

# Maintenance and Performance Verification of the BAX® System X5 Instrument

## Instrument Maintenance

The BAX® System X5 instrument does not require any regular maintenance procedures. If desired, basic cleaning and upkeep can be performed by following the instructions below.

Check the area around the BAX® System X5 instrument to ensure that the air flow is unrestricted.

## Cleaning the Instrument Casing

Remove dust and debris by wiping the instrument surfaces with a lint-free cloth. If needed, the casing can be wiped off with a damp cloth using mild soap or common disinfectants, such as 70% ethanol. Do not use cleansers containing iodine or acetone.

## Cleaning the Sample Wells

1. Use a lint-free swab soaked in 70% ethanol to gently clean the inside of the wells.
2. Dry the wells with a lint-free cloth or dry swab and remove small particles with an air duster.

## Instrument Check

The instrumentation, software and assays that make up the BAX® System X5 have been designed to work together for ease of use and reliability. Careful design has created a system that does not require maintenance other than cleaning, as described in Section I of the BAX® System User Guide.

**Self-diagnostics:** The BAX® System automatically performs self-diagnostics at power up and at the start of each process run to ensure the hardware is operating properly. If any of these tests fail, the system will prevent you from operating the cyclor/detector until the problem is corrected.

**Signal checks:** BAX System X5 assays use an intercalating dye which emits a fluorescent signal in response to light when bound to double stranded DNA (dsDNA). The BAX® System X5 measures the dissociation of the intercalating fluorescent dye from the dsDNA when gently heated. The resultant data is analyzed by the software to generate a graph of the melting of the PCR product and proprietary algorithms are applied to the data to generate a final result.

The BAX® System automatically checks every sample to confirm that the signal is within the proper range for accurate detection, and the system returns an error for any sample that is outside acceptable limits.

For all assays, the PCR tablets contain an internal positive control to assure the amplification process was successful. If the system does not detect a change in signal where expected for the positive control, it returns an Indeterminate result for that sample.

## Performance Verification

Although the original BAX® system instrument requires a verification procedure using special plates from Hygiena®, the BAX® System X5 instrument does not require plate verification and is calibrated at the time of manufacture. The BAX® system X5 does not need any additional calibration. To most accurately test the BAX® System X5 instrument's overall performance, you can complete a full process run using lysis buffer on PCR tablets. When results are returned, check the graphs to ensure control (INPC) peaks appear within the proper temperature range. This indicates that the instrument is running normally. For details about proper INPC or target peak temperatures, see the BAX® System X5 User Guide.