Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2116917	06/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bay Clinical Laboratories	185 Admiral Cochrane Drive #120b, Annapolis, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the laboratory director , and the testing person, the laboratory did not perform the transportation effect of patient samples when performing toxicology testing. Findings: 1. The laboratory did not document the "Sample transportation effect verification" procedure to ensure the integrity of samples that were transported to the laboratory for LCMS toxicology testing. 2. The procedure stats that the laboratory should ensure the stability of patient samples that have been stored and transported to the laboratory for LCMS testing. 3. The testing person stated that the stability studies would have been performed prior to patient testing. 4. The lab director and the testing person confirmed that documentation of the "Sample transportation effect verification" procedure was not performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing data, interview with the laboratory director,

	and the testing person, the laboratory did not evaluate all proficiency testing results that were received from the proficiency testing agency. Findings: 1. The laboratory has a "CAP UT Survey Result Assessment" form that is used to evaluate the results that were received from the PT agency for LCMS testing. 2. The laboratory did not complete the "Acceptable Low -30%/Acceptable High +30%" section on the assessment form for the CAP Tox UT-A 2019 and the CAP Tox UT 2018 events to assess that obtained values were within acceptable limits for passing. 3. The testing person confrimed that the "Acceptable Low -30%/Acceptable High +30%" was not perfomed on the "CAP UT Survey Result Assessment" form for the CAP Tox UT-A 2019 and the CAP Tox UT 2018 events.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the laboratory director (LD), and the testing person, the laboratory did not complete validation studies on the LCMS analyzer. Findings: 1. The laboratory has three LCMS analyzers for performing drug toxicology testing. Only one is used for ethanol levels. 2. The analyzer used for ethanol levels did not have a completed method comparison performed with the other two LCMS analyzers. 3. The LD stated that the method comparison was done but the data was not reviewed and analyzed to produce the completed values that ensure the accuracy between the analyzers.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing data, interview with the laboratory director, and the testing person, the laboratory director failed to ensure that all proficiency testing results that were received from the proficiency testing agency were evaluated. Findings: Refer to D5211