

Corrective Action Plan Traceability Documentation

Incident Date: January 29, 2022 – February 04, 2022

Incident Type: Procedural

Incident Description:

Traceability documentation for the week of January 29, 2022 was not filled out correctly. The designated number for the Cayman Mix was not updated. Not only was a new Cayman Mix used, but a dilution of the new mix was used. This traceability form was recorded as part of the case files when the final reports were sent out. Neither the analyst nor the reviewer noticed the inaccuracy at the time of completion. The realization occurred when an analyst was putting together case files the following week.

LOG-20-03 Case Documentation and Records

"3.4.12 The entirety of the case record should enable the test to be repeated under conditions as close as possible to the original conditions to ensure traceability.

3.4.13 Reference materials utilized to ensure test validity shall be indicated in the case file using the appropriate traceability form (TOX-01 or CS-20)."

LOG-11-03 Case Review

"3.4.4 The technical reviewer shall place his/her initials on the analytical data, traceability forms, Laboratory worksheet, and review checklist as well as electronically initial to verify the final report with a four digit pin."

Proposed Corrective Action(s):

1. Establish which cases were worked the week of January 29, 2022.
2. Amend the traceability form and place a corrected copy in each case file with the analyst's and reviewer's initials.

Timeframe for Corrective Action(s): one week

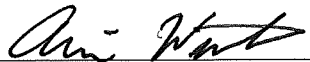
Comment(s): This form was used in the interim while our Standard Operating Procedures (SOPs) are being revised. Under the proposed SOPs going forward, this would be considered an incident, and an incident form completed.

Alif Y. Seized Drugs
Applicable Analyst / Discipline


03/15/22
Date

Ulti. M. Seized Drugs
Applicable Analyst / Discipline


03/19/22
Date ²² (EP)



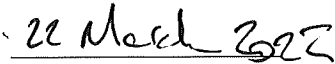
Lab Quality Manager



Laboratory Director



Date



Date