expiry date is indicated on the label of each reagent. The expiry date indicated on the outer label refers to the reagent with the shortest stability contained in the kit. The freeze-thaw cycle testing has shown that up to 12 cycles for the Plex Mix has no detrimental effects on the quality of the kit.

In use stability: After removal from the freezer the Plex Mix and the HISTO TYPE Rainbow LC480 plates have been shown to be stable at ambient temperature for 2 hours before setting up the PCR. The pipetted PCR plates can be stored in the fridge in the dark for up to 16 hours before the PCR run is started.

6. TEST PROCEDURE

6.1 Precautions and special remarks

Molecular genetic techniques are extremely sensitive methods and should only be performed by qualified personnel with experience in molecular genetic techniques.

Special precautions must be met to avoid contamination and thus false reactions:

- Wear suitable gloves (preferably powder-free) during work.
- Use tips with filter insert or integrated stamp.
- Work in two different areas for pre-amplification (DNA-isolation, preparation of the reactions) and post-amplification (detection); use two separate rooms if possible.
- Use devices and other materials only at the respective workplaces and do not exchange them.

6.2 DNA Isolation

The specimen material for the isolation of the genomic DNA must be sent in appropriate collection systems. For genomic material from whole blood use only EDTA or citrate anticoagulants. The presence of heparin may potentially inhibit the PCR reaction (2), therefore such collection systems are not suitable and must not be used. It is recommended to use CE IvD certified kits for the DNA isolation.

Validated DNA Extraction Kits:

- Qiagen QIAamp DNA Blood Kits (columns)

Both, the manual isolation and automated DNA isolation (QIAcube) are validated.

If the standard method established in the laboratory shall be applied for isolation of gDNA without using one of the specified test kits, it must be validated by the user.

The HISTO TYPE Rainbow QS6 test requires 10 – 20 ng DNA per well. The purity indices must be in the following range:

- OD_{260} / OD_{280} = > 1,5 and < 2,0 — Higher values are an indicator for the presence of RNA, lower values indicate protein contamination.
- OD_{260} / OD_{230} = > 1,8 — Lower values indicate contamination with carbohydrates, salts or organic solvents.

6.3 Entering sample information into PlexTyper® Software

It is mandatory to use PlexTyper® Software to analyse HISTO TYPE Rainbow data. It is advisable to enter the sample information into PlexTyper® before setting up the PCR amplification to obtain the unique RUN ID. All import files must be prefixed with a PT number.

When saving a test in PlexTyper®, the software assigns a **Run ID** to the test which is displayed in red in the summary window shown below. This is a consecutive number prefixed with PT (PT1, PT2, PT3….) which is linked to the sample identity and is used as a prefix on the PCR machine export file to correctly link the PCR export to the sample identity.

This Run ID should be used when setting up the file identity in the PCR machine. If the PCR excel export file is not pre-labelled with the RUN ID the file can be manually prefixed with the correct PT Run ID before import into PlexTyper®.

6.4 PCR setup

A pre-mix consisting of Plex Mix, water and DNA is made for the amplification that is subsequently dispensed in the wells 1-95. In well 96 there is the negative control (no template control = NTC) which should only contain water and Plex Mix.

- The reaction volume for each PCR preparation is 10 µl
- For a single well the following reagents must be pipetted into a reaction tube:

2 µl Plex Mix
1 µl DNA specimen (10-20 ng/µl)
7 µl Molecular grade water

For other DNA concentrations the pre-mix has to be modified accordingly (see below).

A **negative control (NTC)** should be performed. Therefore prepare a PCR reaction with molecular grade water instead of DNA.

2 µl Plex Mix
8 µl Molecular grade water

DNA concentration 10-20 ng/µl

- Add **805 µl** molecular grade water to the vial with 230 µl Plex Mix and mix (vortex briefly 1-3 sec).
- After mixing, pipette **10 µl** of the mix into the NTC well (well 96; position H12 -see also Figure 1 and 2).
- Then pipette **115 µl** DNA into the vial with the remaining Plex Mix-water-mixture and mix (vortex briefly 1 – 3 sec).
- Distribute 10 µl of the DNA/Plex Mix/water solution into each of the wells 1-95 of the HISTO TYPE Rainbow QS6 plate (please note figure 1 and 2). The NTC well (well 96; position H12) must not be filled with the DNA mix as this will cause the NTC to be positive and can invalidate the test!

DNA with other concentrations

For DNA of different stock concentrations use the dilution table below to adjust the DNA to working concentration.

- Add **8 µl** Molecular grade water and **2 µl** Plex Mix to the NTC (well H12). The NTC well (well 96; position H12) must not be filled with the DNA mix!
- Pipette the DNA and the molecular grade water into the remaining 228 µl Plex Mix according to the following table and mix (vortex briefly 1-3 sec).

Depending on the concentration of DNA, pipette the applicable volumes in the table below to the 228 µl Plex Mix remaining in the vial after setting up the NTC.

Concentration of the DNA [ng/µl]	Molecular grade water [µl]	DNA volume [µl]
2 - 4	350	870
5 –9	690	230
10 - 19	805	115
20 – 39	860	60
40 – 79	890	30
80 – 150	905	15
151 - 200	912	8

- Distribute **10 µl** of the DNA-Plex Mix-water solution into each of the wells 1-95 of the HISTO TYPE Rainbow QS6 plate.

Please note: When pipetting into the PCR wells it is important not to allow the pipette tip to contact the dried mix (dyed blue) in the bottom of the well. It is advisable to pipette to the side of the well to allow the 10 µl to mix by gravity with the dried mix (see Figure 1).

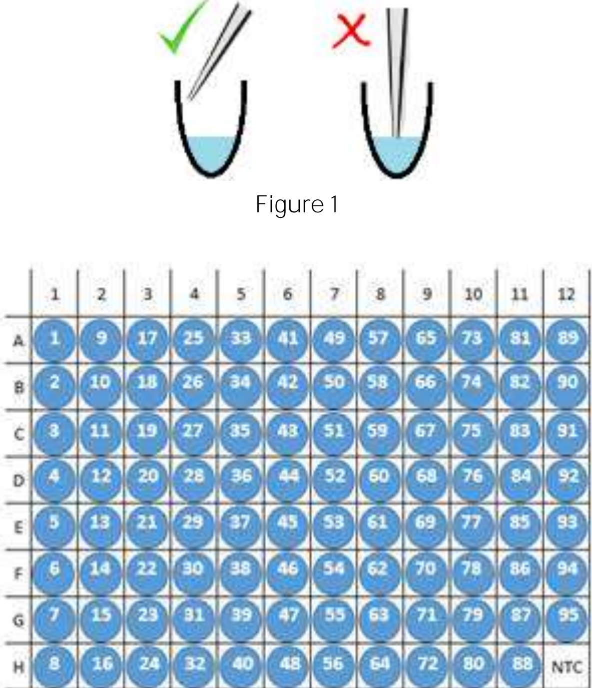


Figure 1

Figure 2: HISTO TYPE Rainbow QS6 plate. In wells A1 to G12 are the dried specific mixes (blue coloured). In well H12 there is the dried NTC (also blue).

Seal the PCR plate with the supplied qPCR seal and briefly spin the liquid down. Make sure that the plate is **completely sealed**, particularly at the edge of the plate. Make sure that the liquid has contacted the dried mix and there are **no bubbles** or air gaps in the reaction wells. If bubbles appear, gently tap the tubes on the laboratory bench to remove them, or preferably careful spin it down (10 sec).

Place the sealed PCR plate in the QS6 instrument. Please use the correct plate holder and orientation as per the notes below.

Note: Please make sure that you place the reaction plate into the cycler in the correct orientation as shown in Figure 2 above where the NTC well is in the bottom right corner, position H12.

Note: For the HISTO TYPE Rainbow plates a special plate holder for the QuantStudio™ 6 Flex System is required, which is included in the first starter package (REF 726321). For more information please contact BAG Diagnostics.

6.5 PCR-Program

Please note: HISTO TYPE Rainbow uses custom fluorophores. Prior to use instruments must be calibrated with the Custom Dye Calibration Kit available from BAG Diagnostics, REF 728260.

It is strongly recommended to use the run template **"QS6_fast_96_Rainbow.edt"** provided by BAG Diagnostics. If it is not used, set up and save a PCR protocol with the following parameters according to the manufacturer's user guide for the QuantStudio™ 6 Flex System.

HISTO TYPE RAINBOW QS6 PCR program set up:

Use the following parameters to set up the PCR program.

Instrument type:	QuantStudio™ 6 Flex System
Block type:	Fast 96-Well **(0.1 mL)**
Experiment type:	Comparative Ct (ΔΔCt)
Reagent type:	TaqMan® Reagents
Run properties:	Standard

Define Targets:

Please note: Custom dye instrument calibration must be performed prior to initial use of a new QS6 instrument. For instructions on how to perform custom dye calibration please refer to "QuantStudio™ 6 and 7 Flex Real-Time PCR Systems MAINTENANCE AND ADMINISTRATION Guide".

Target Name	Reporter	Quencher
TAMRA	TAMRA	NFQ-MGB
FAM	FAM	NFQ-MGB
Orange560	O560	NFQ-MGB
RED	R610	NFQ-MGB
Q670	Q670	NFQ-MGB

Passive Reference: None

Assign: Assign all targets to each well.

Run Method:

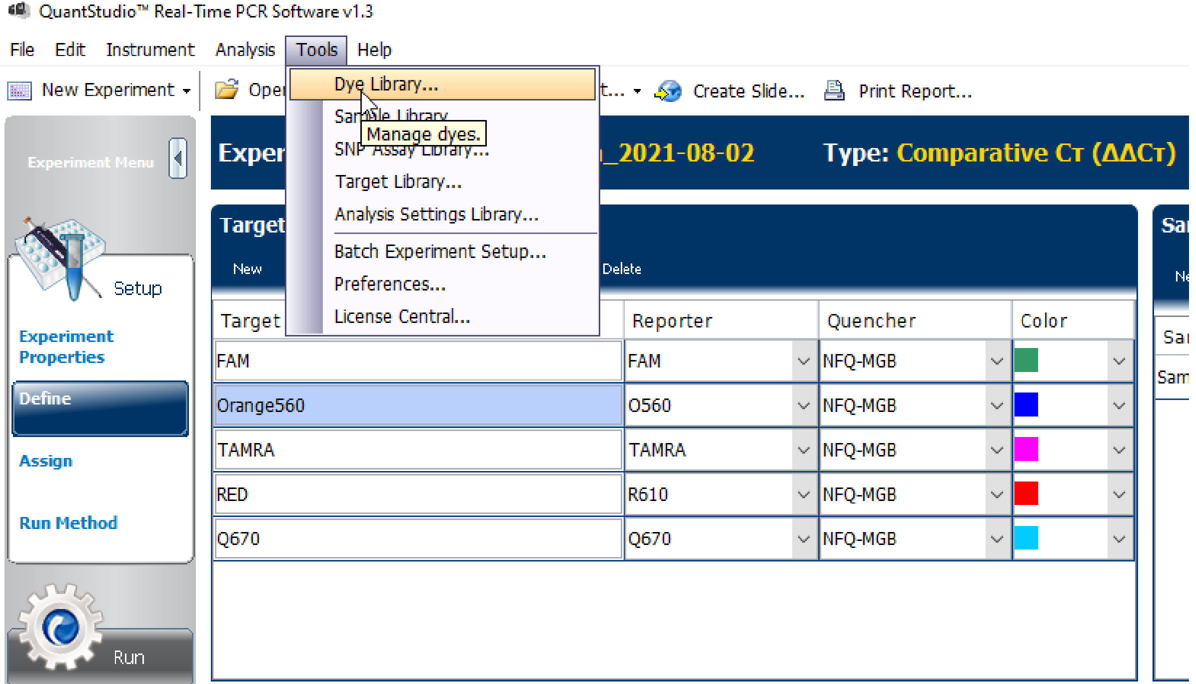
Reaction volume 10 µl

Stage	Cycles	Data Collection	Target (°C)	Hold (hh:mm:ss)	Ramp rate (°C/s)
Hold Stage	1	Off	96	00:02:00	2.5
PCR Stage	13	Off	98	00:00:05	2.5
			68	00:00:25	2.2
PCR Stage	37	Off	98	00:00:05	2.5
		On	68	00:00:25	2.2

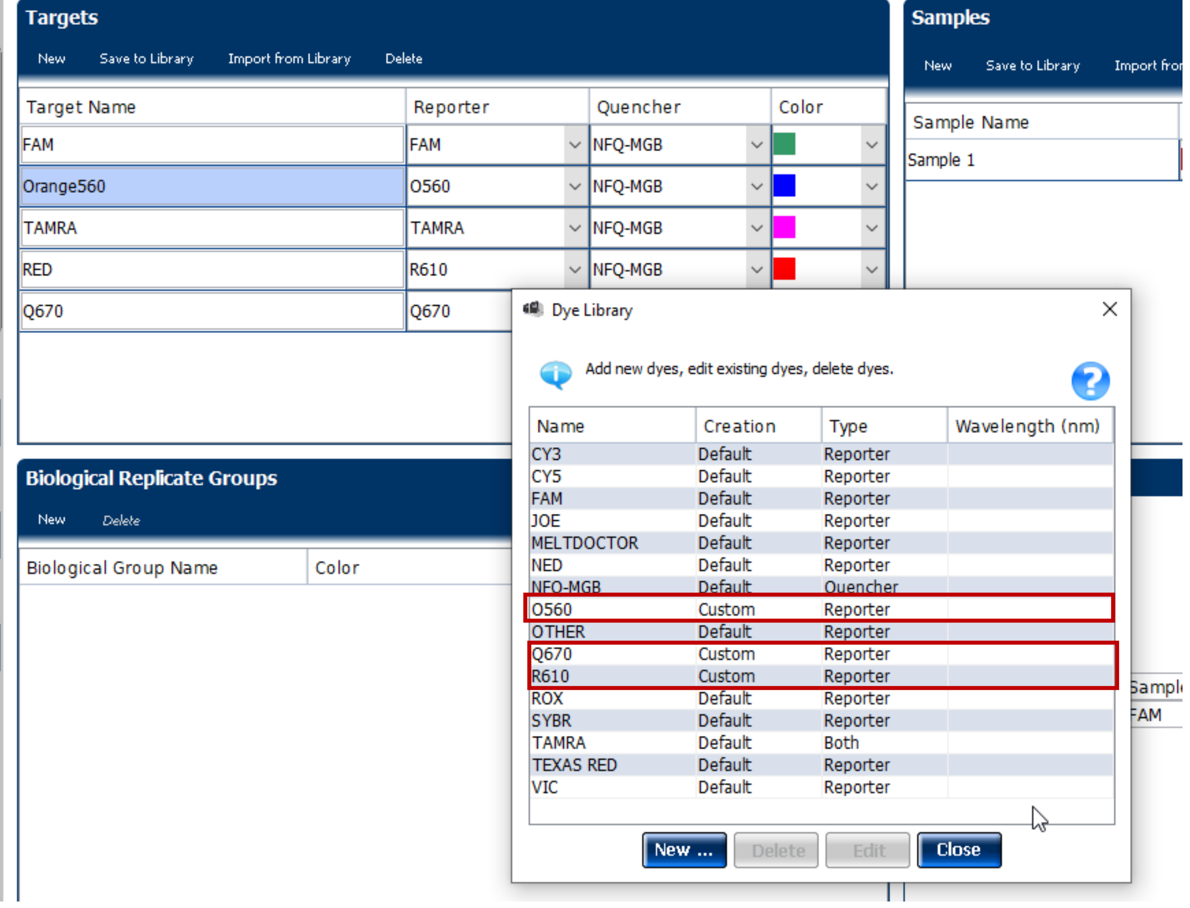
6.6 Import run template and define dyes

Save the **QS6_fast_96_HISTO TYPE Rainbow.edt** file in the **templates** folder of the QuantStudio™ Real-Time PCR Software.

As some of the dyes used in the kit are custom dyes they need to be added to the **Dye Library** in the **Tools** section.

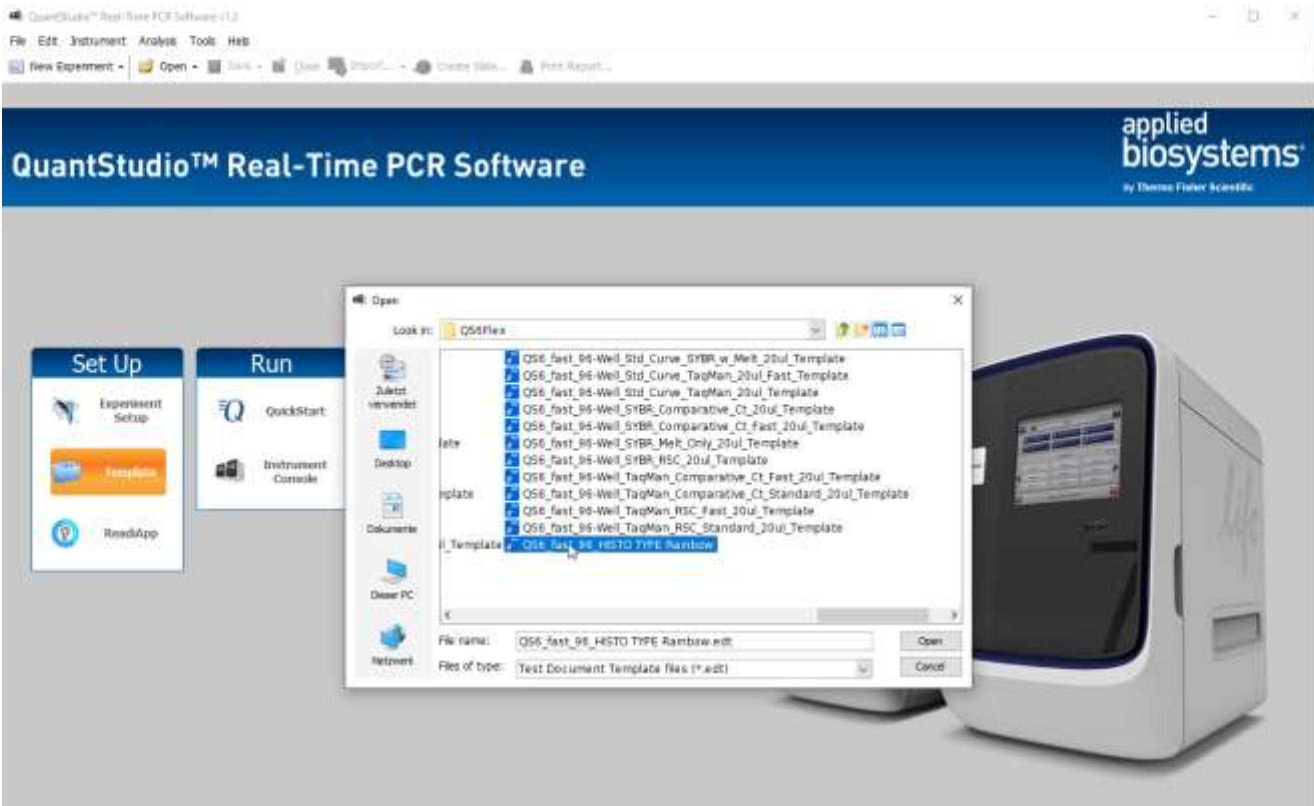


With the **New** button add the dyes O560, Q670 and R610 to the dye library as shown below. The naming of the dyes (Reporter) must be exactly as described, respectively shown in the screenshot below.

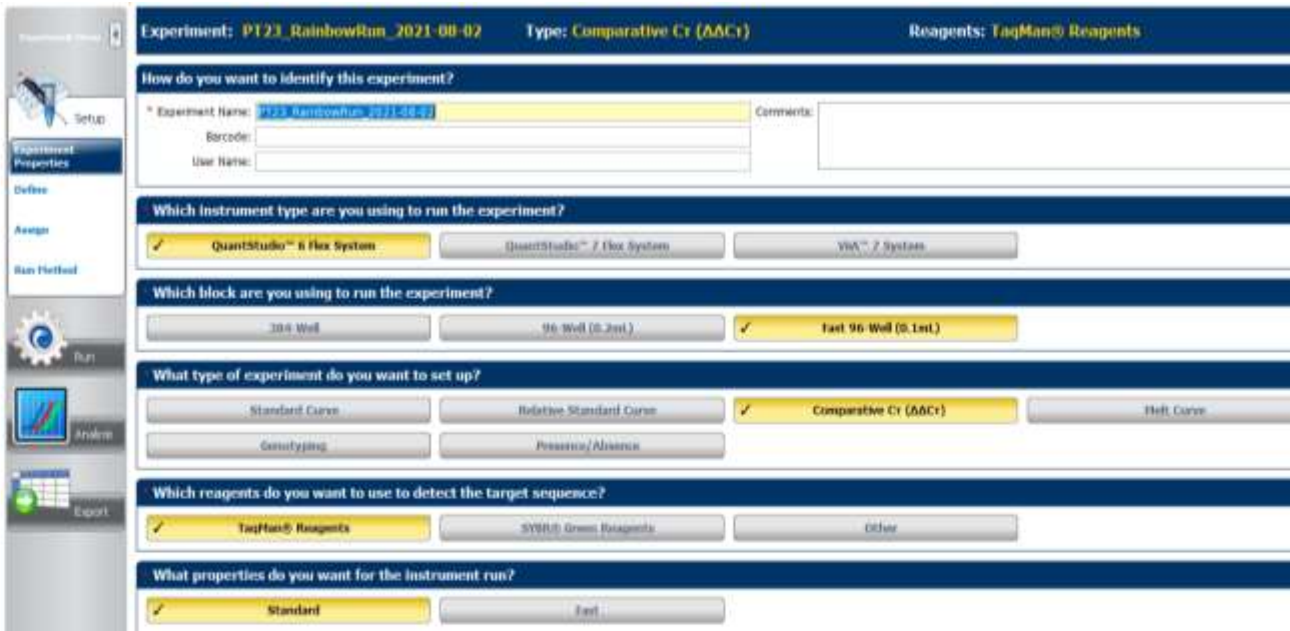


6.7 Perform the real-time PCR run

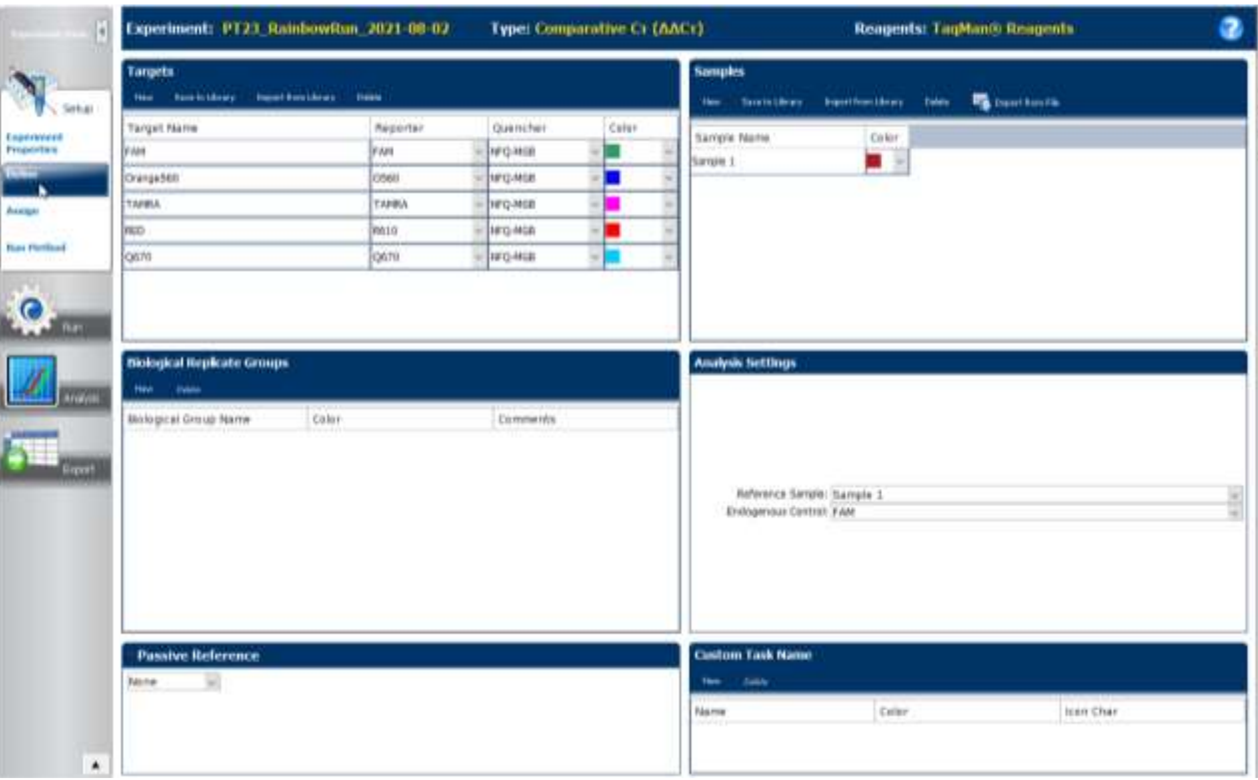
In the QuantStudio™ Real-Time PCR Software select the **QS6_fast_96_HISTO TYPE Rainbow.edt** file under **Setup** and **Template** in the **templates** folder and press **Open**.

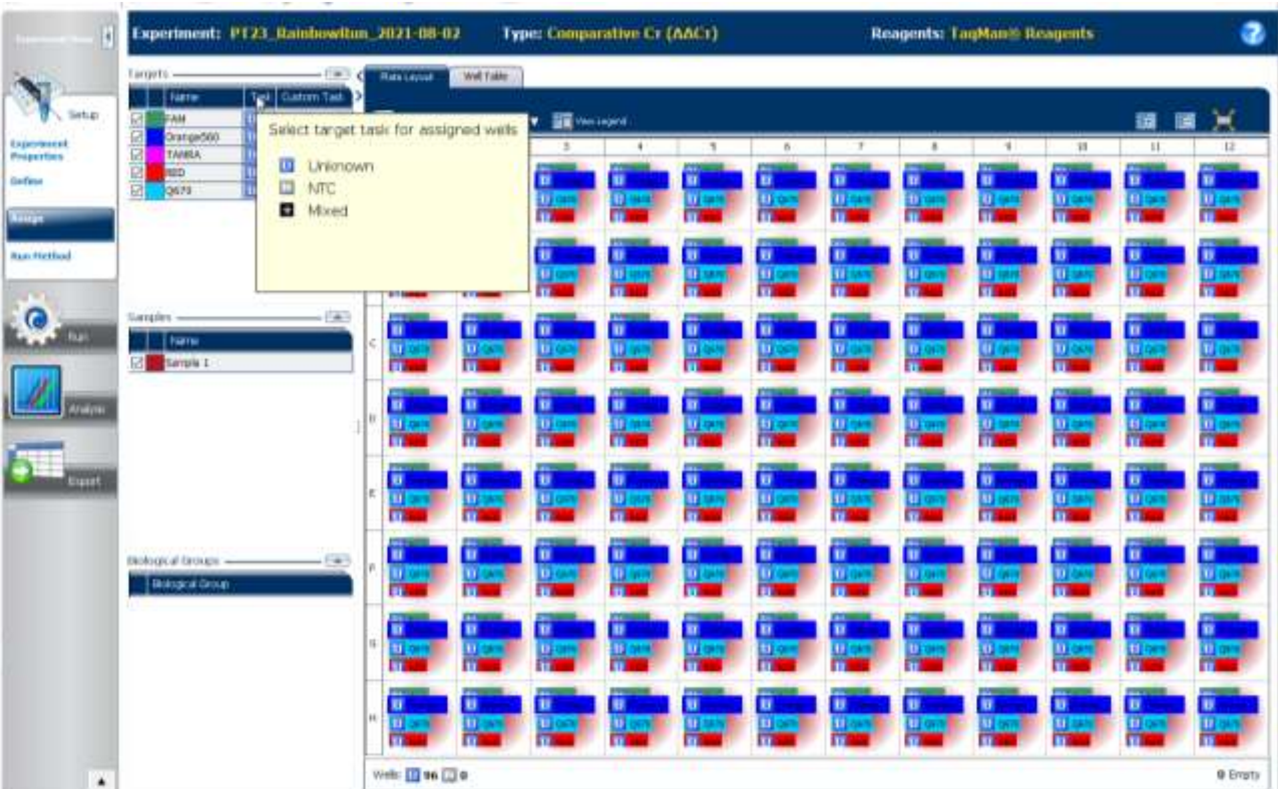


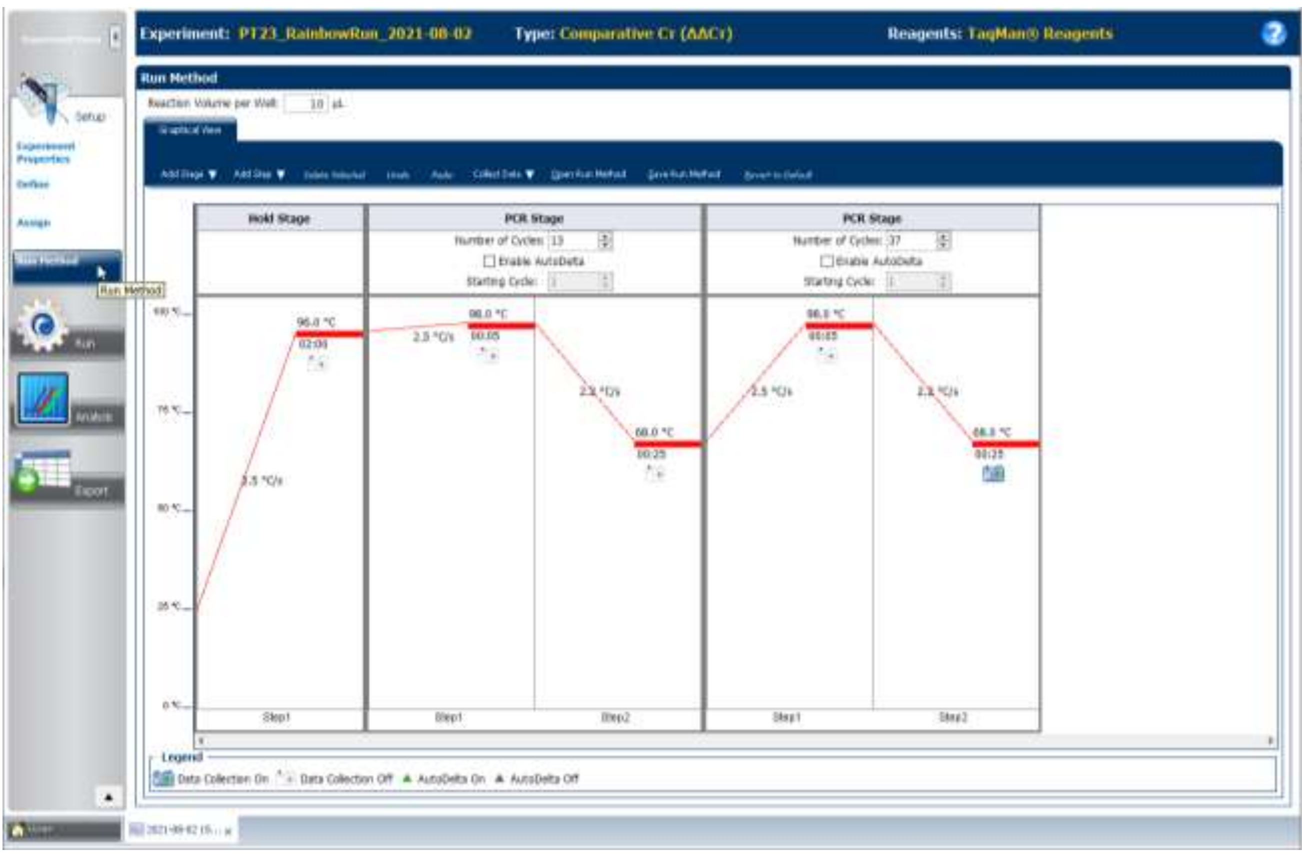
The screen with **Experiment Properties** opens and you can name your experiment here. The name should begin with the RUN ID created in the PlexTyper® Software (PT1, PT2, PT3....). All the other properties are already defined in the run template.



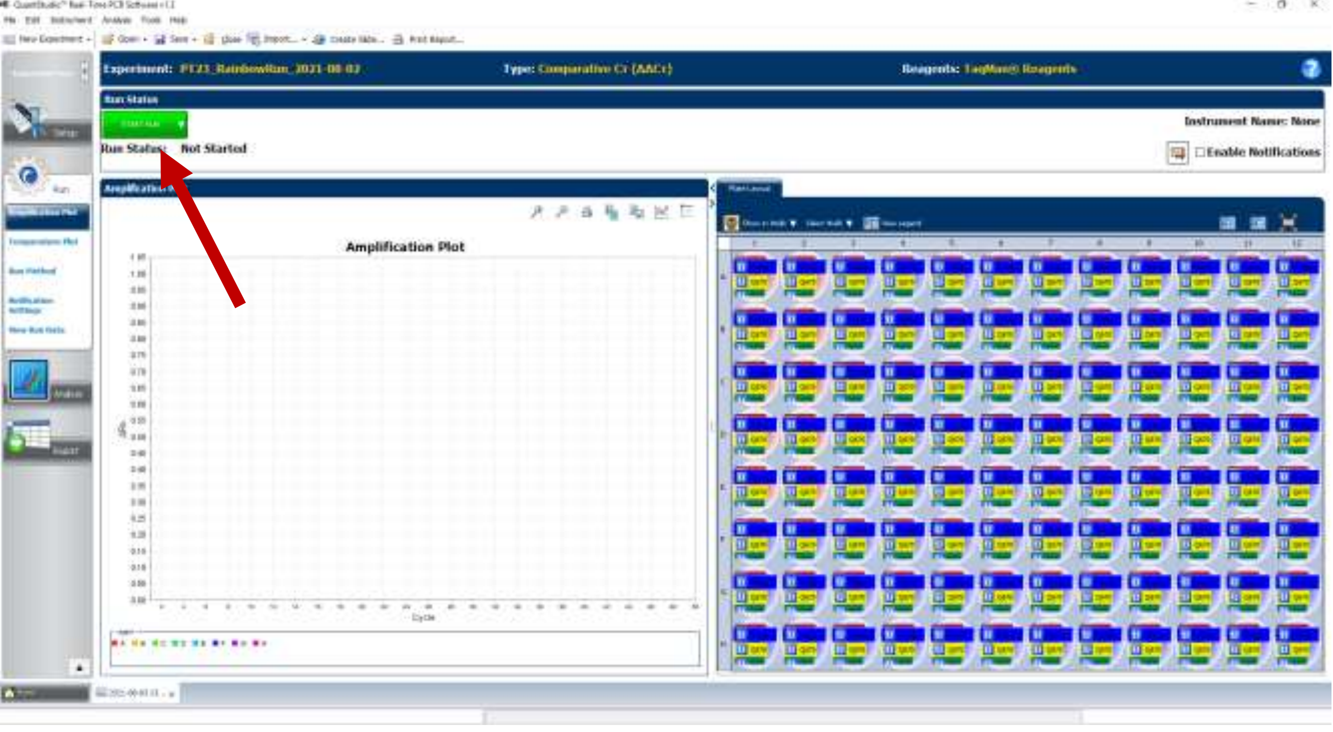
All the settings in the sections **Define, Assign** and **Run Method** are defined in the run template as shown below and must not be changed.







To start the run go to the **Run** section and press the green **Start Run** button.

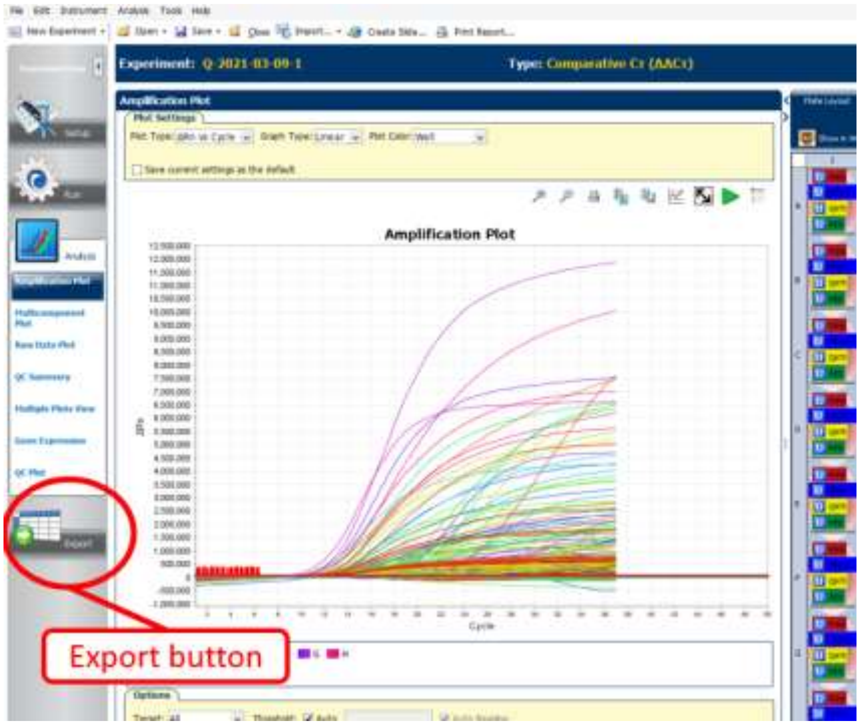


6.8 Export of results from the QuantStudio™ 6 Flex System

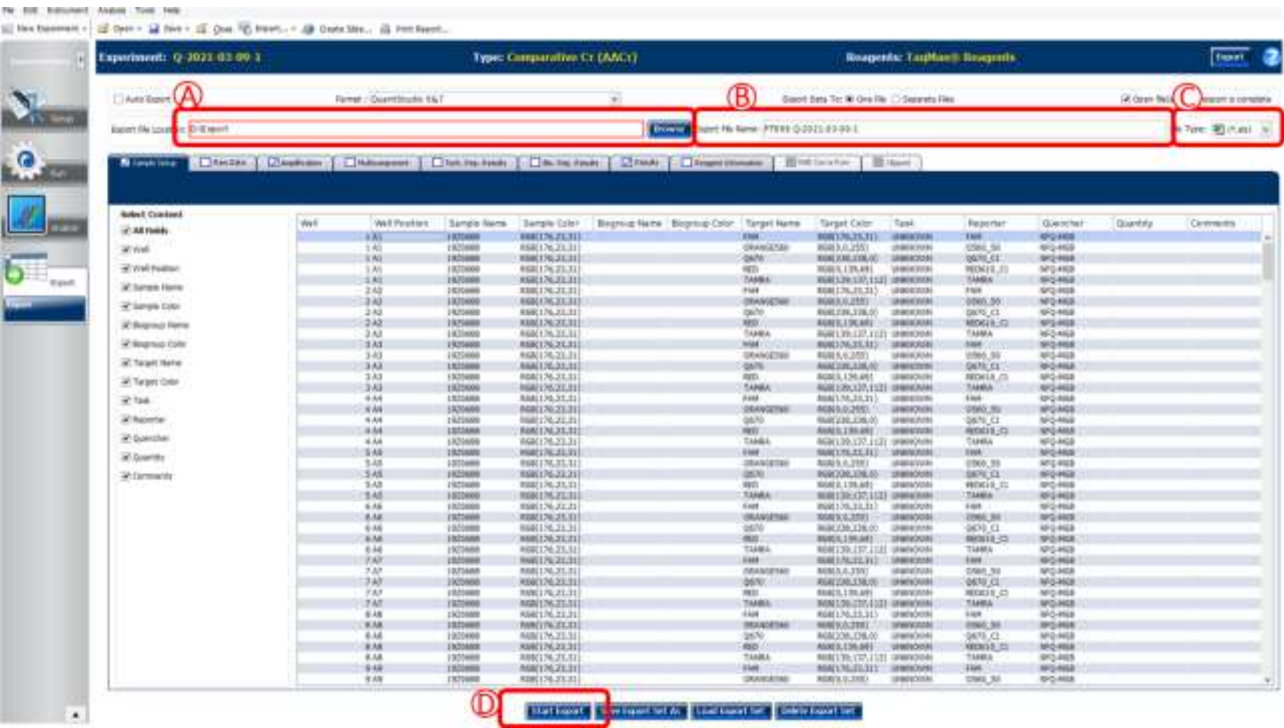
After the PCR run is complete there is no requirement for analysis in the Applied Biosystems software. For analysis in PlexTyper® an excel file needs to be exported using either the machine software or the separate QuantStudio™ Real-Time PCR Software.

Export the raw data in excel format with the following steps.

1) Navigate to the export button and select export.



2) In QuantStudio™ Real-Time PCR Software software (with reference to image below) (A) select the folder location where you want the export to go, select open folder to save. (B) If required rename the file by prefixing with the PT appropriate run ID from entering the sample in PlexTyper® prior to running test. (C) If not selected, select excel format, (D) select export. The **Sample Setup** and the **Amplification** tab must be selected.



3) If the experiment file has not been set up in the QuantStudio™ 6 Flex System with the PT prefix number it should now be given the correct prefix obtained when the sample idenity and run identity was entered into PlexTyper®.

6.9.1 Evaluation and interpretation of the results

For evaluation and interpretation of the data it is mandatory to use the PlexTyper® software (available free of charge from BAG Diagnostics) in conjunction with the kit specific data files. The kit files required for the evaluation are available from the BAG Diagnostics download server (www.service.bag-diagnostics.com).

Please make a note of the lot number of the kit. The interpretation kit files are product and lot specific. Use of incorrect kit files could result in incorrect genotyping. For interpretation of the results the raw data must be transferred from the thermocycler to a computer running the PlexTyper® software (e.g. with a suitable USB drive).

HISTO TYPE Rainbow QS6 is a 5-channel, 96 well multiplex genotyping test. It is possible to view data on the amplification machine software, but it is not possible to interpret without use of the PlexTyper® software. For QuantStudio™ 6 Flex System analysis colour compensation must be applied.

6.10 Import of the results file into the PlexTyper® software

Please follow the instructions for use for the PlexTyper® software for interpretation of the data.

Open the PlexTyper® software. From the home screen choose View plates with no associated results under Plates. A list opens with all tests that are not linked with raw data yet. There is a global Search field at the top of the table to search the whole table.

Double click on the required test to be interpreted; this opens the results summary window . Select **Import File** and select the excel file with the correct PT RUN ID prefix (e.g. PT999.xls) exported from the QuantStudio™ 6 Flex System.

Initial loading of the kit file data takes approximately 45 seconds, unless it is already open, the bottom left corner of the screen shows a progress bar. After that the results for user review are presented.

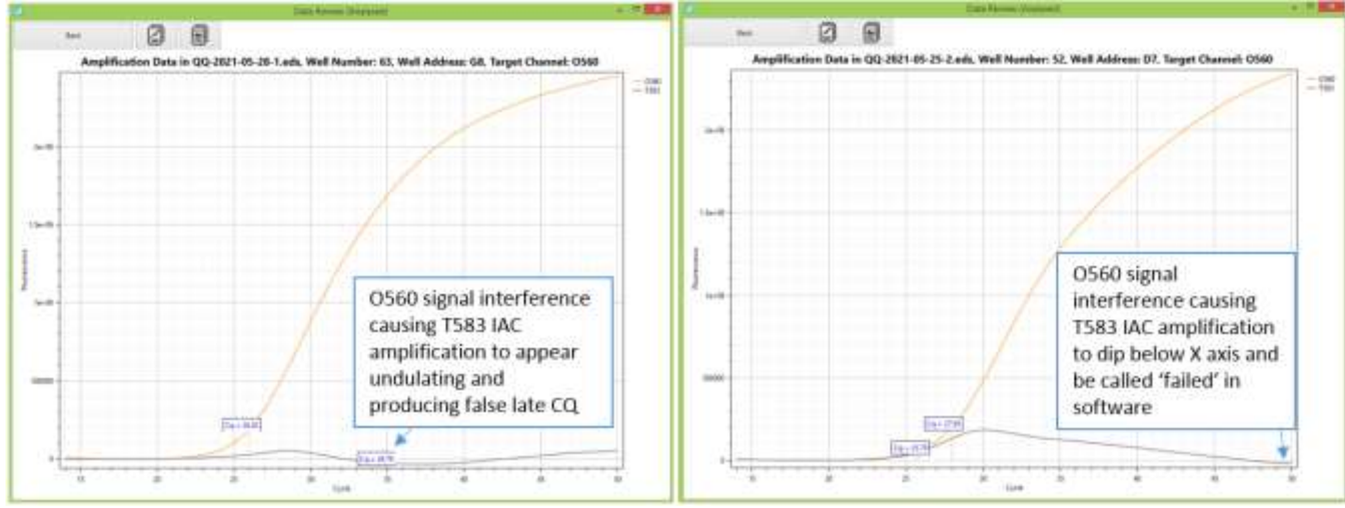
A negative control (NTC) is used as contamination control. If DNA or contaminating amplicon is inadvertently added to the NTC reaction a positive signal will occur. If the Cq is less than 36 it will be detected as possible contamination by the PlexTyper® software and a warning message is generated. Amplification signals above Cq 36 in the NTC are regarded as PCR artefacts and are disregarded. If PCR contamination is suspected, it is advisable to follow local decontamination guidelines and to exchange the reagents.

The raw data collected from the cycler-specific software will be imported into the PlexTyper® software. Based on the Cq values, RFUs (relative fluorescence units), quality scores and the curve progression the PlexTyper® software determines the molecular genetic HLA pattern of the specimens used (see instructions for use for PlexTyper® for details). Positive reactions are determined based on the Cq ratio between the the Cq of the internal amplfication control (IAC) and the Cq of the HLA allele specific reaction (exception see below).

Special consideration for analysis of HISTO TYPE Rainbow QS6 results:

In these kits a strong allele specific O560 signal may affect the appearance of the TAMRA IAC amplification due to emission wavelength interference. This can result in sporadic IAC failure due either to a false late IAC Cq value, or the reaction failing due to the fluorescence values being negative in the last cycle. Figures below illustrate the possible appearances of the TAMRA IAC signals when the O560 signal is strong.

If the IAC amplification is deemed negative, or late due to O560 interference this can lead to no result being found for the affected HLA gene locus. To automatically correct for this the thresholds relating to the IAC have been modified for reactions where this phenomenon has been observed (reactions 7, 20, 43, 52, 63, 84 & 85) so that correct genotypes can be generated automatically. The software generates a message to inform the user about it.



It may still happen that the problem occurs in other reactions as well or that non-optimal shapes of the amplification curve for other fluorophores result in a failure to generate an automatic result in PlexTyper® . For a general procedure to deal with failed automatic generation of results please refer to the PlexTyper® instructions for use (see chapter: How to investigate 'No results' at an HLA locus).

7. WARNINGS AND DISPOSAL INSTRUCTIONS

HISTO TYPE Rainbow QS6 is **designed for in vitro diagnostic use**. The kit should only be used by specially trained, qualified personnel. All work should be performed in accordance with Good Laboratory Practice.

All materials of biological origin used in the test to obtain DNA (e.g. blood) should be considered as potentially infectious. Therefore, appropriate safety precautions are recommended when handling biological materials as required by Good Laboratory Practice standards.

Biological materials must be inactivated before disposal (e.g. by autoclaving). Disposable materials must be autoclaved or incinerated after use. Spilled potentially infectious material should be removed immediately with an absorbent paper towel and the contaminated area disinfected with an appropriate disinfectant or 70% Ethanol. Material used to remove spills must be inactivated before disposal (e.g. by autoclaving).

Disposal of all specimens, unused reagents and waste should be in accordance with the legislation of the respective country and the local authorities.

Microbial contamination of reagents while taking aliquots should be avoided. The use of sterile disposable pipettes and pipette tips is recommended. Do not use reagents looking cloudy or showing signs of microbial contamination.

The Plex Mix contains the hazardous substance 2-methylisothiazol-3(2H)-one at a concentration of < 0.05%. The following hazardous material labeling is applicable:

Symbol: Warning

See chapter 13 for hazard and precaution statements.

A material safety data sheet (MSDS) for the Plex Mix is available for download from www.bag-diagnostics.com. No further MSDS are required according to article 31 of REACH regulation (EC) no. 1907/2006 and the regulation (EC) no. 1272/2008.

8. KIT SPECIFICATIONS

The combination of primers and probes allows the determination of human HLA class I and II alleles according to lot-specific data (low to medium resolution, detection of all alleles with the exception of single rare alleles). The accuracy and reproducibility of the reactivity of the test kit is checked for each lot with control specimens with known HLA-alleles. The kit determines the HLA-Loci A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1.

8.1 Specific performance characteristics

8.1.1 Diagnostic sensitivity and specificity

A total of 116 DNA samples pre-typed for the relevant HLA loci or international reference cell lines were tested with the HISTO TYPE Rainbow QS6 kit to show the correct reactivity. There was a 100% concordance of results with the pre-typings for all loci.

Locus	Number of sample pre-typed for the locus	concordant	% concordance
A	116	116	100%
B	116	116	100%
C	116	116	100%
DRB1	115	115	100%
DRB3	113	113	100%
DRB4	113	113	100%
DRB5	113	113	100%
DQA1	114	114	100%
DQB1	114	114	100%
DPA1	113	113	100%
DPB1	114	114	100%

8.1.2 Analytical sensitivity and measuring range

Validation tests have shown that variation of the amount of DNA from 8 ng to 30 ng per reaction has no significant effect on the specific detection of HLA alleles.

8.1.3 Analytical specificity / cross reactive substances

Eight substances that might interfere with the assay were tested and the following concentrations were shown to have no detrimetal effect on the results:

Substance	Maximal non-inhibitory concentration
Protein (BSA)	0.2 mg/ml
TE (Tris/EDTA, pH 8.0)	7 mM Tris, 0.7 mM EDTA
NaCl	20 mM
Ethanol	1%
Haemoglobin	0.01 mg/ml
Sodium Citrate	7 mM
DNA extraction buffer 1 (Qiagen QIAamp DNA Blood Kits)	1%
DNA extraction buffer 2 (Qiagen QIAamp DNA Blood Kits)	2%

9. LIMITS OF THE METHOD

During DNA isolation, special attention must be paid to the fact that the RT-PCR method reacts very sensitively to cross-contaminations. Special care should be taken to avoid contamination of kit reagents and other laboratory materials with amplicons or DNA.

The performance of a negative control without DNA in well H12 is strongly recommended. No fluorescence signal below 36 Cq should be detected in the NTC (H12) with molecular grade water. In the case of signal development in the negative control, the PCR laboratory workplace may have to be decontaminated from DNA and the reagents exchanged if necessary.

All devices (e.g. pipettes, real-time cyclers) must be calibrated according to the manufacturer's specifications.

10. INTERNAL QUALITY CONTROL

Internal quality controls for new lots can be performed with a combination of DNA specimens with known HLA type. An internal control to verify successful amplification is included in the dried oligomixes.

Performance of negative controls (well H12) to detect possible contaminations is recommended. For this purpose, prepare a test without DNA (NTC), see section 6.4.

11. TROUBLESHOOTING

For interpretation trouble shooting please see the Instructions for Use for PlexTyper® Software.

Symptom	Possible Reason	Potential Solution
TAMRA signals weak or absent across whole plate	Presence of an inhibitor in the DNA.	Try a different extraction or sample.
	Insufficient DNA in the reaction.	Repeat test with correct amount of DNA.
	Wrong amplification parameters.	Check PCR program.
	Contaminated or degraded DNA.	Check concentration / quality of DNA. Check DNA on a gel. Repeat DNA isolation.
	Degraded Fluorescent probes or primers.	Avoid exposure to light and frequent thawing and freezing. Observe storage conditions.
Poor or no TAMRA signal in individual wells	Bubbles in the reaction / residual liquid at the inner wall of the tube.	Careful pipetting. Spin down PCR plate.
	User error.	Ensure all wells receive the required volume of reagents.
	Evaporation of the reagents due to incorrect closing of the PCR tubes.	Make sure that the PCR tubes are closed properly. Caution with adhesive foils in the edge area.
	Strong Q560 signal supressed TAMRA signal resulting in potential false negative allele specific results.	Use data review in PlexTyper® to correct results.
Signal in the Negative Control	Contamination with DNA or amplicon in the negative control.	Repeat the test. Decontaminate the workplace.
	Amplification due to PCR artefact.	Review after import into PlexTyper®, if the signal may be below the thresholds or the data may in fact be OK (please note the PlexTyper® Instructions for Use).

12. TRADE NAMES USED

QuantStudio™ 6 Flex System is a tradename of Applied Biosystem (Thermo Fisher Scientific)

TaqMan® is a tradename of Roche Molecular Systems Inc.

®Cal Fluor & Quasar Dyes are the registered trademark of LGC Biosearch Technologies

13. EXPLANATION OF THE SYMBOLS USED ON THE LABELS

Symbol	Explanation
Σ	Sufficient for n tests
	Storage temperature / Upper temperature limit
	Consult to instruction for use
	Manufacturer
	Use by
CONT	Content, contains
eIFU	Electronic instructions for use
HLA TYPING	Intended use: HLA typing
IVD	For in vitro diagnostic use
LOT	Batch code
PCRFOIL	PCR foil
PCRPLATE	PCR plates
PLEX MIX	Plex Mix: Mastermix, contains dNTPs, Taq polymerase, reaction buffer
REACTIONMIX	Reaction mixes
REF	Catalogue number
RTU	Ready to use
	Warning (see chapter 7) H317 May cause an allergic skin reaction. Precautionary statements P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read carefully and follow all instructions. P302+P352 IF ON SKIN: Wash with plenty of water. P280 Wear protective gloves/protective clothing/eye protection/ face protection/hearing protection. P333+P313 If skin irritation or rash occurs: Get medical advice/ attention. P501 Dispose of contents/container in accordance with local/ national regulation.

14. LITERATURE

1. Mack, S.J. et al., 2013. Tissue Antigens 81, 194–203

2. Beutler, E. et al., 1990. BioTechniques 9:166

For further information please refer to our website www.bag-diagnostics.com or contact us directly at info@bag-diagnostics.com