HSC.22190 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

TEMPERATURE-DEPENDENT EQUIPMENT

Inspector Instructions:

READ	• Sampling of thermocycler monitoring logs • Sampling of alert system checks • Sampling of LN2 monitoring records
ASK	• What back-up options are available in the event of an electrical power failure? • How is the storage unit alert system monitored? How was the response time validated? • How does the laboratory ensure the individual wells of the thermocycler are maintaining accurate temperature?

*****REVISED** 12/26/2024***

HSC.22531 Alarm System **Phase II**

All sample and reagent storage units are monitored continuously (24 hours per day) with an in laboratory or remote alarm system.

NOTE: All storage units must have a continuous monitoring and alert system (in laboratory or remote). The laboratory must be able to demonstrate how this system works, and that there is a process to ensure a timely response to an alarm.

Evidence of Compliance:
- ✓ Records of continuous monitoring that includes alarms

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(a)(1)].

HSC.22562 Alarm System Checks **Phase II**

Alarm systems are checked for functionality initially and at specified periodic intervals.

NOTE: The alarm system must be checked at specified periodic intervals to ensure proper function.

Evidence of Compliance:
- ✓ Records of alarm testing

HSC.22593 Power Failure Back-up **Phase II**

The alarms continue to function if the power is interrupted.

NOTE: Alarm systems must have a source of power separate from the house current, in order to allow proper monitoring during power failures. This can be accomplished by a separate circuit, power failure alarm, or battery power.

HSC.22625 Cell Freezers **Phase II**

The laboratory monitors and maintains adequate liquid nitrogen (LN2) levels in cell freezers.

NOTE: The system must ensure that an adequate supply of liquid nitrogen is present to maintain optimal cell storage temperature.

Evidence of Compliance:
- ✓ Records of monitoring of LN2 levels

*****REVISED** 12/26/2024***
HSC.22775 Thermocycler Temperature Checks **Phase II**

Individual wells (or a representative sample thereof) of thermocyclers are checked for temperature accuracy before being placed in service and at least annually thereafter.

NOTE: A downstream measure of well-temperature accuracy (such as productivity of amplification) may be substituted to functionally meet this requirement. For closed systems this function should be performed as a component of the manufacturer-provided preventative maintenance.

Evidence of Compliance:
- ✓ Records of thermocycler verification

REFERENCES
1) Saunders GC, *et al*. Interlaboratory study on thermal cycler performance in controlled PCR and random amplified polymorphic DNA analyses. *Clin Chem.* 2001;47:47-55
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR1252(b)].

COLORIMETERS, SPECTROPHOTOMETERS, AND FLUOROMETERS

The following requirements apply to stand-alone instruments; they are not applicable to instruments embedded in automated equipment for which the manufacturer's instructions must be followed.