



Instrument performance verification – Validation of PCR cyclers

Instrument models covered:

PCR cyclers by all manufacturers

PCR Cycler instrument verification consists of:

- **Instrument functionality check**
 - Low voltage internal power supply check
 - Display and keyboard controls functionality
- **PCR cycler temperature validation**
 - Temperature Accuracy Validation – Two-point validation at 85°C and 45°C
 - Temperature Transition Validation – In the range from 95°C to 35°C (or to 4°C according to the PCR cycler type)
 - Validation of the standard temperature cycle durability - Validation of the duration of 6 consecutive standard cycles (95°C and 55°C for 30 seconds)
 - Validation of block temperature uniformity - Validation of temperatures 95°C and 60°C (or other values depending on the cycler type) for 8 different sample block positions
- **Documentation**

After the device validation, the following documentation is provided to the customer:

 - PCR cycler validation protocol (for each block separately)
 - Calibration protocol of the measuring assembly (Copy)
 - Certification of the service engineer training for PCR cycler validation (Copy)
 - Certification of the service engineer technical expertise in electrical engineering (Copy)

METHODOLOGY OF PCR-qPCR CYCLER TEMPERATURE VALIDATION

We use following calibrated measuring sets:

- FLUKE THERMOMETER digital display, type CNX t3000, calibrated with the GREISINGER GTF101-5 temperature probe as a measuring assembly in the temperature range from 0°C to 95°C.
- ALPHA TECHNICS THERMOMETER digital display, type 4690, calibrated with probe types: ALPHA TECHNICS - 9-CH 0,2mL, ALPHA TECHNICS - 9-CH 0,1mL as a measuring assembly in the temperature range from 0°C to 110°C.