appliedbiosystems

CALIBRATION AND PERFORMANCE
CHECK RECORD

QuantStudio™ 6 and 7 Flex Real-Time PCR Systems

Pub. No. MAN0019267 Rev. A.0

The *QuantStudio™ 6 and 7 Flex Real-Time PCR Systems Calibration and Performance Check Record* is a document designed to allow end users to perform and record the results of dye calibration and an instrument performance check. This document does not take the place of a qualification service performed by a certified Thermo Fisher Scientific field service engineer.

IMPORTANT! This document does not represent qualification of the QuantStudio™ 6 or 7 Flex Real-Time PCR System.

Customer and service information

Customer organization name:	
Customer contact name:	
Customer contact title:	
Customer organization location:	
Date performed:	
Performed by:	

Instrument information

Instrument model:	○ QuantStudio™ 6 Flex ○ QuantStudio™ 7 Flex
Instrument serial number:	
Sample block and heated cover type:	○ 96-Well ○ Fast 96-Well ○ 384-Well ○ Array Card **Note:** The Array Card block uses the 384-Well heated cover.
Sample block serial number:	
Heated cover serial number:	

Responsibilities

Customers should ensure that the *QuantStudio™ 6 and 7 Flex Real-Time PCR Systems Maintenance and Administration Guide* (Pub. No. 4489821 (v1.5 or earlier) or MAN0018828 (v1.6 or later)) is available, and that the appropriate consumables (listed in each section) have been obtained.

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Optical calibrations

✓	Task

☐ Obtain the appropriate calibration plates listed below.

	Fast 96-Well	96-Well	384-Well	Array Card
ROI and background kit	☐ 4432426	☐ 4432364	☐ 4432320	N/A
Normalization plates kit[1]	☐ 4432432	☐ 4432370	☐ 4432308	N/A
FAM™ dye plate[1]	☐ 4432389	☐ 4432327	☐ 4432271	N/A
TAMRA™ dye plate[1]	☐ 4432414	☐ 4432352	☐ 4432296	N/A
ROX™ dye plate[1]	☐ 4432402	☐ 4432340	☐ 4432284	N/A
VIC™ dye plate[1]	☐ 4432396	☐ 4432334	☐ 4432278	N/A
NED™ dye plate[1]	☐ 4432420	☐ 4432358	☐ 4432302	N/A
SYBR GREEN™ dye plate[1]	☐ 4432408	☐ 4432346	☐ 4432290	N/A
ABY™ dye plate[1]	☐ A24734	☐ A24738	☐ A24736	N/A
JUN™ dye plate[1]	☐ A24735	☐ A24737	☐ A24733	N/A
MUSTANG PURPLE™ dye plate[1]	☐ 4457328	☐ 4461599	☐ 4457334	N/A
10-dye spectral calibration kit[2]	☐ A26342	☐ A26343	☐ A26341	N/A
Array Card calibration kit	N/A	N/A	N/A	☐ 4432314

☐ Follow the instructions in the user guide to complete the ROI, background, and uniformity calibrations.

ROI:	☐ Passed
Background:	☐ Passed
Uniformity:	☐ Passed

Note: If the background calibration fails, clean the block according to the instructions in the user guide.

For Fast 96-Well, 96-Well, and 384-Well sample blocks with QuantStudio™ Software v1.5 or earlier only. If not applicable, select **"N/A" below, then skip to the next section in this table.**

☐ **N/A**

☐ Follow the instructions in the user guide to complete the desired pure dye calibrations.

Note: To run the normalization calibration and the performance check, the instrument must be calibrated for FAM™, TAMRA™, ROX™, and VIC™ dyes at minimum.

Dye	Result	Dye	Result
FAM™ dye	○ Passed ○ Not calibrated	SYBR GREEN™ dye	○ Passed ○ Not calibrated
TAMRA™ dye	○ Passed ○ Not calibrated	ABY™ dye	○ Passed ○ Not calibrated
ROX™ dye	○ Passed ○ Not calibrated	JUN™ dye	○ Passed ○ Not calibrated
VIC™ dye	○ Passed ○ Not calibrated	MUSTANG PURPLE™ dye	○ Passed ○ Not calibrated
NED™ dye	○ Passed ○ Not calibrated		

☐ Follow the instructions in the user guide to complete the normalization calibrations.

FAM™ / ROX™	☐ Passed
VIC™ / ROX™	☐ Passed

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[1] Not applicable to QuantStudio™ Software v1.6 or later.

[2] Not applicable to QuantStudio™ Software v1.5 or earlier.

<table>
<tr><th>✓</th><th>Task</th></tr>
<tr><td colspan="2">For Fast 96-Well and 96-Well sample blocks with QuantStudio™ Software v1.6 or later only. If not applicable, select "N/A" below, then skip to the next section in this table.
☐ N/A</td></tr>
<tr><td>☐</td><td>Follow the instructions in the user guide to complete the pure dye calibrations.
<table>
<tr><th>Plate</th><th>Dyes</th><th>Result</th></tr>
<tr><td>Plate 1</td><td>FAM™, VIC™, ROX™, SYBR GREEN™</td><td>☐ Passed</td></tr>
<tr><td>Plate 2</td><td>ABY™, JUN™, MUSTANG PURPLE™</td><td>☐ Passed</td></tr>
<tr><td>Plate 3</td><td>NED™, TAMRA™, Cy5™</td><td>☐ Passed</td></tr>
</table></td></tr>
<tr><td colspan="2">For 384-Well sample block with QuantStudio™ Software v1.6 or later only. If not applicable, select "N/A" below, then skip to the next section in this table.
☐ N/A</td></tr>
<tr><td>☐</td><td>Follow the instructions in the user guide to complete the pure dye calibrations.
<table>
<tr><th>Plate</th><th>Dyes</th><th>Result</th></tr>
<tr><td>Plate 1</td><td>FAM™, VIC™, ROX™, TAMRA™, SYBR GREEN™</td><td>☐ Passed</td></tr>
<tr><td>Plate 2</td><td>ABY™, JUN™, MUSTANG PURPLE™, NED™, Cy5™</td><td>☐ Passed</td></tr>
</table></td></tr>
<tr><td colspan="2">For Array Card sample block only. If not applicable, select "N/A" below, then skip to the next section in this document.
☐ N/A</td></tr>
<tr><td>☐</td><td>Follow the instructions in the user guide to complete the pure dye calibrations.
<table>
<tr><td>FAM™</td><td>☐ Passed</td></tr>
<tr><td>ROX™</td><td>☐ Passed</td></tr>
<tr><td>VIC™</td><td>☐ Passed</td></tr>
</table></td></tr>
<tr><td>☐</td><td>Follow the instructions in the user guide to complete the normalization calibrations.
<table>
<tr><td>FAM™ / ROX™</td><td>☐ Passed</td></tr>
<tr><td>VIC™ / ROX™</td><td>☐ Passed</td></tr>
</table></td></tr>
</table>

Comments

If you have no comments, enter "Not applicable" below.

Performance check

✓	Task
☐	Obtain the appropriate RNase P plate listed below.

	Fast 96-Well	96-Well	384-Well	Array Card
RNase P Instrument Verification Plate/Kit	☐ 4351979	☐ 4432382	☐ 4455280	☐ 4432265

For Fast 96-Well, 96-Well, and 384-Well sample blocks only. If not applicable, select "N/A" below, then skip to the next section in this table.

☐ **N/A**

☐ Follow the instructions in the user guide to run the RNase P plate to complete the performance check. The instrument passes the installation specification if the inequality holds and the instrument successfully distinguishes between unknown populations A and B with a statistical confidence level of 99.7%. Performance is verified by the analysis equation below:

$[(\mathrm{CopyUnk}_2) - 3(\sigma_{\mathrm{CopyUnk2}})] > [(\mathrm{CopyUnk}_1) + 3(\sigma_{\mathrm{CopyUnk1}})]$ where:

- $\mathrm{CopyUnk}_2$ = Average copy number (Qty Mean) of unknown population B (10000-copy population)
- $\sigma_{\mathrm{CopyUnk2}}$ = Standard deviation (Qty SD) of unknown population B (10000-copy population)
- $\mathrm{CopyUnk}_1$ = Average copy number (Qty Mean) of unknown population A (5000-copy population)
- $\sigma_{\mathrm{CopyUnk1}}$ = Standard deviation (Qty SD) of unknown population A (5000-copy population)

Maximum number of outliers that can be removed:

Sample block	Unknown outliers	Standard outliers	NTC outliers
Fast 96-Well or 96-Well	6 per population	1 per population	0
384-Well	10 per population	2 per population	0

When the run is complete, perform a primary analysis of the data and enter the values:

$\mathrm{CopyUnk}_2$ (Qty Mean 10K)	$\sigma_{\mathrm{CopyUnk2}}$ (Qty SD 10K)	Unknown B (10K) outliers
$\mathrm{CopyUnk}_1$ (Qty Mean 5K)	$\sigma_{\mathrm{CopyUnk1}}$ (Qty SD 5K)	Unknown A (5K) outliers
Standard (1.25K) outliers	Standard (2.5K) outliers	Standard (5K) outliers
Standard (10K) outliers	Standard (20K) outliers	NTC outliers

Performance check: ☐ Passed

✓	Task

For Array Card sample block only. If not applicable, select "N/A" below, then skip to the next section in this document.

☐ **N/A**

☐ Follow the instructions in the user guide to prepare and run the RNase P kit to complete the performance check. The instrument passes the installation specification if the inequality holds and the instrument successfully distinguishes between unknown populations A and B with a statistical confidence level of 99.7%. Performance is verified by the analysis equation below:

$[(\mathrm{CopyUnk}_2) - 3(\sigma_{\mathrm{CopyUnk2}})] > [(\mathrm{CopyUnk}_1) + 3(\sigma_{\mathrm{CopyUnk1}})]$ where:

- $\mathrm{CopyUnk}_2$ = Average copy number (Qty Mean) of unknown population B (1600-copy population)
- $\sigma_{\mathrm{CopyUnk2}}$ = Standard deviation (Qty SD) of unknown population B (1600-copy population)
- $\mathrm{CopyUnk}_1$ = Average copy number (Qty Mean) of unknown population A (800-copy population)
- $\sigma_{\mathrm{CopyUnk1}}$ = Standard deviation (Qty SD) of unknown population A (800-copy population)

Maximum number of outliers that can be removed:

Sample block	Unknown outliers	Standard outliers	NTC outliers
Array Card	4 per population	4 per population	0

When the run is complete, perform a primary analysis of the data and enter the values:

$\mathrm{CopyUnk}_2$ (Qty Mean 1.6K)	$\sigma_{\mathrm{CopyUnk2}}$ (Qty SD 1.6K)	Unknown B (1.6K) outliers
$\mathrm{CopyUnk}_1$ (Qty Mean 800)	$\sigma_{\mathrm{CopyUnk1}}$ (Qty SD 800)	Unknown A (800) outliers
Standard (200) outliers	Standard (400) outliers	Standard (800) outliers
Standard (1.6K) outliers	Standard (3.2K) outliers	NTC outliers

Performance check: ☐ Passed

Comments

If you have no comments, enter "Not applicable" below.

Approval

Customer Name:

Customer Signature:

Date:

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For descriptions of symbols on product labels or product documents, go to **thermofisher.com/symbols-definition**.

Revision history: Pub. No. MAN0019267

Revision	Date	Description
A.0	15 April 2020	New document.

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