



02-10-2016

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Via Electronically

**Variability of Alcohol Results - Corrective Action**

CDPHE inspection report finding B.4.s

**Problem Statement:**

On 12-07-2015 it was determined that alcohol testing results varied between analysts who conducted the tests.

**Immediate Action Taken:**

- Conducted analysis on same ten cases by six scientists. Determined an issue existed with one scientist's results.
- One scientist removed from casework.
- Evaporation experiment completed leading to the root cause.
- Notified the toxicology scientists to immediately cap all vials after sampling.
- Notified the Colorado Department of Public Health and Environment.

**Root Cause:**

Scientist's sampling process where 100 ul of blood sample was being sampled into a head space vial (without internal standard solution) and not capped quickly enough causing evaporation of the volatile substance. Existing procedures did not specify sampling instructions in a manner that would have prevented the root cause.

**Corrective Action:**

1. Identify the 123 positive alcohol cases completed by the one scientist.

Responsible: Toxicology Program Manager  
Time to complete: Completed December 2015

2. Reanalyze 123 cases from the scientist resulting in 56 affected cases outside the 10% range of the original reported results.

Responsible: Toxicology Staff  
Time to complete: Completed January 2015

3. Notify the agencies affected by the 56 cases.

Responsible: Executive Staff  
Time to complete: Completed

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4. Send 10 samples from the 56 affected cases to an outside laboratory for verification of the amended results.  
  
Responsible: Toxicology Program Manager  
Time to complete: Completed - All results were acceptable
5. Issue amended reports for the 56 cases.  
  
Responsible: Toxicology Staff  
Time to complete: Completed January 2016
6. Revise TOX 10-10 to specify sampling instructions to include capping times to prevent evaporation.  
  
Responsible: Toxicology Program Manager  
Time to complete: Completed January 2016
7. Toxicology scientists trained on revised TOX 10-10 procedure.  
  
Responsible: Toxicology Program Manager  
Time to complete: Completed January 2016
8. Issue quality reports to customers for the remaining 67 cases that were not affected notifying them their cases were not affected.  
  
Responsible: Toxicology Staff  
Time to complete: February, 2016
9. Send an additional 78 samples from the remaining toxicology scientists' casework from the beginning of the toxicology program to an outside laboratory for verification.  
  
Responsible: Toxicology Program Manager  
Time to complete: Completed February 2016 – All results were acceptable.
10. Courtroom testimony training for toxicology scientists.  
Responsible: Toxicology Program Manager  
Time to complete: Completed February, 2016
11. Literature search to review the volatility of ethanol within a sample.  
  
Responsible: Toxicology Program Manager  
Time to complete: March, 2016

**Monitoring:**

1. Two samples from two alcohol batches per scientist sent to outside lab for reanalysis  
  
Responsible: Toxicology Program Manager/Toxicology Staff  
Time to complete: April 2016
2. Two samples from each alcohol batch per scientist reanalyzed by another scientist internally  
  
Responsible: Toxicology Program Manager /Toxicology Staff  
Time to complete: July 2016