DUI AND DUID LABORATORY CERTIFICATION ONSITE EVALUATION REPORT TO DETERMINE COMPLIANCE WITH THE STATE BOARD OF HEALTH RULES PERTAINING TO TESTING FOR ALCOHOL AND OTHER DRUGS
(5 CCR 1005-2)

COLORADO BUREAU OF INVESTIGATION (CBI) TOXICOLOGY LABORATORY
79 SILICON DRIVE
PUEBLO WEST, CO 81007

ONSITE COMPLAINT INSPECTION PERFORMED

JANUARY 14, 2016

BY
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DUI-DUID LABORATORY CERTIFICATION PROGRAM
COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT
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Name: CBI – Pueblo Laboratory
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Date: January 27, 2016

Introduction

An onsite inspection was conducted by Department staff at the Colorado Bureau of Investigation (CBI) Pueblo laboratory on **January 14, 2016** as part of the complaint investigation process. Evaluation of personnel training records, equipment, standard operating procedures and corrective action documentation related to the collection, labeling and analyses of DUI-DUID Blood Alcohol samples was performed in order to verify compliance with the provisions in the Colorado Board of Health Rules Pertaining to Testing of Alcohol and Other Drugs (5 CCR 1005-2).

Complaint Summary

The Department was notified by two separate complainants on December 14, 2015 and again on December 21, 2015 regarding the labeling of blood alcohol specimens and blood alcohol test results reported by the Colorado Bureau of Investigation (CBI) Toxicology Laboratory.

On December 31, 2015, CBI reported to the Department that they had identified discrepancies with some of their blood alcohol test results and that an internal root cause analysis and investigation had been initiated.

A formal complaint investigation was initiated by the Department to determine if the allegations of the complainants were either substantiated or unsubstantiated. Initial interviews of the complainant(s) were conducted and requests for additional documentation were made by the Department as part of the investigation process. Upon completion of the complainant interviews and receipt of the requested supporting documentation, an onsite inspection was then performed.

The onsite inspection was conducted at the CBI-Pueblo laboratory by Department staff on January 14, 2016. The onsite inspection included, but was not limited to, the review of personnel training records, equipment records, testing data, corrective action documentation and staff interview for the purposes of investigating the allegations received by the Department and to verify compliance with the certification requirements for forensic toxicology laboratories found in the Colorado Board of Health Rule (5CCR 1005-2).

This inspection report includes the findings resulting from the complaint investigation.

Inspection Findings

B. Standard Operating Procedure Manual

4.) Does the Standard Operating Procedure (SOP) manual include the following criteria and processes for laboratory personnel to follow?

a.) Specimen receiving

Based on review of Standard Operating Procedures, Specimen Labels, Forensic Collection Kits and Lab Director Interview, the laboratory failed to follow the Tox 4: Handling of Toxicology Evidence procedure to ensure that the specimen labeling instructions provided in the CBI forensic blood specimen collection kits are consistent with the established policy.
Findings Include:

a. The Tox 4: Handling of Toxicology Evidence procedure states that at minimum, samples must be labeled with an agency case number or unique identifier and the subject's first and last name.
b. Samples collected using the CBI forensic toxicology collection kit do not include labeling instructions that specify that this information be included on the blood tubes themselves.
c. Samples are received in a sealed CBI forensic toxicology collection kit and do contain the required case number and subject's first and last name. However, this information is provided on separate forms included in the CBI forensic collection kit, but is not found on the samples themselves.
d. Review of the chain of custody records revealed that discrepancies in labeling are documented and recorded by CBI upon receipt and accessioning.
e. Samples sent out for secondary testing to another certified forensic toxicology laboratory have a CBI accessioning label affixed to the sample in the form of a unique identifying laboratory number that also contains a bar code in addition to a specimen security seal containing the law enforcement officer's initials and date.
f. The Lab Director confirmed that the specimen labeling instructions provided in the CBI forensic collection kits are not consistent with the labeling procedures found in Tox 4: handling of Toxicology Evidence procedure.

o.) Recording and reporting assay results?

Based on review of Standard Operating Procedures, Test Reports, Analytical Data and Lab Director interview, the laboratory failed to include criteria for accepting or rejecting analytical data when repeat duplicates differ greater than 10% between analytical runs prior to reporting results for one case reported on September 14, 2015.
Findings Include:
a. One blood alcohol test reported on September 14, 2015 provided a result of *"present greater than 0.186 g/100mL"*.
b. The reported result contained the following notation; *"*Ethanol analysis performed multiple times. Although all quality control measures were acceptable, analytical results for ethanol were not consistent with each other and precision could not be obtained. The determined ethanol concentrations ranged from 0.186 to 0.263 g/100mL."*
c. Review of test data revealed that the sample had been tested by different analysts on different days that resulted in variations in the reported results greater than 10% from run-to-run.
d. Review of test data revealed that the sample quality control measures met the established acceptability criteria in each analytical run each day of analysis.
e. The Lab Director stated that the decision was made to include all the results from each analytical run in the form of a range for this case on the final report.
f. The Lab Director confirmed that the TOX 10-10: Ethanol Analysis by Headspace Gas Chromatography (HS/GC-FID) procedure in use at the time of the analysis did not include instruction for reporting results in the form of a range when variations from analytical run-to-run exceeded 10%.

s.) Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by the testing analyst(s).

Based on review of Standard Operation Procedures, Test Reports, Analytical Data, Experimental Data, Personnel Training Records, Equipment Records, Corrective Action Reports and Lab Director Interview, the laboratory failed to include sufficient step-by-step detail in the TOX 10-10: Ethanol Analysis by Headspace Gas Chromatography (HS/GC-FID) standard operating procedure used by testing analyst(s) performing blood alcohol testing to ensure the sequence of sample pipetting and headspace vial capping instructions are clearly specified to prevent evaporation of ethanol from the sample.
Findings Include:
a. As part of a quality assurance review, on December 7, 2015, it was discovered that the results of one analyst performing blood alcohol testing were consistently lower than that of the other analysts.
b. Further investigation revealed that the analyst's analytical run and sampling set-up technique

varied from the other analysts resulting in evaporation of the alcohol contained in the sample prior to analysis.
c. The standard operating procedure in use failed include specific instructions for the order of pipetting and capping of the headspace vials during the analytical run and sampling set-up.
d. A total of 56 samples among 5 different batches were impacted with erroneously low results reported since July 1, 2015.
e. The Lab Director confirmed that the TOX 10-10: Ethanol Analysis by Headspace Gas Chromatography (HS/GC-FID) standard operating procedure used by testing analyst(s) failed to include sufficient step-by-step detail to prevent evaporation of sample ethanol during the set-up of the analytical run.

PLAN OF CORRECTION

The plan of correction must include, but is not limited to, the corrective actions taken by the laboratory to identify all potentially impacted test results, the corrective actions taken by the laboratory correct the identified problems and the quality assurance measures put into place by the laboratory to prevent the deficiencies from re-occurring in the future. In addition, the plan of correction must include who will be responsible for monitoring the corrective actions taken and how these corrective actions will be monitored on an ongoing basis.

Certification of the **CBI-Pueblo Toxicology Laboratory** will remain effective from **September 4, 2015 through June 30, 2016** pending an acceptable plan of correction is provided with applicable supporting documentation to the Department's Certification Program ***within 15 days*** of receipt of this report.