Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1045429	11/25/2019
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
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to verify the accuracy of testing for the toxicology testing. Refer to D5217. 2. The laboratory failed to enter test requisitions accurately. Refer to D5309. 3. The laboratory failed to establish and verify the performance specifications for 3 (MS14, MS15, and MS16) Micromass Mass Spectrometer analyzers and for 7 drugs in use and on the "Forensic Fluids Laboratories Testable Drugs" chart. Refer to D5423. 4. The laboratory failed to perform and document the annual preventive maintenance (PM) for 14 (MS2 - MS15) of 15 Micromass Mass Spectrometers instruments. Refer to D5429.
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 record review and interview with the Laboratory Director (LD) and Data Analyst (DA), the laboratory failed to verify the accuracy of testing for the toxicology testing for 2 (2018 and 2019) of 2 years at least twice annually. Findings include: 1.

	Record review for the verification of accuracy for the toxicology testing revealed there was no documentation to show the testing was completed at least twice annually in 2018 and 2019 for the following parent and/or metabolite analytes as follows: a. Therapeutic drugs 1. Valproic Acid b. DRUG 1. Disulfiram 2. Ethyl Glucuronide (EtG) 3. Ethyl Sulfate (EtS) 4. Gamma Hydroxybutyric Acid 5. Methaqualone 6. Salvinorin A 2. During the phone interview on 12/02/19 at approximately 10:18 am, the LD acknowledged bi-annual verification of accuracy was not performed and documented for all tests. During the phone interview on 12/03/19 at approximately 3: 17 pm, the DA confirmed the above tests did not have bi-annual verification of accuracy performed and documented.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: . Based on record review and interview via a phone call with the Laboratory Director (LD), the laboratory failed to enter test requisitions accurately for 3 (#4, #5, and #8) of 9 patient testing reviewed. Findings include: 1. Record review of patient (#4, #5, and #8) test requisitions and final reports from December 2017 to September 2019 revealed the following discrepancies: Patient #4 a. The tests indicated on the requisition and not signed by the ordering physician on 9/13/18 revealed the following tests ordered: Amphetamine, Methamphetamine, THC, Cocaine, Opiates, Benzodiazepine, Barbiturates, Methadone, Oxycodone, Buprenorphine, Tramadol, K2, and Fentanyl. c. The final report included the following tests not indicated on the requisition: Norbuprenorphine Patient #5 a. The tests indicated on the requisition and not signed by the ordering physician on 11/30/18 revealed the following tests ordered: Amphetamine, Methamphetamine, THC, Cocaine, Opiates, Benzodiazepine, Barbiturates, Methadone, Oxycodone, Buprenorphine, Tramadol, K2, and Fentanyl. b. The final report included the following tests not indicated on the requisition: Benzoylecgonine (BZE) and Ecgonine Methyl Ester (EME) Patient #8 a. The tests indicated on the requisition and not signed by the ordering physician on 6/27/19 revealed the following tests ordered: Amphetamine, Methamphetamine, THC, Cocaine, Opiates, Benzodiazepine, Methadone, Oxycodone, Buprenorphine, Fentanyl, and Alcohol. b. The final report included the following tests not indicated on the requisition: Alprazolam (Xanax), Bromazepam, Chlordiazepoxide, Clonazepam (Klonopin), 7-aminoclonazepam, Diazepam, Nordiazepam, Estazolam, Flunitrazepam, Flurazepam, Lorazepam (Ativan), Lormetazepam, Midazolam, Nitrazepam, Oxazepam, Prazepam, and Temazepam. 2. During the interview via a phone call on 12/02/19 at approximately 10:18 am, the LD acknowledged the test requisitions did not contain the names of the confirmatory testing (metabolites) completed with a positive screening result.
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: . A Based on record review and interview with the Laboratory Director (LD), the laboratory failed to establish and verify the performance specifications for 3 (MS14, MS15, and MS16) of 15 Micromass Mass Spectrometer analyzers for each toxicology analyte/metabolite for 23 (1/22/18 to 1/21/19) of 24 months of operation. Findings include: 1. Record review of the "Validation Book" revealed for MS14, MS15, and MS16 Micromass Mass Spectrometer the only analyte or metabolite documented was 6-MAM. 2. Lack of documentation for accuracy, precision, analytic specificity, analytic sensitivity, and interfering substances was not available on the day of the survey for all the toxicology testing. 3. During the interview on 11/25/19 at 2:30 pm, the LD acknowledged the validation studies for the 3 Micromass Mass Spectrometers lacked full documentation of the performance specifications. B . Based on record review and interview with the Laboratory Director (LD) and the Data Analysts (DA), the laboratory failed to establish and verify the performance specifications for 2 (November 2018 to November 2019) of 2 years reviewed. Findings include: 1. Record review of the "Validation Book" revealed a lack of documentation for 2 of 2 years for the following analytes/metabolites listed on the "Forensic Fluids Laboratories Testable Drugs (PT=Proficiency, BI=Biannual)" chart as follows: a. Valproic Acid b. Disulfiram c. Ethyl Glucuronide (EtG) d. Ethyl Sulfate (EtS) e. Gamma Hydroxybutyric Acid f. Methaqualone g. Salvinorin A 2. During the phone interview on 12/03/19 at approximately 3:17 pm, DA acknowledged the tests had only been run since 11/2019 for a portion of the tests expect Salvinorin A which had been run since 3 /2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to perform and document the annual preventive maintenance (PM) for 14 (MS2 - MS15) of 15 Micromass Mass Spectrometers instruments in 2018 and /or 2019. Findings include: 1. Record review for each Micromass Mass Spectrometer instrument revealed a lack of documentation for the annual PM performed by the company "Waters" as follows: a. MS2 - due 8/2019 b. MS3 - due 7/2019 c. MS4- due 7/2019 d. MS5 - due 8/2019 e. MS6 - due 4/2018 and 4/2019 f. MS7 - due 2/2019 g. MS8 - due 6/2019 h. MS9 - due 7/2019 i. MS10 - due 8/2019 j. MS11 - due 11/2018 and 11/2019 k. MS12 - due 8/2019 l. MS13- due 7/2019 m. MS14 - 1/2019 n. MS15 - 1/2019 2. During the interview on 11/25/19 at approximately 3:07 pm, the LD acknowledged the "Waters" preventive maintenance records were not included in the

	maintenance binder for each instrument and that the "Waters" technical service person was on-site on the day of the survey.
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 document review, observation, and interview with the Laboratory Director (LD), the laboratory failed to ensure for 1 (Testing Personnel #15 {TP15}) of 21 TP who perform highly complex toxicology testing met the educational requirements at 42 CFR 493.1489. Refer to D6171.
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 document review and interview with the Laboratory Director (LD), the laboratory failed to ensure 1 (Testing Personnel #15 {TP15}) of 21 high complexity TP met the educational requirements at 42 CFR 493.1489. Findings include: 1. Record review of TP credentials revealed the educational requirements were not met for 1 (TP15) of 21 testing personnel performing highly complex toxicology testing. 2. During the interview on 11/25/19 at 10:10 am, the LD confirmed TP15 did not meet the educational requirements at CFR 493.1489. 3. The laboratory was given 7 additional days to supply the necessary educational documents. The documents were not received.