Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1045429	08/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Forensic Fluids Laboratories Inc	225 Parsons Street, Kalamazoo, MI	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of its toxicology testing at least twice annually for 19 (January 2022 to August 2023) of 19 months of testing. Findings include: 1. A review of the laboratory's records revealed a lack of verification of accuracy for 19 months for its toxicology testing on the following analytes: a. Depakote b. Disulfiram c. Ethyl Glucuronide (EtG) d. Ethyl Sulfate (EtS) 2. An interview on 8/29/2023 at 2:00 pm, the TS confirmed the laboratory had not performed verification of accuracy testing for the analytes listed above from January 2022 to August 2023.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to include in its test procedure the acceptability criteria for its qualitative toxicology enzyme-linked immunoassay (ELISA) when one of two sets of controls fails for 2 (August 2021 to August 2023) of 2 years reviewed. Findings include: 1. A verbal walkthrough of the qualitative toxicology enzyme-linked immunoassay (ELISA) testing process on 8/29 /23 at 9:25 am with Testing Personnel #11 revealed the laboratory aliquots samples into library boxes and leaves four slots open in the beginning and the end of the plate for its quality control standards. Two sets are added in case one fails. 2. A review of the laboratory's "Meconium ELISA Processing" procedure revealed a section titled "Sign the plate to either Pass or Fail" stating, "To fail a plate with passing or failed standards, with the plate selected click the sign button, select "Failed" from the dropdown, and enter password. To pass a plate with one set of standards, with the plate selected click the sign button, select "Pass" from the dropdown, and enter password then have another data reviewer review, sign, and pass or fail the plate. Two unique passing signatures are required to pass a plate that has one set of passing standards." 3. A review of the laboratory's "Ethyl Alcohol Oral Fluid Assay" procedure revealed a section titled "Data Review" stating, "Results Tab: All QC needs to say valid and the R-Value should be greater than or equal to 0.99." 4. A review of the laboratory's "Oral Fluid ELISA Screening" procedure revealed a section titled "Sign the plate to either Pass or Fail" stating, "To fail a plate with passing or failed standards, with the plate selected click the sign button, select "Failed" from the dropdown, and enter password. To pass a plate with one set of standards, with the plate selected click the sign button, select "Pass" from the dropdown, and enter password then have another data reviewer review, sign, and pass or fail the plate. Two unique passing signatures are required to pass a plate that has one set of passing controls." 5. An interview on 8/29/23 at 11:44 pm with the General Supervisor revealed that when one set of quality control standards fail, the testing personnel will look at the optical density of nearby samples and make their acceptability determinations based on that information. The General Supervisor confirmed this process or acceptability criteria is not included in the test procedures listed above.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any

	other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to establish accuracy performance specifications for its Xylazine testing for 2 (June 2023 to August 2023) of 2 months since the test was put into use. Findings include: 1. A review of the laboratory's "Validation of Screening Plates" revealed a lack of establishment of performance specifications for the accuracy of its Xylazine testing. 2. The surveyor requested the establishment of performance specifications for establish accuracy for Xylazine testing on 8/29/23 at 11:00 am and it was not made available. 3. An interview on 8/29/23 at 2:29 pm with the General Supervisor confirmed the laboratory failed to establish accuracy performance specifications for Xylazine testing.