

BIO: Equipment Calibration and Maintenance

Introduction

Equipment and instruments will be routinely calibrated, maintained, and serviced. Only properly operating equipment should be employed.

QAS 10.1

QAS 10.2.1

QAS 10.3

Equipment inventory

An inventory of equipment requiring calibration and maintenance is stored as a section in the *Temperature Log*. For each piece of equipment, this inventory includes:

- the manufacturer
- model
- serial number
- acquisition date

Operation manuals

The manufacturer's operation manuals are stored in the extraction area, the amplification and typing room, or in the Biology Unit conference room.

Equipment calibration and maintenance logs

Calibration and maintenance logs are kept in binders located in the extraction area, amplification and typing room, next to the instrument, or in the possession of the DNA Technical Lead.

Logs will be kept for 5 years.

Glassware and plastic supplies

Glassware and plastic supplies may be autoclaved where appropriate. Plastic supplies can be purchased pre-sterilized.

Centrifuges

Centrifuges are visually inspected before every use.

The centrifuges are cleaned with ethanol. If a spill occurs, the surfaces are wiped immediately with ethanol followed by 10% bleach.

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Calibration and maintenance

Calibration and maintenance of equipment and instruments may consist of

- calibration
- performance checks
- preventive and routine maintenance
- repairs

These tasks will be performed by analysts in the Biology Unit or by qualified contractors, as appropriate.

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Schedule

The following table lists the schedule for the calibration, performance checks, and preventative maintenance of equipment and instruments:

QAS 10.2

Item	Calibration	Performance checks	Preventative maintenance
balance	annually by qualified contractor	semiannual check with NIST-traceable weights	
microscopes			annually by qualified contractor
pipettes	annually by qualified contractor		
pH meter	prior to use		
heat blocks		semiannual check with NIST-traceable thermometer	
refrigerators		monthly temperature check; semiannual check with NIST-traceable thermometer	
freezers		weekly temperature check; semiannual check with NIST-traceable thermometer	
NIST-traceable thermometers	Replaced before calibration expires (~ 2 years)		

Routine maintenance on all equipment is performed by the analysts as needed.

NOTE: See manufacturers' maintenance manuals for procedures on performing routine maintenance.

Repair

Repair of equipment and instruments is performed by an analyst or service technician depending upon the severity of the problem, instrument warranty, and established service contract.

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Pipettes

Pipettes are cleaned on a regular basis.

The pipettes are calibrated annually by an outside vendor. Each pipette must pass specifications for both accuracy and precision. See table above for frequency. All calibration worksheets are kept in the *Pipette Calibration* logbooks.

Heat blocks

The temperature of the heat blocks is checked and recorded each time they are used. Results for each heat block are recorded on the appropriate extraction form. The temperature is also recorded semi-annually. See [Semi-annual performance checks](#).

If the temperature is out of the desired range, the unit is adjusted until the desired temperature range is achieved. For significant temperature adjustments, a NIST-traceable thermometer should be used to verify that the desired range has been reached.

Performance checks

The following must undergo a performance check before use in casework:

[QAS 8.6](#)
[QAS 8.7](#)
[QAS 10.2](#)
[QAS 10.4](#)

- new instruments and equipment
- serviced instruments and equipment that have undergone a substantial repair
- instruments with modified or upgraded software

The performance check requirements are found in the calibration and maintenance logs.

The following can be used for performance checks:

- quality control samples
- samples from validation studies
- training samples
- proficiency samples
- known samples

NOTE: Casework samples cannot be used for performance checks.

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Semi-annual performance checks

The temperature of the refrigerators, freezers, and heat blocks is verified and recorded every six months with a NIST-traceable thermometer that has been calibrated by an outside vendor before purchase.

The balance will be checked every six months with NIST-traceable weights.

- Records for the semi-annual checks are stored in the *Temperature and Balance Calibration* logbooks.

Qiagen BioRobot

The instrument manufacturer performs planned maintenance semi-annually on each instrument. Annual maintenance records are stored in a *Vendor Maintenance Records* logbook in the possession of the DNA Technical Lead.

At the end of each use, DNA analysts perform routine maintenance by cleaning the piercing unit of the pipettor head.

ABI Prism 7500[®] Sequence Detection System

The instrument manufacturer inspects each instrument annually. Routine maintenance is performed monthly by analysts, including

- background assay
- check of lamp intensity
- system hardware test
- hard drive defragmentation

Records are located in the *AB 7500 Maintenance* logbook located in the amplification and typing laboratory.

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Perkin Elmer 9700 Thermal Cyclers

In order to insure that the thermal cyclers are functioning properly, the following tests must be performed.

- Visual inspection (with every use): The sample block is inspected visually. Any material is removed using a cotton swab dipped in ethanol.
- Calibration verification (semi-annually): The *Calibration Verification Test* is performed using a probe and digital thermometer.
 - Refer to pages 2-3 to 2-7 in the *Thermal Cycler Temperature Verification System: For GeneAmp PCR Systems with a 0.2 mL Sample Block User Guide* for directions on performing the test.
 - Results are recorded in the *9700 Calibration and Maintenance* logbook located in the amplification and typing room.
 - IMPORTANT: Do not use a thermal cycler unless it passes this test.
- Temperature non-uniformity (semi-annually): This is performed using a probe and digital thermometer.
 - Refer to pages 2-8 to 2-12 in the *Thermal Cycler Temperature Verification System: For GeneAmp PCR Systems with a 0.2 mL Sample Block User Guide* for directions on performing the test.
 - Results for each well are recorded in the *9700 Calibration and Maintenance* logbook located in the amplification and typing room. The recorded results are compared with the data displayed on the *Summary Screen*.

NOTE: The laboratory designates the thermometer and probe used for temperature verification and uniformity as critical equipment that are calibrated yearly by a certified vendor. These records are kept in the *9700 Calibration and Maintenance* logbook.

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ABI PRISM® Genetic Analyzers

The ABI PRISM® 3130 and 3500xL Genetic Analyzers are inspected annually by the instrument manufacturer.

- Yearly inspection and routine maintenance: The manufacturer inspects each instrument yearly and routine maintenance is performed as necessary.
- Computer maintenance: Defragmenting the hard drives is performed as needed on each instrument.
- Database storage maintenance: As needed, all 3130 stored data files are deleted to make room for new data. Prior to deleting, all data files are copied to a CD or external drive that is kept near the instrument.

Maintenance/QC logbooks are kept with each instrument. Each 3130 logbook contains the following:

- run logs
 - each entry includes
 - date
 - plate name
 - polymer, buffer, or water replacement
 - date of spectral calibration
 - lot number of POP-4 polymer
 - serial number of capillary array
 - number of injections on array
- performance checks
 - each entry includes
 - reason for performance check
 - name of the run
 - results for control samples
- maintenance performed
- calibration information

Note: Run log data for the 3500xL Genetic Analyzers is stored electronically.

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ABI PRISM® computers

As needed, the following maintenance is performed on the genetic analyzer computers:

- the hard drive is defragmented
 - all 3130 stored data files are deleted
 - Prior to deleting, all data files are copied to a CD or external hard drive that is kept near the instrument.
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Refrigerators and freezers

The temperature of each refrigerator is checked monthly and semi-annually. The temperature of each freezer is checked weekly and semi-annually. See *Semi-annual performance checks*. Results for each unit are recorded in the *Temperature* logbooks.

- Individual refrigerators and freezers are labeled with the desired temperature range.
 - The desired temperature range for refrigerators that contain critical reagents is $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.
 - The desired temperature range for refrigerators that do not contain critical reagents is $5^{\circ}\text{C} \pm 5^{\circ}\text{C}$.
 - The desired temperature range for freezers that contain critical reagents is $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$.
 - The desired temperature range for freezers that do not contain critical reagents is $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$.
 - If the temperature is out of the desired range, the unit is adjusted until the desired temperature range is achieved. For significant temperature adjustments, a NIST-traceable thermometer should be used to verify that the desired range has been reached.
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Balances

Refer to *Assuring Quality of Results*, [*AQR: Balance Calibration Checks and Maintenance*](#) in the *Quality Manual* for information on calibrating, calibration checks, and maintenance of balances.

The calibration of the balances is checked monthly using the following masses:

- 5 mg
 - 1g
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