Deviation from Documented Procedures Form

Date of Deviation: August 19, 2022

Type of Deviation: Preliminary Reporting of Dangerous Drugs using Pharmaceutical Identification only

Describe the Deviation:
On July 22, 2022, laboratory case number BCCL-22-1177 was assigned to analyst Sebastian Frommhold for case work-up. The case was prioritized as In-jail meaning that the subject of the evidence was currently being detained until Laboratory results were finalized. On July 27, 2022, the analyst began the work-up of the case which included the primary exhibit of interest - 46 elliptical-white tablets with the logo of G31 – marked as exhibit 4-1. Other items in the case included 23 round orange tablets with the logo of MYLAN327 – marked exhibit 2, and 34 white capsules with the logo 103 – marked exhibit 4-2. Pharmaceutical identification indicated the drug contained within the exhibit 4-1 was gabapentin, a dangerous drug (a device or a drug that is unsafe for self-medication and that is not included in Schedules I through V or Penalty Groups 1 through 4 of Chapter 481 of the Texas Health and Safety Code) with a preliminary weight charge being over 28 grams. Charging mechanisms for the State of Texas are grouped by designations in the Texas Health and Safety Code as well as the weight of the substance. In this case, Chapter 483 deals with dangerous drugs designations. Due to the weight classification of exhibit 4-1 being greater than 28 grams, a statistical sample plan was used to cull the number of items into a manageable analytical scheme. The statistical plan required 21 items of exhibit 4-1 to be analyzed to demonstrate with a 95% confidence level that at least 90% of the 46 tablets contained the identified substance. Due to the statistical sampling plan utilized, exhibit 4-1 was subdivided into exhibits 4-1-1 through 4-1-22. Exhibits 4-1-1 through 4-1-21 are identified as an elliptical white tablet with the logo of G31. Exhibit 4-1-22 is identified as 25 elliptical white tablets with the logo of G31. Pharmaceutical identification of exhibit 2 indicated the substance as haloperidol. Pharmaceutical identification of exhibit 4-2 indicated the substance as gabapentin. Instrumental analysis on the 21 samples of exhibits 4-1-1 through 4-1-21 began on July 27. The first sample of exhibit 4-1-1 yielded a mass spectral identification of gabapentin. The remaining 20 samples (4-1-2 through 4-1-21) also yielded a mass spectral identification of gabapentin; however, each of the blank mass spectral runs preceding the actual tablet samples contained a contaminate peak. The contaminate peak in the blank samples confers that 20 tablet samples would need to be re-analyzed to confirm the suspected substance. Before this re-analysis could take place, the Laboratory was contacted by the Brazoria County District Attorney's advising that only one tablet needed confirmation, not the entire weight charge of over 28 grams. Based on this information and the identification of exhibit 4-1-1 already being confirmed, exhibits 4-1-2 through 4-1-21 are no longer in need of analysis. In order not to have the analyst re-analyze the 20 samples and better utilize their time and resources, the logo from the 20 samples will be used to provide a preliminary identification of gabapentin for exhibits 4-1-2 through 4-1-21. Additionally, exhibit 2, exhibit 4-1-22 and exhibit 4-2 will also use pharmaceutical identification as a preliminary means of identification.

Corresponding SOP(s):

CS-05-06

6.2 The analyst must determine the appropriate sampling techniques, methods of recovery, extraction procedures, and instrumental analysis to be used for identification of a compound on a case-by-case basis.

6.2.1 Required Analytical Procedures

6.2.1.1 One positive structural elucidation instrumental test (GC/MS) and at least one other different positive test from the table below (e.g. chemical spot tests, pharmaceutical identification, GC/MS from a different column) is required for identification of an unknown substance. Pharmaceutical information from packaging (such as blister packs) or manufacturer's information may be used as an acceptable reference source for comparison. The combination of tests chosen much identify the specific substance present and must eliminate the possibility of a false positive identification. Presumptive testing may occur as deemed necessary by the analyst.

Category A *Mass Spectroscopy*	*Category B* *Gas Chromatography* *Microcrystalline Tests* *Pharmaceutical ID*	*Category C* *Color Tests* *Immunoassay*
	Cannabis Only: *Macroscopic Examination* *Microscopic Examination*	

Reason for Deviation: Confirmation of certain exhibits was not required after receiving communication from the Brazoria County District Attorney's Office that these exhibits were not needed in the charging process of the subject. Unfortunately, analysis had already started. In an effort to better utilize resources and bring the case to completion, preliminary identification was utilized on some exhibits.

Laboratory Number(s) (if applicable): BCCL-22-1177

Applicable Analyst_____ Date_____

Applicable Analyst_____ Date_____

Quality Assurance Manager_____ Date_____

Laboratory Director _____ Date_____