

CFX Qualification Plate — 384-Well Plate Format

About the Plate

The CFX qualification plate is an optimized assay predisposed in a 384-well plate format for performance validation on the CFX384™ or CFX384 Touch™ real-time PCR detection system. The plate includes template DNA, SYBR® Green supermix, primer mix, and nuclease-free water. The CFX qualification plate can be incorporated into an instrument qualification procedure.

- Demonstrates a 2-fold discrimination with a 99.7% confidence level
- Provides a streamlined workflow with predisposed plate, predefined thermal cycling protocol, and plate templates
- Provides 1-click pass/fail performance result with CFX Manager™ software
- Includes criteria for pass/fail performance result

Contents

One 384-well plate

Storage

Store at -20°C .

Running the Plate

Note: Always wear gloves when handling the CFX qualification plate.

1. Thaw the CFX qualification plate in the aluminum bag at room temperature for 5–10 min or until contents are thawed.

Important: The plate contents are light sensitive. Do not thaw the plate outside of the aluminum bag.

2. Once the contents are thawed, centrifuge the plate at $2,000 \times g$ for 2 min.
3. Place the plate into your CFX instrument.
4. Launch CFX Manager software 3.1.
5. Click the **Run** tab in the menu bar and select **Qualification Plate Run** (Figure 1).
6. Select your CFX instrument.
7. Enter the plate's bar code number and click **Start Run** (Figure 2).

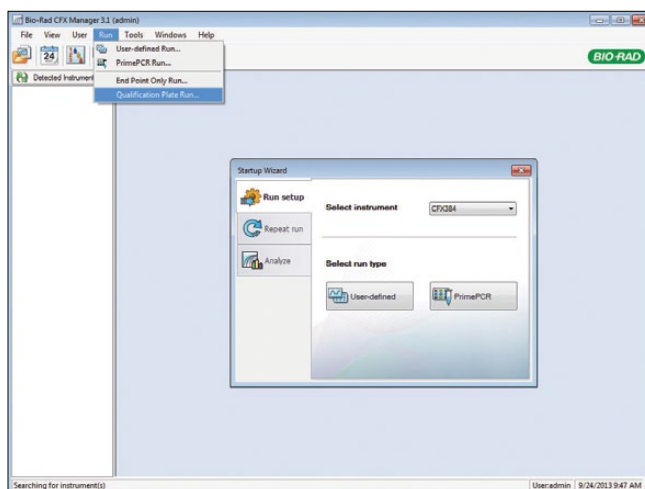


Fig. 1. Selecting Qualification Plate Run in the Run dropdown menu.

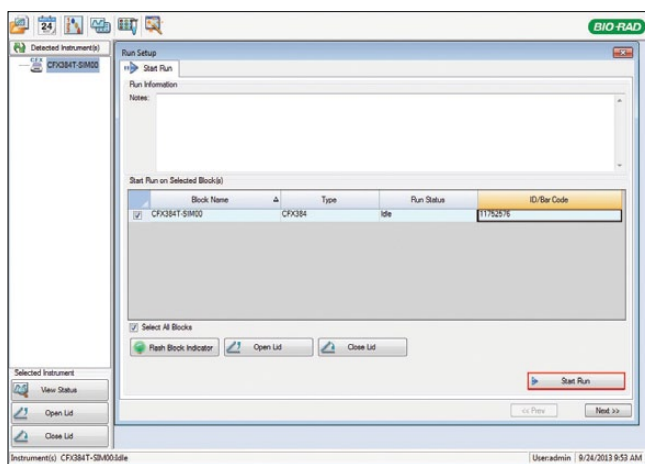


Fig. 2. Selecting Start Run in the Run Setup window.



Analyzing the Data

Click **Tools** from the menu bar. Select **Qualification Plate Report** for a pass/fail performance result (Figure 3).

Note: Up to ten wells per unknown group and four wells per no template control (NTC) and standard (STD) group can be excluded from analysis to meet passing criteria. Any NTC wells with a nonspecific product melt peak may be excluded. After excluding wells, repeat the step above for a new performance result. If your plate fails after well exclusion, contact Technical Support at 1-800-424-6723, option 2.

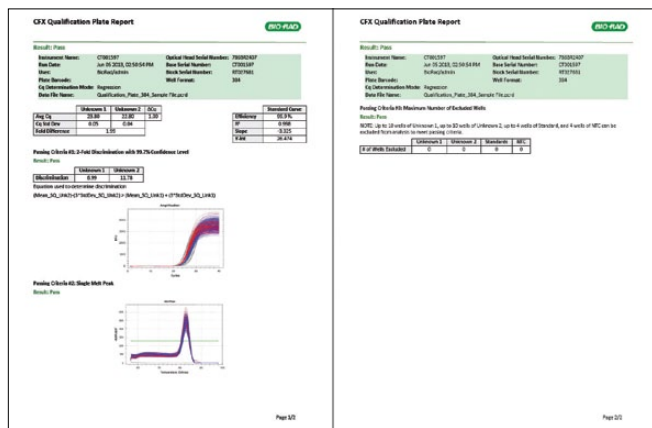


Fig. 3. CFX Qualification Plate Report window.

Passing Criteria

1. 2-Fold Discrimination with 99.7% Confidence Level

$$(\text{Mean_SQ_Unk2}) - (3 \times \text{Stdev_SQ_Unk2}) > (\text{Mean_SQ_Unk1}) + (3 \times \text{Stdev_SQ_Unk1})$$

2. Single Product Melt Peak

Definitions

- Mean_SQ_Unk2 = the average starting quantity of unknown 2
- Stdev_SQ_Unk2 = the standard deviation of the average starting quantity of unknown 2
- Mean_SQ_Unk1 = the average starting quantity of unknown 1
- Stdev_SQ_Unk1 = the standard deviation of the average starting quantity of unknown 1

Note: Quantification cycle (Cq) determination mode is automatically set to regression. CFX384 qualification plate data must be analyzed in regression mode to determine pass/fail results.

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Bio-Rad's real-time thermal cyclers are covered by one or more of the following U.S. patents or their foreign counterparts owned by Eppendorf AG: U.S. Patent Numbers 6,767,512 and 7,074,367.



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Laboratories, Inc.**

Life Science
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