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ROOT CAUSE ANALYSIS REPORT
RCA# 2020-01
November 2, 2020

Executive Summary

On January 3, 2020, the Office of Chief Medical Examiner (OCME) Quality Assurance Director was informed of an event which occurred in the Forensic Toxicology Laboratory (Forensic Toxicology). This event resulted in an incorrect result reported by Forensic Toxicology. After careful review, the QA Director determined that this was a "significant event" within the meaning of Title 17, Chapter 2, Section 17-207 of the Administrative Code of the City of New York. On September 18, 2020, OCME assembled a Root Cause Analysis (RCA) Committee to identify the causal factors and corrective actions to be taken for this event, which was identified as RCA# 2020-01.

The RCA Committee met and reviewed the laboratory's testing process and identified areas for improvement. The committee identified the sample switch which occurred during the aliquoting step as the root cause for this event. In addition to the corrective measures taken by the laboratory, the RCA committee recommends that the laboratory consider using two identifiers on the aliquot tube label to match the specimen with the tube or implementing a double-check by a second analyst during the aliquoting step. The committee also recommends that the laboratory amend its nonconforming work procedure to hold cases potentially impacted by an error.

Background

The primary mission of the Forensic Toxicology Laboratory includes conducting postmortem analysis to determine the absence or presence of drugs and their metabolites, or other toxic substances, in human body fluids and tissues. The laboratory also performs analysis on cases submitted by the New York City Police Department, District Attorney Offices, or other law enforcement agencies to determine the absence or presence of alcohol and other drugs.

The Evidence Unit transports and delivers samples to be tested to Forensic Toxicology. Trained Forensic Toxicology staff will then schedule the initial tests for the case. Criminalists prepare the samples to be tested and perform the screening tests. If confirmatory tests are scheduled, then technical staff will aliquot, extract, and analyze the samples. An analyst will then review the sample data, calibrators, and controls and submit the processed data to a supervisor for second review and approval. Clerical staff will then draft all approved results into the Forensic Toxicology Report Management System and submit the report for technical review. After the laboratory report is signed out, clerical staff perform a final check for clerical errors and upload the report to the Case Management System.

See Appendix A for a diagram of the workflow.

Event Description
On December 10, 2019, staff aliquoted and extracted samples for analysis. Samples from Case 1 and Case 2 were run next to each other on the same batch.

On December 20, 2019, Assistant Director B reviewed Case 2 results and noted a discrepancy between the screening result and the confirmatory result for the femoral blood specimen. Repeat analysis was scheduled.

On December 26, 2019, Assistant Director A completed the technical review for Case 1. A report was issued for Case 1 which stated that cocaine and benzoylecgonine were detected in the femoral specimen by LC/MS but not detected in the vitreous specimen.

On December 30, 2019, a criminalist was assigned to review the results of the batch processed on December 10 due to suspected incorrect aliquoting of Case 2 samples.

On December 31, 2019, the criminalist informed Assistant Director B that repeat results for Case 2 and the original Case 1 results were consistent and suggested a misaliquot of samples in the December 10 batch. Multiple tests were scheduled to confirm or rule out a sample switch during aliquoting. Staff notified the medical examiner, who had received the results for Case 1, of the discrepancy.

On January 2, 2020, repeat analysis of the entire batch processed on December 10 was scheduled to determine if other cases were impacted. The repeat batch was run the following day.

On January 9, 2020, a report was issued for Case 2. Laboratory staff confirmed that cocaine and its metabolites were not detected and that an amended report was necessary for Case 1.

On January 10, 2020, an amended report was issued for Case 1. Assistant Directors A and B compared the results of the original December 10 batch against the results of the repeat January 3 batch. The results were found to be consistent and no other issues were identified.

See Appendix B for a detailed chronology of events.

Review of Remedial Actions Taken by Forensic Toxicology
The RCA committee reviewed the immediate remedial actions taken by the laboratory after discovering the issue. The actions taken are listed below:

- Forensic Toxicology immediately notified the medical examiner of the error and amended the laboratory report.

- Two retrospective studies were conducted.
    - Retrospective study 1: All cases aliquoted and processed from the original December 10 batch were repeated and reviewed. The repeat results were found to be consistent and no other issues were identified during the review.

    - Retrospective study 2: All cases reviewed and signed out by the Assistant Director on December 26 were re-reviewed. No issues were identified.

The RCA committee found the actions taken by the laboratory to be appropriate.

Causes and Contributing Factors

The RCA committee further examined the workflow and employed cause and effect analysis to identify the cause and contributing factors for the sample switch. Using this methodology, the RCA committee identified the following causal factors:

1. *A criminalist unintentionally switched samples while aliquoting a batch of cases for extraction.*

   Evidence:
   The RCA committee reviewed the laboratory's workflow for the preparation of samples. In addition, the Root Cause Analysis officer reviewed the standard operating procedures describing the workflow.

   During sample preparation, a criminalist uses a 3-rack system for aliquots. Rack 1 holds empty, labeled aliquot tubes. Rack 2 holds the labeled specimen tubes. Rack 3 is empty; it does not hold any tubes or specimens. The criminalist begins by matching an empty tube from Rack 1 with the corresponding specimen tube from Rack 2. The criminalist verifies the case number on both labels and places both tubes in Rack 3 for aliquoting. After the aliquot is taken, the criminalist returns the aliquoted specimen to Rack 1.

   The laboratory's review of the December 10 batch found that the repeat results for Case 2 and the original results for Case 1 were consistent. A review of the December10 batch list found that the samples were run next to each other, which further suggested the likelihood of a sample switch. Additional testing conducted by the laboratory confirmed that the sample switch occurred during the aliquoting step.

   Management observed the criminalist's aliquot technique and verified that protocol was followed. No issues were identified with training or past performance. During an interview, the criminalist recalled that it was a busy afternoon but could not recollect how the sample switch could have occurred. She believes that she may have sped up her process because she did not think she could utilize overtime for less than an hour.

   The committee noted that the laboratory's case numbers are made up of nine alphanumeric characters. The case numbers involved in the sample switch are identical except for the last digit. The committee also noted that the case number is the only identifier used to match the specimen with the corresponding empty aliquot tube. Matching a list of numbers, some of which could be very similar, can understandably lead to error.

   The misaliquot was identified as the root cause for the error. Taken together, the nearly identical case numbers, the practice of using only one identifier to match the specimen to the aliquot tube, and the possibility that the criminalist sped up her process likely led to the sample switch.

2. *Assistant Director A was not aware of the issue or internal investigation involving the December 10 batch and his case.*

Evidence:
The laboratory's nonconforming work procedure requires that it document and investigate nonconformities. Investigations are to be documented and reviewed by the section supervisor and the laboratory quality assurance manager.

When laboratory staff discovered the aliquot error, they immediately began the investigation process. However, staff involved in the investigation did not inform Assistant Director A that his case was involved in the sample switch and that the December 10 batch was being re-reviewed. If Assistant Director A had been made aware of the investigation, Case 1 could have been placed on hold and the report would not have been submitted for technical review. This would have prevented the incorrect report from being issued until the investigation was completed and the issue was resolved.

3. *The positive results for cocaine/benzoylecgonine in the femoral blood specimen and the negative results for cocaine/benzoylecgonine in the vitreous specimen could have been investigated further.*

Evidence:
The RCA committee discussed the reported results and asked if the error could have been identified during technical review. Committee members noted that the laboratory report stated cocaine and benzoylecgonine were detected in the femoral blood specimen but not detected in the vitreous specimen. Subject matter experts informed the group that compounds may not be detected in all tissues during toxicology analysis. Different results could be due to a variety of reasons such as nature of the compound, exposure route, dosage, absorption, metabolism, age, weight, and gender of the decedent.

During the technical review, Assistant Director A found the positive results to be consistent with the decedent's history of drug use, the scene report (which stated that glassine envelopes were found in the decedent's apartment), and the laboratory's own screening and confirmatory results. Additionally, the committee learned that the vitreous data indicated cocaine and benzoylecgonine to be present in the sample but in low quantities. The result was reported as "Not Detected" because the low quantities did not meet the reporting criteria as stated in the procedure. The committee concluded that although the results could have been investigated further, there was sufficient evidence to confirm the decedent's previous drug use and to report the positive results.

During the review of the laboratory report, the committee noted that it was signed out one day after the Christmas holiday. A review of staffing levels found that the laboratory was short-staffed due to the holidays. However, the committee determined that staffing was not a cause or contributing factor for the error. Assistant Director A was not under any pressure to sign out reports.

See Appendix C for the cause and effect analysis.

Corrective Action Plan
Before the RCA committee met, Forensic Toxicology informed the committee of the following:

- Managers provided feedback to the criminalist who aliquoted the samples. They emphasized the importance of communicating to managers if work cannot be completed within the normal hours and if help and/or overtime is needed.

- Managers discussed the importance of communicating task updates to managers with all staff. Managers also reminded staff that if overtime is required to complete a task, they should speak with a manager who will either grant overtime or advise them to leave the task for the following day.

- Managers discussed the case and the importance of reviewing inconsistent screening and confirmatory results with all technical reviewers. They also discussed the delegation of duties while completing a technical review.

- Managers proposed amending the laboratory's nonconforming work procedure. The modification involves placing the entire test batch and all potentially impacted cases on hold until the investigation has been completed.

The RCA committee reviewed the above actions and found them to be appropriate. In addition to these measures, the RCA committee recommends the following actions to address the identified causal factors:

1. Forensic Toxicology should enhance the visual inspection step which is used to match specimens during aliquoting. The committee recommends that the laboratory consider adapting the "two patient identifiers" system used in healthcare to match specimen tubes to aliquot tubes. The use of two identifiers, such as case number, full name, or date of birth, improves the reliability of the sample verification process. Modifying the tube label to include a second identifier could aid the criminalist in identifying and distinguishing cases, especially if the case numbers in the batch are similar or nearly identical. If modifying the label is not feasible, the laboratory may also want to consider having the aliquot step observed by a second criminalist to ensure accuracy.

2. Forensic Toxicology should formally amend the laboratory's nonconforming work procedure so that involved cases are held during an investigation. If a preliminary investigation determines that cases have been potentially affected by an error, staff should notify management immediately. Working with management, case work for these cases should be suspended and reports should be withheld until the investigation has been completed. The laboratory should also consider flagging cases or entering case notes in their laboratory information management system to notify and alert technical reviewers of cases being held.

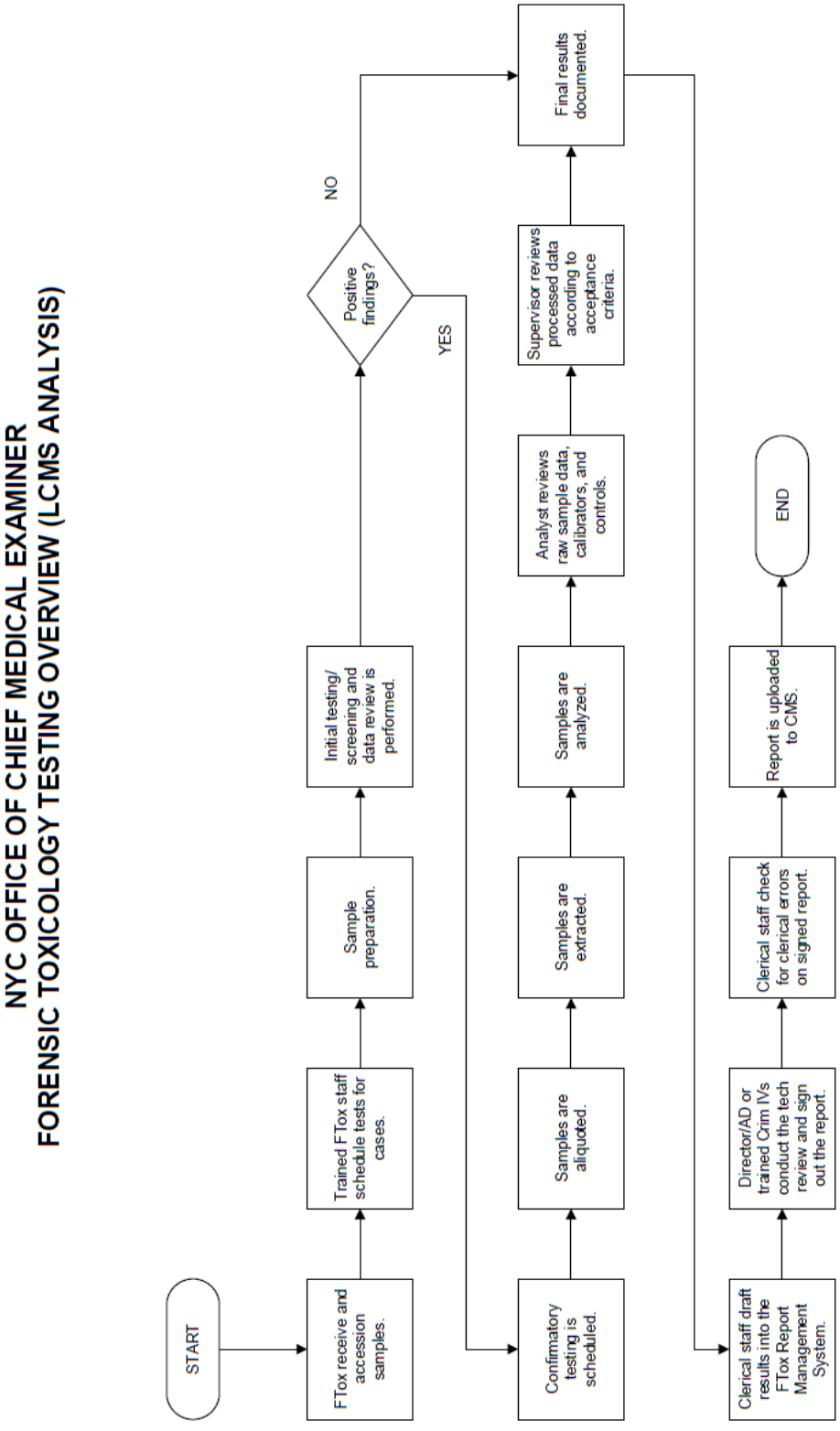
Lastly, the committee suggests that Forensic Toxicology train additional staff to sign out cases. This will provide more support for managers and facilitate the delegation of duties during periods of low staffing.

Summary of Corrective Actions

Causal Factor	Corrective Action	Recommended Completion Date
A criminalist unintentionally switched samples while aliquoting a batch of cases for extraction.	1. Observe aliquoting technique and provide feedback to the criminalist who aliquoted the samples. 2. Discuss the importance of communicating task updates to managers with all staff. 3. Enhance the visual inspection step which is used to match specimens during aliquoting.	Completed Completed February 2021
Assistant Director A was not aware of the issue or internal investigation involving the December 10 batch and his case.	1. Amend the laboratory's nonconforming work procedure so that involved cases are held during an investigation	February 2021
The positive results for cocaine/benzoylecgonine in the femoral blood specimen and the negative results for cocaine/benzoylecgonine in the vitreous specimen could have been investigated further.	1. Discuss the case and the importance of reviewing inconsistent screening and confirmatory results with all technical reviewers	Completed

The Quality Manager and Laboratory Director will monitor the implementation and effectiveness of improvements.

Appendix A


NYC OFFICE OF CHIEF MEDICAL EXAMINER
FORENSIC TOXICOLOGY TESTING OVERVIEW (LCMS ANALYSIS)
START
FTox receive and accession samples.
Trained FTox staff schedule tests for cases.
Sample preparation.
Initial testing/ screening and data review is performed.
Positive findings?
NO
YES
Confirmatory testing is scheduled.
Samples are aliquoted.
Samples are extracted.
Samples are analyzed.
Analyst reviews raw sample data, calibrators, and controls.
Supervisor reviews processed data according to acceptance criteria.
Final results documented.
Clerical staff draft results into the FTox Report Management System.
Director/AD or trained Crim IVs conduct the tech review and sign out the report.
Clerical staff check for clerical errors on signed report.
Report is uploaded to CMS.
END

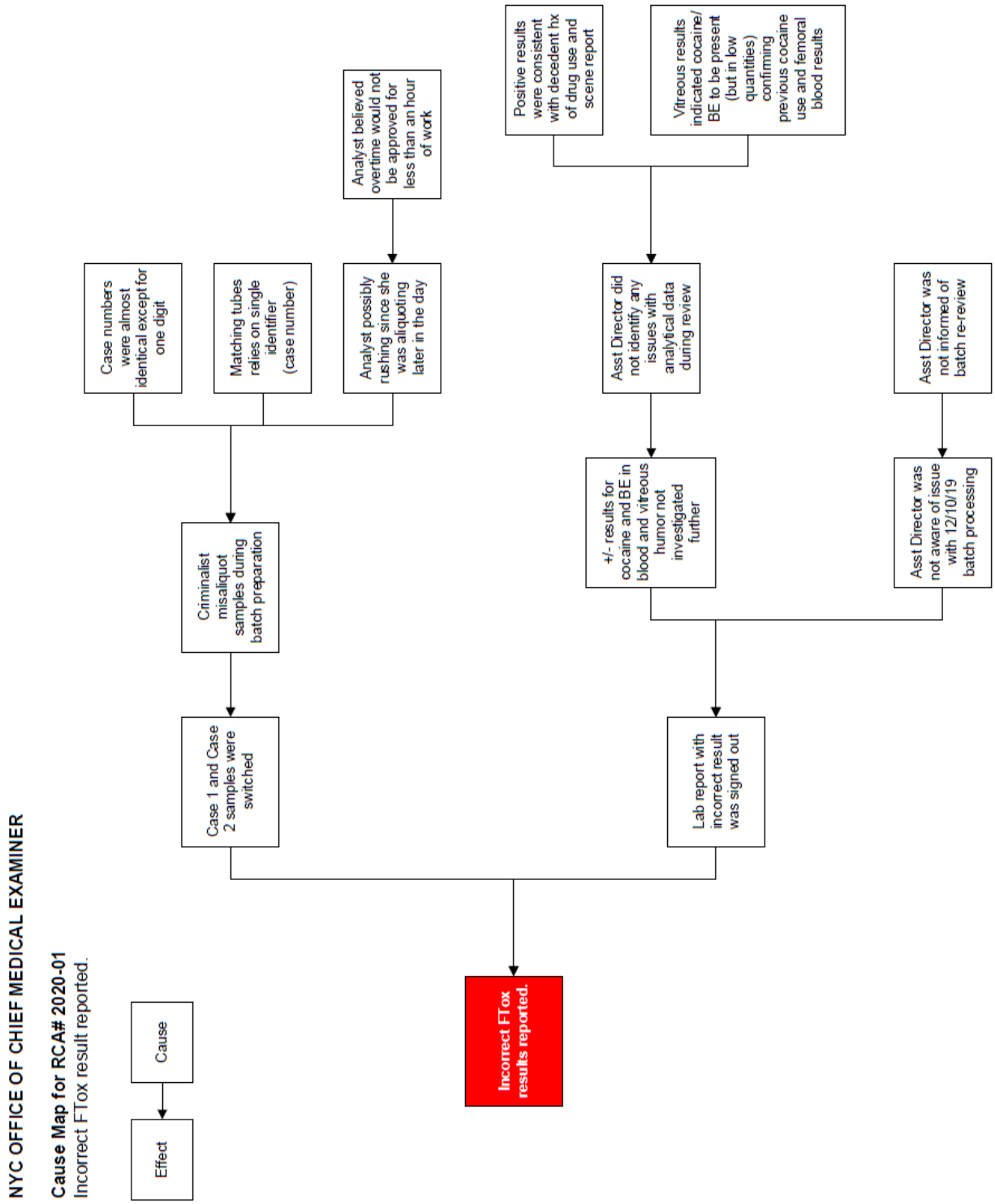
Appendix B

CHRONOLOGY OF EVENTS

DATE	SOURCE OF INFORMATION	EVENT
10/22/19	Laboratory Report	Forensic Toxicology received multiple specimens for Case 1, an accidental drug overdose case.
12/10/19	Email	Staff aliquoted and extracted samples for analysis. Samples from Case 1 and Case 2 were next to each other on the same batch.
12/20/19	Email	Assistant Director B reviewed Case 2 results and noted a discrepancy between the screening result and the confirmatory result for the femoral blood specimen. Repeat analysis was scheduled.
12/26/19	Laboratory Report	Assistant Director A completed the technical review for Case 1. A report was issued for Case 1 which stated that cocaine and benzoylecgonine were detected in the femoral specimen by LC/MS but not detected in the vitreous specimen.
12/27/19	Email	Repeat results for the Case 2 femoral blood specimen were reviewed and approved. The results were passed on to Assistant Director B.
12/30/19	Email	A criminalist was assigned to review the results of the batch processed on 12/10/19 due to suspected incorrect aliquoting of Case 2 samples.
12/31/19	Email	The criminalist informed Assistant Director B that the repeat results for Case 2 and the original Case 1 results were consistent and suggested a misaliquot of samples in the 12/10/19 batch. Staff notified the medical examiner, who had received the results for Case 1, of the discrepancy.

		Multiple tests were scheduled to confirm or rule out a sample switch during aliquoting. Tests included retesting Case 1 femoral blood and vitreous specimens and testing Case 1 brain and urine specimens.
1/2/20	Email	Repeat results for the Case 1 femoral specimen were found to be inconsistent with the reported results and the repeat results for the vitreous specimen were found to be consistent. Repeat analysis of the entire batch processed on 12/10/19 was scheduled to determine if other cases were impacted.
1/3/20	Email	Results for Case 1 brain specimen did not detect cocaine and its metabolites. The repeat batch of 12/10/19 was run.
1/8/20	Laboratory Report	Assistant Director A completed the technical review for Case 2.
1/9/20	Laboratory Report	Results for Case 1 urine specimen did not detect cocaine and its metabolites. Based on retest results, it was confirmed that cocaine and its metabolites were not detected and that an amended report was necessary for Case 1. A report was issued for Case 2.
1/10/20	Email	Laboratory staff notified the medical examiner of the error. An amended report was issued for Case 1. Assistant Directors A and B compared the results of the 12/10/19 original batch against the results of the 1/3/20 repeat batch. The results were found to be consistent and no other issues were identified.

Appendix C


NYC OFFICE OF CHIEF MEDICAL EXAMINER
Cause Map for RCA# 2020-01
Incorrect FTox result reported.
Cause
Effect
Incorrect FTox results reported.
Case 1 and Case 2 samples were switched
Criminalist misaliquot samples during batch preparation
Case numbers were almost identical except for one digit
Matching tubes relies on single identifier (case number)
Analyst possibly rushing since she was aliquoting later in the day
Analyst believed overtime would not be approved for less than an hour of work
Lab report with incorrect result was signed out
+/- results for cocaine and BE in blood and vitreous humor not investigated further
Asst Director did not identify any issues with analytical data during review
Positive results were consistent with decedent hx of drug use and scene report
Vitreous results indicated cocaine/BE to be present (but in low quantities) confirming previous cocaine use and femoral blood results
Asst Director was not aware of issue with 12/10/19 batch processing
Asst Director was not informed of batch re-review