Quality Division Use Only

Quality Tracking #:	2019-IA-11	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Seized Drugs
Date of Discovery:	07/15/19	**Date of Incident:**	04/05/18

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2018-05121	**040613418**

Description of Non-conformance:

During the 2019 Seized Drugs section internal audit, it was noted that case 2018-05121 did not have a record of the completion of the required negative reagent control on the examination sheet for item 004-01. This was the only instance of its kind observed in the 93 cases that were reviewed during the internal audit.

Additional Information/Follow-Up:

In the Seized Drugs section, positive and negative control checks are performed on a monthly basis for stock reagents. After these monthly control checks are completed on the stock reagents, Seized Drug analysts must dispose and replace the aliquots kept in their work areas. Analysts must also perform a negative control check on the work area aliquots during casework analysis to ensure the chemical spot tests are not contaminated at the time of use. Per the reagent logbook, the stock reagents used for the chemical spot test completed on item 004-01 passed both the positive and negative checks for that month.

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:
Item 004 was recalled to document the verification of the negative control check and for the chemical spot test to be re-performed on item 004-01 on 8/12/2019. The results of the chemical spot test were consistent with those originally observed and recorded in the case examination sheet. In addition, the report was amended on 8/13/2019 to document this verification and to inform stakeholders that the results of analysis were consistent with those previously reported. The amended report had the following statement: "This report amends Laboratory Report #: 0001 dated April 9, 2018 to document the verification of the negative quality control check for the chemical spot test for item 004-01. Results of analysis were consistent with those previously reported on April 9, 2018. Please refer to Quality Report # 2019-IA-11 for more information. In addition, the test methods used on the reported items were added to this report."

Section Manager: James Miller **Date:** 08/20/19

Division Director: Amy Castillo **Date:** 08/21/19

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

Technical Leader: N/A **Date:** N/A

CODIS Administrator: N/A **Date:** N/A

Quality Director: Erika Ziemak **Date Closed:** 08/23/19