



**Quality Division Use Only**

Quality Tracking #:	2022-IA-08	Classification:	Incident
Non-Conformance Level:	N/A	Section:	Biology/DNA
Date of Discovery:	05/27/22	Date of Incident:	05/27/22

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

**Description of Non-conformance:**

Three instruments in the laboratory were labeled with an expired date of next service, and therefore not with the current period of validity as is required by the Quality Manual. In addition, two analysts were not able to articulate where to locate the equipment documentation that indicated the instrument was in fact up to date even if the labeling hadn't been updated.

**Additional Information/Follow-Up:**

During the May 2022 Forensic Biology internal audit the audit team observed three instrument labels (for Tecan A, QIAcube F, and EZ1 F) that had the period of validity listed as expiring in May 2021. Upon review of records, it was verified that all three instruments had the appropriate performance checks and/or preventive maintenance performed (within the 14 months allowed per the DNA Maintenance SOP), therefore this posed no technical risk to any of the casework. Rather, this issue was solely isolated to the out-of-date labeling on these three instruments. In addition, when asked about where to find the records to verify the instruments in question were ready to be used in the laboratory, two analysts indicated that the Operations Coordinator maintains that documentation. Although the Operations Coordinator is responsible for the maintenance of equipment, it is also important for staff members that use the equipment to be familiar with the documentation and to actively question an expired label.



**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:**

The Operations Coordinator has replaced all labels on the instruments with a new labeling system: one label indicates the date of the last preventive maintenance and a second label indicates the date the next preventive maintenance is due. At the technician's meeting, the technician supervisor explained this internal audit nonconformance and the new labeling system. In addition, she explained to the analysts where to locate documentation related to preventive maintenance and/or performance checks and stressed the importance of questioning expired labels.

Section Manager: Courtney Head Date: 09/12/22  
Division Director: Amy Castillo Date: 09/20/22

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

Technical Leader: Cheron Maxwell Date: 09/01/2022  
CODIS Administrator: Jennifer Clay Date: 09/12/2022

Quality Director: Erika Ziemak Date Closed: 09/21/22