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Via Electronically

**Reporting - Corrective Action**

CDPHE inspection report finding B.4.o

**Problem Statement:**

CDPHE B.4.o requirements state “Does the laboratory have established criteria of acceptability not to exceed 10% for variances between the results of the blood ethanol analysis using different aliquots and between different columns”. An ethanol range was reported for a single case because of variance (greater than 10%) in analysis.

**Immediate Action Taken:**

- Notified toxicology scientists not to report a range.

**Root Cause:**

TOX 10-10: Ethanol Analysis by Headspace Gas Chromatography (HS/GC-FID) had specific language stating the results had to be within 10%, however did not have specific language in the Quality Control and Acceptance Criteria for subsequent results that may not be within 10% between analytical batches.

**Corrective Action:**

1. Revise TOX 10-10 to provide procedures for reporting ethanol results that are greater than 10% between analytical batches

Responsible: Toxicology Program Manager  
Time to complete: Completed

2. Train toxicology staff on new procedure

Responsible: Toxicology Program Manager  
Time to complete: Completed

3. Train administrative review staff on new procedure.

Responsible: Toxicology Program Manager  
Time to complete: Completed



## **Monitoring:**

1. While conducting batch reviews, technical reviews (TRV), and writing reports, reviewers will ensure the reported casework conforms with TOX 10-10

Responsible: Toxicology Program Manager/ Toxicology Staff

Time to complete: Continuous

