



Quality Division Use Only

Quality Tracking #:	2022-068	Classification:	Incident
Non-Conformance Level:	N/A	Section:	Seized Drugs
Date of Discovery:	11/29/22	Date of Incident:	11/21/22

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
N/A	N/A

Description of Non-conformance:
The temperatures for two Seized Drugs (SD) freezers were not manually recorded the week of November 21, 2022.

Additional Information/Follow-Up:
Per the Quality Manual, refrigerators and freezers used to store temperature sensitive chemicals and critical reagents are to be checked periodically to ensure proper operation. HFSC allows the monitoring of temperature for these units to be completed through a temperature monitoring system or to be recorded manually in a temperature log. For sections opting to record and track temperatures manually, the Quality Manual states that these should be completed on a weekly basis.

The refrigerators and freezers located in the SD section are used to store drug standards and stock reagents. The SD section stores and conducts re-verification of drug standards according to the manufacturer's recommendation. Quality checks on stock reagents are performed on a monthly basis. The stock reagents are not temperature sensitive; they are stored refrigerated to extend the shelf life.

Since there had been two other previous instances where temperatures were not manually recorded (refer to Quality Report 2020-057), the section decided to install a temperature monitoring system to prevent this from re-occurring. Although the contents of both the SD freezers and refrigerators are not critical, moving to an automated temperature monitoring system will eliminate the manual record keeping function and allow staff to focus on other laboratory tasks.

Summary of Root Cause Analysis:
Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.
N/A



Actions Taken:

On August 2, 2023, the temperature monitoring system was installed in all SD refrigerators and freezers. SD section staff were notified via email and advised to continue manually recording the temperature weekly as the manual system is phased out into the automated system.

Section Manager: James Miller

Date: 08/24/23

Division Director: Amy Castillo

Date: 09/07/23

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.

Technical Leader: N/A

Date: _____

CODIS Administrator: N/A

Date: _____

Quality Director: Jackeline Moral

Date Closed: 09/18/23