# Thermocycler Temperature Accuracy Verification

PURPOSE/PRINCIPLE

This procedure provides instructions for verifying the ABI 2720 thermocycler temperature calibration and the temperature uniformity in a 0.2 ml sample block.

#### POLICY STATEMENT

* DiaSorin Liaison thermocyclers are checked for temperature accuracy bi-annually by a DiaSorin Diagnostic Specialist and a calibration certificate is generated for instrument records
* The BD MAX is a closed system and thermocycler accuracy checks are performed as part of the preventative maintenance performed by a BD Field Service Representative
* The ABI 2720 thermocyclers are checked for temperature accuracy by BioMed bi-annually. Testing includes block accuracy and temperature non-uniformity testing to meet CAP requirement MIC.646141
* Thermocyclers are tested for temperature accuracy before implementation and at least annually thereafter

## DOCUMENTATION/RECORDS

* Records maintained in BioMed and Molecular B422

## MATERIALS REQUIRED

|  |  |  |
| --- | --- | --- |
| **Equipment** | **Reagents** | **Supplies** |
| 2720 Temperature Verification Kit (PN 4317939) | Light mineral oil | Cotton swabs |
| ABI thermocycler #1 asset 026801 |  |  |
| ABI thermocycler #2 asset 028017 |  |  |

## SAFETY CONSIDERATIONS

* Standard precautions
* Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination

**PROCEDURE A:** Follow the activity below to measure block accuracy

Block Accuracy

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Molecular** | 1 | BioMed will contact the molecular department to schedule verification testing | Scheduled Bi-Annually |
|  | 2 | Decontaminate instrument prior to BioMed testing |
| **BioMed** | 3 | Two set points will be measured, 85⁰ C and 45⁰ C, to determine block accuracy |  |
|  | 4 | The instrument is programmed to accept a Pass/Fail; result ± 0.75⁰ C |  |
|  | 5 | Results will be recorded on a Data Log: Calibration Verification and maintained by BioMed |  |
| **Molecular** | 6 | Request a copy from BioMed for the molecular records; place in equipment service manual | Room B422 |

**PROCEDURE B:** Follow the activity below to measure temperature non-uniformity

Temperature Non-Uniformity

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
|  | 1 | This test will be performed in conjunction with the block accuracy verification | Scheduled Bi-Annually |
| **BioMed** | 2 | 8 Wells, A1, A12, C4, C9, F4, F9, H1, and H12, will be checked for temperature uniformity |
|  | 3 | Two set points will be measured, 95⁰ C and 55⁰ C, to determine well uniformity |  |
|  | 4 | The instrument is programmed to accept a Pass/Fail; result ± 1.0⁰ C |  |
|  | 5 | Results will be recorded on a Data Sheet: Temperature Non-Uniformity and maintained by BioMed |  |
| **Molecular** | 6 | Request a copy from BioMed for the molecular records; place in equipment service manual | Room B422 |

**PROCEDURE C:** Follow the activity below for alternate testing

Alternate testing: Measuring robustness of amplification and digestion

| **Activity** | Step | **Action** | **Related Doc** |
| --- | --- | --- | --- |
|  | 1 | Alternate testing may be substituted to meet the CAP MIC.64614 requirement to determine adequate PCR amplification and exonuclease digestion | Annually |
| **GenMark****RVP** | 2 | From each ABI thermocycler #1 and #2, send 3 packaged runs to GenMark for analysis | MB 11.06 Troubleshooting Guide |
|  | 3 | The internal control will be evaluated to determine that the signal generated by the eSensor XT-8 is at expected levels (~200nA) |  |
| **Molecular** | 4 | Place a copy of the analysis in equipment service manual | Room B422 |

**REFERENCES**

1. Microbiology Checklist requirement : CAP MIC.64614, College of American Pathologists Accreditation Program [www.cap.org](http://www.cap.org)
2. User Guide: Thermal Cycler Temperature Verification System for GeneAmp PCR System 2720, 9600, 9800, and Veriti Thermal Cyclers, Applied Biosystems, Part Number 4411933 Rev C 8/2009

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| --- | --- |
| Historical Record |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | 1 | P. Ackerman | 06/21/2017 | Initial Version |