Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1045429	11/13/2024
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
D0000	An unannounced complaint investigation was completed on November 13, 2024 at Forensic Fluids Laboratories, Inc by the State of Michigan Licensing and Regulatory Affairs Department. During the investigation, it was determined the laboratory was out of compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to follow its procedures for fentanyl analysis and reporting for one (Patient #1) of five patient test records reviewed. Findings include: 1. A review of the laboratory's "Drug Specific Guidelines" revealed a section titled "Fentanyl (FENT)" stating, " If FENT screen is positive and confirmation is 0.5 -0.9 ng/mL, submit an UF for Fentanyl Trace. Do not report this value in LIMS" and the cutoff values for screening and confirmation were "1.0 ng/mL." 2. A review of Patient #1's test report with oral fluid toxicology testing performed and reported on 8/27/24 revealed the result of "Negative" for fentanyl. 3. A review of the analytical data from the run with Patient #1's sample revealed the specimen was negative for the drug screen the laboratory received a result of "0.928" for fentanyl concentration during confirmation testing. 4. A review of the laboratory's Salesforce program for documenting calls to clients revealed a call to client ordering the testing for Patient #1 was notified of "trace Fent" on 8/28/24. 5. An interview on 11/13/24 at 2:28 pm with the Laboratory Director confirmed calling results obtained below the cutoff values had been a practice of the laboratory.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to ensure patient names were accurately entered on test reports for one (Patient #2) of five patient test records reviewed. Findings include: 1. A review of the test request and test report for Patient #2 receiving testing on 8/22/24 revealed a discrepancy in patient last name. 2. An interview on 11/13/24 at 2:56 pm with the General Supervisor confirmed the name on Patient #2's test report was inaccurately entered.