Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2054829	07/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ohio River Laboratory/Ipath Llc	6776 Southwest Freeway Suite 600, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 review of the laboratory policy, laboratory records available, and confirmed in interview, the laboratory failed to verify the accuracy of the confirmatory toxicology testing by LCMS at least twice annually. Findings were: 1. Review of the laboratory policy Proficiency Testing (TEST - 18.01) under Split Proficiency Testing revealed "two to three times each year (depending upon the analyte and the type of EPT [external proficiency testing] performed, at approximately equivalent intervals, a set of at least 5 PT samples are prepared by this lab's supervisor and further sub-divided into two sub-samples each: one for testing in-house and one for sending to a CLIA-certified reference lab who routinely performs the same tests desired ona similar platform/method ....when testing is complete, the composition of each PT sample is revealed by the lab supervisor/director and results are compared ...individual analytes fail PT if: the test result concentration is more than 20% lower or higher than the expected concentration." 2. Review of the laboratory records revealed the laboratory performed the toxicology confirmatory testing by LCMS for the following 47 analytes. 6 MAM 7 Amino Clonazepam Alpha-OH-alprazolam Amitryptiline Amphetamine Benzoylecogonine Buprenorphine Carisoprodol codeine

	Cyclobenzaprine EDDP EtS Fentanyl Gabapentin Hydrocodone Hydromorphone Lorazepam MDA MDMA Meperidine Meprobamate Methadone Methamphentamine Methylphenidate Morphine Naloxone Naltrexone Norbuprenorphine Nordiazepam Norfentanyl Normeperidine Norfentanyl Normeperidine Nortryptiline O-Desmethly-cis-tramadol Oxazepam Oxycodone Oxymorphone PCP Phentermine Pregabalin Ritalinic Acid Tapentadol Temazepam THC-COOH Tramadol Zolpidem 3. Review of the laboratory records from 2018 and 2019 revealed the laboratory performed an accuracy assessment in 2018 with CLIA lab 45D1061571. 4. Review of the accuracy assessment [proficiency testing] revealed no accuracy assessment for 5 of 47 analytes. EtS Fentanyl Meperidine Naltrexone Normeperidine 5. Review of the accuracy assessment [proficiency testing] revealed documentation of 15 of 47 analytes that did not meet the laboratory policy for acceptability for proficiency testing. Fifteen of the 47 analytes had a percent (%) difference of greater than 20%. Analyte: 7 Amino Clonazepam; lab result 11.2; Reference lab result 8.8; % difference 21.4 Analyte: Alpha-OH-alprazolam; lab result 20.1; Reference lab result 14.67; % difference 27 Analyte: Amphetamine; lab result 30.1; Reference lab result 39.6; % difference 31.6 Analyte: codeine; lab result 19; Reference lab result 14.7; % difference 22.6 Analyte: EDDP; lab result 18.3; Reference lab result 13.23; % difference 27.7 Analyte: Gabapentin; lab result 316; Reference lab result 215.19; % difference 31.9 Analyte: MDA; lab result 44.5; Reference lab result 32.47; % difference 27 Analyte: Methadone; lab result 22.4; Reference lab result 27.88; % difference 24.5 Analyte: Methamphentamine; lab result 30.6; Reference lab result 41.55; % difference 35.8 Analyte: Methylphenidate; lab result 14.8; Reference lab result 10.83; % difference 26.8 Analyte: O-Desmethly-cis-tramadol; lab result 21.3; Reference lab result 16.66; % difference 21.8 Analyte: Oxymorphone; lab result 21.8; Reference lab result 14.23; % difference 34.7 Analyte: PCP; lab result 7.3; Reference lab result 4.72; % difference 35.3 Analyte: Phentermine; lab result 23.7; Reference lab result 11.5; % difference 51.5 Analyte: Temazepam; lab result 18; Reference lab result 10.51; % difference 41.6 6. An interview with the general supervisor on 07/23/19 at 1535 hours in the administrative area confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, the quality assurance documents and interview of facility personnel, the laboratory failed to monitor and assess problems in general laboratory systems. Refer to D5217
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on the laboratory's policies, surveyor observation of reagents in use, the laboratory's 'Daily Maintenance Checklist for SCIEX 4500 LCMS/MS' from April 2019-June 2019 and staff interview, it was revealed the laboratory failed to label 3 bottles of reagent with the preparation and expiration dates. Findings include: 1. A review of the laboratory's policy titled "LC/MS/MS Analytical Procedure Pain Panel" revealed the following: A. Solvent A: 0.1% FA in Water: Add 1 mL of Formic acid to 999 mL of LCMS grade water. Solvent A need to be replace every two weeks. B. Solvent B: 0.1%FA in Methanol: Add 1 mL of Formic acid to 999mL of LCMS grade water. Solvent B need to be replaced once in a month or as needed. C. Needle Wash: Needle wash is prepared by adding 75% LC grade water to 25% of LC grade methanol. Needle wash need to be replaced once in a month or as needed. 2. Surveyor observation of reagents in use on 7/24/19 at 12:00, revealed 3 bottles of reagent sitting on top of the Shimadzu Prominence LC system. One bottle was identified as "A", one bottle was identified as "B" and the third bottle was labeled "Needle Wash". Bottle "A" and bottle "B" were missing the preparation and expiration dates. Bottle 'Needle Wash" was labeled with the preparation date (6/11/18), but no expiration date. 3. Review of the laboratory's 'Daily Maintenance Checklist for SCIEX 4500 LCMS/MS' form from April 2019-June 2019 revealed the following reagents and the dates they were prepared: Solvent A: 4/24/19, 5/12/19, 6/24/19 Solvent B: 4/24/19, 5/12/19 2. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/23/19) on 7/24/19 at 12:30 in the laboratory confirmed the above findings.
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 laboratory records and confirmed in interview, the laboratory failed to document complete verification studies for the LIS (laboratory information systems) implemented in 2019. Findings were: 1. Review of the laboratory records revealed the laboratory had a new LIS system implemented in 2019. 2. Review of the verification studies for the LIS revealed no assessment of the data to determine if the new LIS system were accurate and reliable. 3. An interview with the general supervisor on 07/24/19 at 0955 hours in the administration area confirmed the above findings. He acknowledged that the laboratory should have a policy and assess the data acquired for its acceptability.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to document the calibration verification for the toxicology confirmatory testing by LCMS. Findings were: 1. Review of the laboratory calibration records revealed the laboratory used a laboratory developed method to prepare the 6 levels of standards used for the calibration for the toxicology confirmatory testing by LCMS for the following 47 analytes. 6 MAM 7 Amino Clonazepam Alpha-OH-alprazolam Amitryptiline Amphetamine Benzoylecogonine Buprenorphine Carisoprodol codeine Cyclobenzaprine EDDP EtS Fentanyl Gabapentin Hydrocodone Hydromorphone Lorazepam MDA MDMA Meperidine Meprobamate Methadone Methamphentamine Methylphenidate Morphine Naloxone Naltrexone Norbuprenorphine Nordiazepam Norfentanyl Normeperidine Norfentanyl Normeperidine Nortryptiline O-Desmethly-cis-tramadol Oxazepam Oxycodone Oxymorphone PCP Phentermine Pregabalin Ritalinic Acid Tapentadol Temazepam THC-COOH Tramadol Zolpidem Note: "Calibration material" means a solution that has a known amount of analyte weighed in, has a value determined by repetitive testing using a reference/definitive test method or is traceable to National Institute of Standards and Technology (NIST) reference material, if possible. 2. Review of the laboratory records available revealed no documentation of the calibration verification for the toxicology confirmatory testing by LCMS for the above analytes. 3. An interview with the general supervisor on 7/23/19 at 1550 hours in the administrative area confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance records from 2018 and 2019, it

	was revealed the laboratory's quality assurance plan failed to identify and correct problems with analytic systems. Findings were: 1. The laboratory failed to label 3 bottles of reagent with the preparation and expiration dates. Refer to 5415 2. The laboratory failed to document complete verification studies for the LIS (laboratory information systems) implemented in 2019. Refer to D5421 3. The laboratory failed to document the calibration verification for the toxicology confirmatory testing by LCMS. Refer to D5439
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and confirmed in interview, the laboratory failed to include a disclaimer on test reports for tests not FDA- cleared for the confirmatory toxicology testing. Findings were: 1. A review of the FDA (Federal Drug Administration) website revealed the SciEx 4500 analyzer was not listed on the FDA website. Tests on the analyzer are non-FDA approved, therefore the complexity is high and is a Laboratory Developed Test. 2. Review of the laboratory records revealed the laboratory performed confirmatory toxicology by LCMS for the following 47 analytes: 6 MAM 7 Amino Clonazepam Alpha-OH-alprazolam Amitryptiline Amphetamine Benzoylecogonine Buprenorphine Carisoprodol codeine Cyclobenzaprine EDDP EtS Fentanyl Gabapentin Hydrocodone Hydromorphone Lorazepam MDA MDMA Meperidine Meprobamate Methadone Methamphentamine Methylphenidate Morphine Naloxone Naltrexone Norbuprenorphine Nordiazepam Norfentanyl Normeperidine Norfentanyl Normeperidine Nortryptiline O-Desmethly-cis-tramadol Oxazepam Oxycodone Oxymorphone PCP Phentermine Pregabalin Ritalinic Acid Tapentadol Temazepam THC-COOH Tramadol Zolpidem 4. Random review of 8 patient report for the above drug analytes revealed 8 of 8 test reports did not include the statement "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". Patient identifier 019-05170002 019-51700003 019-06110001 019-06240007 019-05010001 019-05220001 019-06060002 019-06170018 5. An interview with the general supervisor on 07/23/19 at 1540 hours confirmed the above findings. He stated that the laboratory had a new LIS system and somehow the reports reverted back to the old verbiage.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the LIS (laboratory information systems) implemented in 2019, and confirmed in interview, the laboratory director failed to ensure the studies were complete prior to performing patient testing (refer to D5421).
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 the laboratory accuracy assessment, laboratory records, and confirmed in interview, the laboratory director failed to ensure the laboratory identified any problems that require correction action when proficiency testing results are found to be unacceptable or unsatisfactory per the laboratory acceptance criteria. Refer to D5217
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan assured quality testing for high complexity testing. Refer to D5391, D5791