

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:

	<ul style="list-style-type: none"> • Sampling of thermocycler monitoring logs • Sampling of alert system checks • Sampling of LN2 monitoring records
	<ul style="list-style-type: none"> • 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**