Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D1045429	**(X3) Date Survey Completed** 01/19/2022
Name of Provider or Supplier Forensic Fluids Laboratories Inc	**Street Address, City, State** 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**
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to report all SARS-CoV-2 test results every day of patient testing for 3 (October 2021 to January 2022) of 3 months the laboratory has been testing for SARS-CoV-2. Findings include: 1. The surveyor observed the laboratory's Orasure SARS-CoV-2 Antibody ELISA test system on 1/19/22 at 10:36 am. 2. An interview on 1/19/22 at 10:36 am with the LD revealed the laboratory started testing in October 2021 and had not been reporting results to the health department. 3. A review of the laboratory's test records revealed 30 patients had been tested using the Orasure SARS-CoV-2 Antibody ELISA test system and had not been reported to the health department.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.

	1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure personnel performing highly complex testing met the testing personnel qualification requirements of 493.1489. Findings include: 1. The laboratory failed to ensure personnel performing high complexity testing were qualified as testing personnel. Refer to D6171. ***This is a repeated Condition-Level deficiency from the 11/25/19 recertification survey***
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

	control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on record review and interviews with the Laboratory Director, the laboratory failed to ensure personnel performing high complexity testing were qualified as testing personnel for 1 (Immunalysis Direct ELISA Kit oral fluid toxicology screening) of 2 high complexity test systems used by the laboratory. Findings include: 1. A review of the laboratory's "Immunalysis Direct ELISA Kit" package insert and test menu revealed the oral fluid toxicology screening testing performed by the laboratory was categorized as high complexity. 2. A review of the laboratory's "Standard Operating Procedure Title: Oral Fluid ELISA Screening" revealed a section titled, "Washing and Drying ELISA Plates" noting the process to perform plate washing within the test procedure. 3. An interview on 1/19/22 at 3:19 pm with the Laboratory Director revealed staff from other departments will help the laboratory when they are busy by washing ELISA plates. The Laboratory Director confirmed the staff from other departments were not qualified as high complexity testing personnel. ***This is a repeated Standard-Level deficiency from the 11/25/19 recertification survey***