# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 29D2079031	**(X3) Date Survey Completed** 08/07/2025
Name of Provider or Supplier American Toxicology	**Street Address, City, State** 3340 Sunrise Ave Stes 103, 104, & 105, Las Vegas, NV	

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	This Statement of Deficiencies was generated as a result of the on-site complaint investigation (June 24, 2025 - June 26, 2025) and off-site document review (July 1, 2025 - August 6, 2025) conducted with your facility, American Toxicology Institute (29D2079031). The investigation was in response to allegations of: -Failure to perform and evaluate proficiency testing as required - substantiated -Failure to adequately validate screening and confirmatory testing methods - substantiated -Failure to perform and document instrument maintenance - unsubstantiated -Failure to perform quality controls correctly - substantiated -Failure to ensure that quality assessment was performed - substantiated -Failure to comply with safety regulations - substantiated and referred to appropriate authorities The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: General Laboratory Systems was not met. The laboratory failed to: -ensure that policies for assessing personnel competency were followed (refer to D5209) -evaluate

	the inaccurate proficiency testing results obtained from both internal and external events, and perform corrective action (refer to D5221), -establish and maintain an adequate quality assessment program to detect and correct errors in the general laboratory systems when they occurred (refer to D5291). This is a repeat deficiency cited at the CLIA recertification survey on March 6, 2024.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the procedures for assessing personnel competency were followed. Findings include: 1. One of eight testing personnel did not have an annual competency assessment in 2024 for using the AU480. 2. One of eight testing personnel did not have an annual competency assessment in 2024 for using the Architect c4000. 3. One of eight testing personnel did not have an an annual competency assessment in 2025 for using the ABSciex. TP8 had their last annual competency assessment on March 27, 2024. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the laboratory's proficiency testing (PT) documentation, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to document all evaluation and verification activities for external and internal PT events. Findings include: Urine 1. The laboratory failed to ensure that the laboratory director reviewed and approved the correction action and investigation documentation for the Urine Drug Adulterant/Integrity (DAI)-B 2023 PT event performed in August 2023. 2. The laboratory failed to ensure that a complete investigation, including patient impact and corrective action was determined and followed for the following unacceptable results for DAI-B 2023. a. The original result for pH on sample DAI-05 was 11.2. The College of American Pathologists (CAP) indicated that the correct

results were between 11.4 and 12.9. b. The conclusion indicated that the analytical range was up to 11 and that the result should have been entered as greater than 11; however, the validation performed on the AU480 indicated that the analytic range was from 2 to 12. c. The investigation documentation did not address the pH results being out of range or potential patient impact. 3. The laboratory failed to ensure that a complete investigation, including patient impact and corrective action was completed and documented for the unacceptable results in the 202401 in-house spiked blind PT event performed in April 2024. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for Amitriptyline on sample 202401-A was 374 ng/mL for a target of 500 ng/mL, resulting in a -25% difference. c. The original result for Mephedrone on sample 202401-C was 1047 ng/mL for a target of 500 ng/mL, resulting in a 109% difference. d. The original result for Methylone on sample 202401-C was 802 ng/mL for a target of 500 ng/mL, resulting in a 60% difference. e. The original result for Paroxetine on sample 202401-D was 382 ng/mL for a target of 500 ng/mL, resulting in a -24% difference. f. The original result for Aripiprazole 202401-F was 29 ng/mL for a target of 50 ng/mL, resulting in a -42% difference. g. The original result for Cyclobenzaprine 202401-G was 331 ng/mL for a target of 500 ng/mL, resulting in a -34% difference. h. The original result for Phencyclidine 202401-D was 67 ng/mL for a target of 100 ng/mL, resulting in a -33% difference. i. These samples were sent to an external laboratory for testing. i) The results of the in-house spiked blind failed to be confirmed for Amitriptyline, Methylone, and Cyclobenzaprine. ii) The corrective action indicated that the laboratory would only report qualitative results for these analytes. j. No cause or further corrective action was determined for any of the unacceptable results. k. No patient impact was evaluated for any of the unacceptable results. 4. The laboratory failed to ensure that a complete investigation, including corrective action was completed and documented when the investigation found that the following results for DMPM-B 2024 were unacceptable. a. The original result for Oxymorphone on sample DMPM-07 was 856.2. CAP indicated that the correct results were between 86.3 and 364.0. b. The investigation form noted that the sample had a high bias, but did not include any reason for the error. 5. The laboratory failed to ensure that a complete investigation, including corrective action was completed and documented when the investigation found that there were unacceptable results for the 202402 in-house PT event. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for PCP on sample 202402-A was 36.3 for a target of 50 ng/mL, resulting in a -27% difference. c. The original result for Naltrexone on sample 202402-B was 94.3 for a target of 75 ng/mL, resulting in a 26% difference. d. The original result for Alpha-hydroxy midazolam on sample 202402-B was 56.1 for a target of 75 ng/mL, resulting in a -25% difference. e. The original result for Cotinine on sample 202402-D was 184.6 for a target of 150 ng/mL, resulting in a 23% difference. f. The original result for Methylone on sample 202402-E was 196.5 for a target of 150 ng/mL, resulting in a 31% difference. g. The investigation form noted that the samples passed when rerun, but did not have any reason for the error or any corrective action for the laboratory to follow. 6. The laboratory failed to ensure that a complete investigation, including corrective action was completed and documented when the investigation found that there were unacceptable results in the 202401 in-house PT event performed in November 2024. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for EDDP on sample SB2 was 56.3 for a target of 75 ng/mL, resulting in a -26% difference. c. The investigation form noted that the QC had a high bias, but did not have any reason for the error or any corrective action for the laboratory to follow. d. No patient impact was investigated because the repeated PT sample passed. Patient samples were not repeated and are not typically run multiple times. Oral Fluids 7. The laboratory failed to ensure that a complete investigation, including patient impact and corrective action was completed and documented for the unacceptable results in the Oral Fluid Drugs of Abuse (OFD)-B 2024. a. The original investigation indicated that the incorrect results were due to a dilution error. When it was later discovered that the incorrect results were due to a calculation error in the preparation of the calibrators (see OFD-C 2024) there was no investigation into patient impact related to the incorrect calibrations. b. The original result for Buprenorphine on sample OFD- 6 was 44 ng/mL. CAP indicated that the correct results were between 13.5 and 34.2 ng/mL. c. The original result for Diazepam on sample OFD- 7 was 248 ng/mL. CAP indicated that the correct results were between 71 and 169 ng/mL. d. The original result for Morphine on sample OFD- 7 was 124 ng/mL. CAP indicated that the correct results were between 47 and 99 ng/mL e. The original result for Nordiazepam on sample OFD- 7 was 92 ng/mL. CAP indicated that the correct results were between 25 and 74 ng/mL. f. The original result for Fentanyl on sample OFD- 8 was 192 ng/mL. CAP indicated that the correct results were between 5.4 and 13.9 ng/mL. g. The original result for THC on sample OFD-8 was 240 ng/mL. CAP indicated that the correct results were between 70.5 and 234.1 ng/mL. h. The original result for 6-MAM on sample OFD-8 was 44 ng/mL. CAP indicated that the correct results were between 10.3 and 29.7 ng/mL. i. The original result for Amphetamines on sample OFD- 9 was 444 ng/mL. CAP indicated that the correct results were between 179 and 412 ng/mL. j. The original result for PCP on sample OFD- 9 was 88 ng/mL. CAP indicated that the correct results were between 33.7 and 66.5 ng/mL. 8. The laboratory failed to ensure that a complete investigation, including patient impact and corrective action was completed and documented for the unacceptable results in the OFD-C 2024 PT event. a. The investigation indicated that the incorrect results were due to a calculation error in the preparation of the calibrators. b. The error in the preparation of the calibrators resulted in inaccurate results that were significantly different than the target values. c. There was no investigation into the quantitative patient results. d. The original result for Hydrocodone on sample OFD- 11 was 107 ng/mL. CAP indicated that the correct results were between 34 and 90 ng/mL. e. The original result for Hydromorphone on sample OFD- 11 was 87 ng/mL. CAP indicated that the correct results were between 30 and 74 ng/mL. f. The original result for Oxazepam on sample OFD- 11 was 278 ng/mL. CAP indicated that the correct results were between 60 and 228 ng/mL g. The original result for Amphetamines on sample OFD- 12 was 326 ng /mL. CAP indicated that the correct results were between 121 and 283 ng/mL. h. The original result for Cocaine on sample OFD- 12 was 144 ng/mL. CAP indicated that the correct results were between 31 and 101 ng/mL. i. The original result for 6-MAM on sample OFD-13 was 292.8 ng/mL. CAP indicated that the correct results were between 49.2 and 155.7 ng/mL. j. The original result for Methadone on sample OFD-13 was 127 ng/mL. CAP indicated that the correct results were between 44 and 118 ng /mL. k. The original result for PCP on sample OFD- 13 was 66 ng/mL. CAP indicated that the correct results were between 16.7 and 44.8 ng/mL. l. The original result for Buprenorphine on sample OFD-14 was 55.2 ng/mL. CAP indicated that the correct results were between 8.0 and 33.4 ng/mL. m. The original result for BZE on sample OFD-14 was 164 ng/mL. CAP indicated that the correct results were between 52 and 143 ng/mL. n. The original result for Oxycodone on sample OFD-14 was 173 ng/mL. CAP indicated that the correct results were between 55 and 142 ng/mL. 9. The laboratory failed to ensure that a complete investigation, including investigation and corrective action was completed and documented for the unacceptable results in the OFD-D 2024 PT event. a. The original result for Alprazolam on sample OFD-18 was 74 ng/mL. CAP indicated that the correct results were between 21 and 62 ng/mL. b. The investigation form noted that the low QC had a high bias, but did not have any

	reason for the error. c. The remainder of the PT sample OFD-18 had been used in a validation study and was not repeated. d. No indication of the results from the validation study were included. 10. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
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 a review of the laboratory's policies and procedures, a review of the quality assurance documentation, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure that the laboratory complete all quality assurance documentation and assessments. The laboratory failed to ensure that the quality assurance system was adequate to detect and correct inadequate and incomplete proficiency testing evaluations, and to detect and correct missing personnel competency documentation. Findings include: 1. A review of the "Quality Assessment Program" procedure found that investigations for PT were to be performed each month. a. The laboratory failed to document all evaluation and verification activities for external and internal PT events. (refer to D5221) b. The QA checklist (Form F-003V4) from April 2024 did not indicate that there were any unacceptable PT results or any corrective action due to unacceptable PT results. i) A review of the PT results found that the 202401 in-house spiked blind PT event performed in April 2024 had failures for seven analytes and that no quantitative results were to be reported for three of those analytes. 2. A review of the "Quality Assessment Program" procedure found that competency assessments were to be reviewed for due dates each month. a. The QA program failed to detect the missing annual competency assessment in 2024 for one of eight testing personnel performing screening using the AU480. b. The QA program failed to detect the missing annual competency assessment in 2024 for one of eight testing personnel performing screening using the Architect c4000. c. The QA program failed to detect the missing annual competency assessment in 2025 for one of eight testing personnel performing confirmation testing using the ABSciex. TP8 had their last annual competency assessment on March 27, 2024. d. The QA checklist (Form F-003V4) from November 2024 indicated that competencies needed to be performed next month but failed to indicate the personnel who were to be assessed. 3. At the time of the on-site survey (June 24-26, 2025) the laboratory had failed to complete the QA checklist (Form F-003V4) from April 2025, which was dated May 5, 2025. a. The director failed sign this form. b. The tasks section on pages 2-3 were not completed. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel

	between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited in the CLIA recertification survey on March 6, 2024.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: [Analytic System] was not met. The laboratory failed to meet the analytic systems requirements including: - Failure to have written procedures for all tests performed (D5401) - Failure of testing personnel to follow written procedures (D5401) - Failure of written procedures to include calibration and calibration verification procedures (D5403) - Failure to ensure that all changes to written procedures were documented, approved, signed, and dated by the laboratory director before use (D5407) - Failure to verify all unmodified, FDA approved tests performed by the laboratory (D5421) - Failure to validate all modified, FDA approved tests, non-FDA approved tests, and laboratory developed tests (LDT) used by the laboratory (D5423) - Failure to document all activities related to verifications and validations of laboratory testing methods(D5427)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure that testing personnel followed the written procedure manual, and failed to ensure that there was a written procedure manual for all processes performed by the laboratory. Findings include: Screening 1. The laboratory failed to follow the procedure titled "Drug Screen Hair and Urine Testing - Architect C-4000" which indicated that the Specific Gravity assay was to be performed using Microgenics DRI reagents. The laboratory was using Syva reagents at the time of survey. 2. The laboratory failed to ensure that there was a procedure for screening oral fluids for toxicology analytes on the AU480. 3. The laboratory failed to ensure that there was a procedure for screening urine specimens for toxicology analytes on the AU480. 4. The laboratory failed to

ensure that there was a procedure for screening urine specimens for toxicology analytes on the AU5810. General 5. The laboratory failed to ensure that testing personnel followed the "Extended Urine Confirmation for Pain Management Drugs" procedure for reviewing ion ratios on LC-MS/MS data prior to reporting patient results. a. The procedure indicates that the acceptability criteria is, "The ion ratio is within [plus or minus] 30%." The ion ratios between the qualitative and quantitative transitions are stereotypical for each analyte and must pass to ensure that false positives are not reported. b. An interview with the reporting scientist found that the ion ratios are not visible in the data template used in the analysis software. c. The scientist indicated that they compared the quantitative results of both transitions as a proxy to evaluate the ion ratio. They were unable to articulate what an acceptable difference between the quantitative results was. d. The scientist also indicated that on overloaded samples that did not have close quantitative results between the transitions, that the results were reported with no further analysis, including repeating the specimen on dilution to bring it into the linear range of the assay. i. The quantitative results for BZE 1 (quantitative transition) on Specimen 248266 from the run EPP_20250620_A were 5762.2 ng/mL. ii. The quantitative results for BZE 2 (qualitative transition) on Specimen 248266 from the run EPP_20250620_A were 14,403.5 ng/mL. This is a difference of 250% iii. The scientist indicated that this would be reported as positive and not repeated on dilution. 6. The laboratory failed to ensure that testing personnel followed the "Extended Urine Confirmation for Pain Management Drugs" procedure for the transitions to be used for evaluating each analyte. a. The procedure indicated that there are two transitions that are to be captured and analyzed for Aripiprazole (m/z285.2 and m/z 277.9). b. The data from the "URINE_EPP_20250226_A.wiff" file indicates that only one transition was included and evaluated for Aripiprazole. There is no way to evaluate the ratio between the transitions to prevent reporting of false positives with only one transition. 7. The laboratory failed to ensure that testing personnel followed the "Extended Urine Confirmation for Pain Management Drugs" procedure for reviewing retention times (RT) on LC-MS/MS data prior to reporting patient results. a. The procedure indicates that the acceptability criteria is, "The RT must be within [plus or minus] 1% of standards for drugs and IS." Analytes elute from the liquid chromatography column at specific retention times. If the retention time fails to match the standards, there is a risk of reporting a false positive. b. An email received on August 7, 2025, from the reporting scientist found that the retention times are not visible in the data template used in the analysis software and are not assessed. c. A review of the extended urine confirmation run from February 26, 2025, found that retention times for all analytes on the run had shifted significantly. No corrective action was documented for this run. The retention times below are one example from the run but are not exhaustive. i. The RT for the Amphetamine controls were as follows: 3.06, 3.03, 3.00, 2.98, 2.96 minutes. ii. The average RT for the controls is 3.006. Therefore, plus or minus 2% of the RT for the standards is between 2.9459 and 3.0661 minutes. iii. The RT for the positive patient results was 2.90 and 2.92 minutes. Both values are outside of the acceptable RT range.5. The laboratory failed to ensure that the policies and procedures were available to all testing personnel. The reporting scientist indicated by email received on August 7, 2025, that they had not received a copy of the "Extended Urine Confirmation for Pain Management Drugs" procedure until August 7, 2025. The reporting scientist was hired on June 28, 2024. 8. The laboratory failed to ensure that there was a procedure available for the process of verifying un-modified FDA approved test methods, including both qualitative and semi-quantitative assays (such as those used in screening). 9. The laboratory failed to ensure that there was a procedure indicating how to convert the units for urine and blood ethyl alcohol screens from mg/dl to percentages. The initial screening cut-off for ethyl alcohol in

	urine and blood is 0.02%, which converts to 20 mg/dL. 10. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited in the CLIA recertification survey on November 19, 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the procedure manual included all relevant information for specimen testing and reporting. Findings include: Screening 1. The laboratory failed to ensure that there were procedures in place to indicate which calibrators were to be used, including the manufacturer and concentrations, for each urine and oral fluid assay on each of the screening instruments (Architect c4000, AU480, and AU5810). 2. The laboratory failed to ensure that the procedure for screening urine specimens for toxicology analytes on the Architect c4000 included the current and correct list of analytes and testing reagents, including the reagents, calibrators, and controls. 3. The procedure titled "Drug Screen Hair and Urine Testing - Architect C-4000" failed to indicate what controls were to be used with any of the assays listed in it. 4. The procedure titled "Drug Screen Hair and Urine Testing - Architect C-4000" failed to indicate what calibrators were to be used and how to prepare the calibrators for the semi-quantitative method for ethyl alcohol (qAlc). 5. The procedure titled "Drug Screen Hair and Urine Testing - Architect C-4000" failed to indicate the reagents, calibrators, and controls used for MDMA, fentanyl and buprenorphine screening. Confirmation 6.

	The procedure titled "Extended Urine Confirmation for Pain Management Drugs" fails to provide the appropriate criteria and instruction for testing and reporting personnel on how to interpret and report results when dropping the lowest calibrator which causes the cut-off value to fall outside the accurate portion of the reportable range. While the policy permits up to two calibration points to be excluded from the calibration curve, it does not provide specific instructions regarding Fentanyl, Norfentanyl, and Zolpidem in cases where the lowest calibration point is omitted. a. For Fentanyl and Norfentanyl, the lowest two calibrators are 6.3 ng/mL and 12.5 ng /mL. The reportable positive negative cut-off is 10 ng/mL. When the 6.3 ng/mL calibrator is excluded, the accurate linear range is raised above 10 ng/mL. b. In the case of Zolpidem, both the lowest calibration point, and the cut-off value are 10 ng /mL. 7. The procedure titled "Extended Urine Confirmation for Pain Management Drugs" fails to provide the appropriate criteria and instruction for testing and reporting personnel on how to interpret and report results when the highest calibration point is dropped, and the results fall between the highest accurate linearity point and the previous upper limit of the reportable range. The examples below are representative, but not exhaustive. a. The urine testing report for accession number 234162 (collected on 2/20/2025) indicated the following results: i. Oxycodone was reported at 432 ng/mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. ii. Cotinine was reported at 328 ng/mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. b. The urine testing report for accession number 234160 (collected on 2/24/2025) indicated the following results: i. Oxycodone was reported at 396 ng/mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. c. The urine testing report for accession number 234119 (collected on 2/20/2025) indicated the following results: i. Oxycodone was reported at 338 ng/mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. d. The urine testing report for accession number 234110 (collected on 2/20/2025) indicated the following results: i. Oxycodone was reported at 571 ng/mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. ii. Cotinine was reported at 849 ng /mL. The highest calibration point (1000 ng/mL) was removed, making the new highest accurate linearity point 300 ng/mL. 8. The laboratory failed to ensure that the "Extended Urine Confirmation for Pain Management Drugs" procedure included instructions on how to process and report samples that may have been impacted by carry-over from preceding samples that had analyte concentrations above the upper limit of linearity. 9. The laboratory failed to ensure that the policies, procedures, and confirmatory test menu for oral fluids were consistent with each other. 10. The policy titled, "Test List" did not include Tramadol, however, both the policy titled "Oral Fluid - Drugs & Cut-offs" and the procedure titled "Oral Fluid LC/MS-MS Confirmation" indicate that Tramadol is part of the oral fluid test menu. 11. The policy titled, "Test List" included Norfentanyl, however, neither the policy titled "Oral Fluid - Drugs & Cut-offs" nor the procedure titled "Oral Fluid LC/MS-MS Confirmation" indicate that Norfentanyl is part of the oral fluid test menu. 12. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure all changes in procedures were documented and approved by the laboratory director prior to use. Findings include: 1. The changes and additions in reagents being used by the laboratory for the qAlc, MDMA, Fentanyl, Buprenorphine, and Specific Gravity on the Architect c4000 were not approved, signed, and dated by the laboratory director prior to use. 2. The procedure titled "Drug Screen Hair and Urine Testing - Architect C-4000" was last reviewed and approved by the previous laboratory director in 2021. 3. The policy titled "Urine - Drugs & Cut-off levels" was not updated to include screening cut-offs for Buprenorphine and Propoxyphene although the laboratory was screening for these analytes. 4. The policy titled "Urine - Drugs & Cut-off levels" was not signed and approved by the laboratory director. 5. The policy titled, "Oral Fluid - Drugs & Cut-off Levels" indicates that the cut-off level for Buprenorphine is 2.5 ng /mL. It was not updated to match the laboratory practice of using 5 ng/mL as the cut-off per the report for specimen ID 59735 which was collected on 7/2/2025. 6. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure that un-modified FDA approved test methods were completely and adequately verified. Findings include: 1. The laboratory failed to ensure that the LIS conversion of urine and blood screens Ethyl Alcohol units from mg/dL to percentages was

verified. The initial screening cut-off for Ethyl Alcohol in urine and blood is 0.02%, which converts to 20 mg/dL. 2. The laboratory failed to establish and verify the procedures that were being used for client testing. Urine Screening - Architect c4000 3. No coversheet indicating the acceptability criteria for the Architect c4000 verifications was included with the verification packet. 4. No coversheet or other indication of the director's approval for the screening assays on the Architect c4000 was included with the verification packet. 5. The laboratory failed to verify the following assays that are currently being run on the Architect c4000: 6-AM, Fentanyl, and MDMA. Cocaine Metabolite (Benzoylecgonine (BZE)) 6. The correlation data included for urine BZE screening verification on the Architect c4000 did not include the original patient results and could not be adequately evaluated. Specific Gravity (Spg) 7. There is no verification documented for the use of Syva Emit specific gravity reagents on the Architect c4000. Syva reagents were being used to assess specific gravity at the time of survey. The laboratory previously verified specific gravity in urine on the Architect c4000 using the Microgenics DRI reagents. Urine Screening - AU480 8. No coversheet indicating the acceptability criteria for the AU480 verifications was included with the verification packet. 9. No coversheet or other indication of the director's approval for the screening assays on the AU480 was included with the verification packet. 10. The laboratory failed to include reference intervals or cut-offs for any of the analytes included in the verification packet for the AU480, making it impossible to tell if they were appropriately verified around the cut-off concentrations. Amphetamine 11. The laboratory failed to confirm that the urine Amphetamine results on the AU480 correlated with the existing method on the Architect c4000. a. Four of 20 specimen results were excluded. The comments indicate the four results were greater than the reportable range. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. b. Eight of the remaining 16 samples were outside of the 20% difference in accuracy allowed by the "Analytical Method Validation" procedure. Barbiturates 12. The laboratory failed to confirm that the urine barbiturate results on the AU480 correlated with the existing method on the Architect c4000. a. None of the correlation samples tested were above the cut-off of 300 ng/mL indicated in the "Urine - Drugs & Cut-off Levels" policy. Benzodiazepines 13. The laboratory failed to confirm that the urine benzodiazepine results on the AU480 correlated with the existing method on the Architect c4000. a. Three of 20 specimen results were excluded. The comments indicate the three results were greater than the reportable range. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. Ethyl Glucuronide (EtG) 14. The laboratory failed to confirm that the urine EtG results on the AU480 correlated with the existing method on the Architect c4000. The EP Evaluator packet indicated this was verified as a semi-quantitative method. The original correlation study pages for this evaluation stated the semi-quantitative study was performed between August 29, 2022, through September 2, 2022. The EP Evaluator packet from August-September 2022 also stated that "There is no data for this method comparison report." Data from November 4, 2022, was included in the EP Evaluator packet, but was evaluated qualitatively rather than semi-quantitatively. Methadone 15. The laboratory failed to confirm that the urine methadone results on the AU480 correlated with the existing method on the Architect c4000. a. One of 20 specimen results was excluded due to being greater than the reportable range. This result was originally negative with a semi-quantitative value of 237 ng/mL. The result using the new method was 1,082 ng/mL, resulting in a positive qualitative result and a difference of over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. b. None of the original twenty results were above the 300 ng/mL cut-off indicated in the "Urine - Drugs & Cut-off Levels" policy. PCP 16. The laboratory failed to confirm that the urine PCP results on the AU480 correlated with the existing method on the Architect c4000. a. Zero of the 20 original results were greater than the 25 ng/mL cut-off indicated in the "Urine - Drugs & Cut-off Levels" policy. THC /Cannabinoids 17. The laboratory failed to confirm that the urine THC results correlated with the existing method on the Architect c4000. a. Five of 20 specimen results were excluded. The comments indicate the five results were greater than the reportable range. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. b. Four of fifteen of the remaining results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. c. One of the fifteen remaining points which was positive (86 ng/mL) on the original method was negative (27 ng/mL) on the new method when evaluated using the 50 ng/mL cut-off indicated in the "Urine - Drugs & Cut-off Levels" policy. Urine Screening - AU5810 18. The laboratory failed to include appropriate acceptability criteria for semi-quantitative tests on the AU5810 with the EP Evaluator packet for this verification/validation packet. The coversheet indicated that the acceptability criteria for correlation samples was qualitative agreement, rather than a semi-quantitative metric. Barbiturates 19. The laboratory failed to confirm that the urine barbiturates results on the AU5810 correlated with the existing method on the AU480. a. None of the correlation samples were above 300 ng /mL so positive concurrence could not be determined. Benzodiazepines 20. The laboratory failed to assess the accuracy at the upper end of the benzodiazepine assay between 350 and 1000 ng/mL on the AU5810. a. The high control used had a mean of 1935.800 ng/mL and the highest calibrator was at 1000 ng/mL, making it impossible to adequately assess accuracy above this point for patient samples. b. The manufacturer's instructions indicate semi-quantitative accuracy had only been assessed up to 750 ng/mL. c. The "Analytical Method Validation" procedure indicated that, "Concentration values above the highest standard should be regarded as approximate. Where exact quantitation is required, the sample should be diluted into the range of the standard curve." Cocaine Metabolite (BZE) 21. The laboratory failed to confirm that the urine BZE results on the AU5810 correlated with the existing method on the AU480. a. Two of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. EtG 22. The laboratory failed to confirm that the urine EtG results on the AU5810 correlated with the existing method on the AU480. a. Three of the 20 client correlation samples were inappropriate for assessing the accuracy of the assay, as they were above the upper limit of linearity for the assay (2,000 ng/mL) on the original method and could not be accurately quantified. The "Analytical Method Validation" procedure indicated that, "Concentration values above the highest standard should be regarded as approximate. Where exact quantitation is required, the sample should be diluted into the range of the standard curve." b. Five of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Methadone 23. The laboratory failed to confirm that the urine Methadone results on the AU5810 correlated with the existing method on the AU480. a. Two of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Phencyclidine (PCP) 24. The laboratory failed to confirm that the urine PCP results on the AU5810 were accurate and/or correlated with the existing method on the AU480. a. The manufacturer's instructions indicate the sensitivity level of this assay is 1.4 ng/mL. b. The analytical range documented in the verification was 1.4 - 100 ng/mL. c. Seven of ten replicates

	for the negative QC used for accuracy and precision had results of 2.0 ng/mL, which is equivalent to the lowest positive calibrator level, indicating that the laboratory cannot accurately differentiate true negatives from true positives at the lowest sensitivity level of the assay as indicated by the manufacturer. d. Five of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. pH 25. The laboratory misidentified the control levels for pH that were used on the AU5810 in the EP Evaluator packet when compared to the raw data. a. The EP Evaluator documentation on the summary page indicated that UTAK level 1 and level 2 were tested for pH. i. The observed mean on the summary page for level 1 was 3.17. ii. The expected value on the summary page for level 2 was 1.9. b. The raw data indicated that UTAK level 2 and level 4 were evaluated. i. The results for level 2 in the raw data ranged from 3.1 to 3.2. ii. The results for level 4 were 1.9. Oral Fluids - AU480 26. No coversheet indicating the acceptability criteria for these assays was included with the validation packet. 27. No coversheet or other indication of the director's approval for these assays was included with the validation packet. 28. The laboratory failed to include control data from five runs on five separate days for evaluating accuracy and precision, as indicated in the "Analytical Method Validation" procedure. 29. The validation packet included data for the following assays: Amphetamine, Benzodiazepines, Buprenorphine, Cocaine metabolite, Ethyl Alcohol, Methamphetamines, Opiates, and THC. 30. Ten replicates for each analyte's cut-off calibrator were run on a single day (September 25, 2023). These results were documented for each analyte under Simple Precision. 31. Twenty replicates of the high and low control for each analyte were run on a single day (February 16, 2024). 32. The laboratory failed to indicate the target mean of the controls tested for precision in 2024, therefore accuracy could not be determined. No separate accuracy studies were included. 33. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing

personnel between July 1, 2025 and August 6, 2025, the laboratory failed to adequately and completely validate all modified, FDA-approved tests, all non-FDA approved tests, and laboratory developed tests (LDT). Findings include: Urine Screening 1. The laboratory failed to document specificity or sensitivity studies for any of the following screening assays. Architect c4000 2. No coversheet indicating the acceptability criteria for these assays on the Architect c4000 was included with the validation packet. 3. No coversheet or other indication of the director's approval for these assays on the Architect c4000 was included with the validation packet. 4. The correlation data included with the validation packet did not indicate the original patient results and could not be adequately evaluated. Amphetamine 5. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 500, 1000, 1500, and 2000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 300, 500,1000, and 2000 ng /mL. c. The validation does not match the documented test parameters, which were for an Olympus AU400 and indicated the calibrators were to be 0, 250, 500, 750, and 1000 ng/mL. Barbiturates 6. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 100, 200, 500, and 1000 ng/mL. b. The laboratory reported using the Emit calibrator levels 0, 2, 3, 4, and 5 (0, 100, 200, 300, and 800 ng/mL). c. The validation does not match the documented test parameters, which were for an Olympus AU400 and indicated the calibrators were to be 0, 100, 200, 500, and 1000 ng/mL. Benzodiazepines 7. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 100, 200, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 100, 200, 300, and 1000 ng/mL. c. There were no test parameters included with the validation for this assay. Cannabinoids (Tetrohydrocannabinol (THC) and Carboxy-tetrahydrocannabinol (THCA)) 8. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 20, 50, and 100 ng/mL. b. The laboratory is currently using a calibration curve of 0, 20, 50, 100, and 200 ng/mL. c. The validation does not match the documented test parameters, which were for an Olympus AU400 and indicated the calibrators were to be 0, 75, 150, 300, and 1000 ng/mL. Ethyl Alcohol 9. The laboratory failed to validate an appropriate calibrator for the laboratory's presumptive positive cut-off for Ethyl Alcohol screening in urine on the Architect c4000. a. The laboratory's cut-off for presumptive positives is 0.02% or 20 mg/dL. b. The laboratory validation packet only included calibrators at 0 and 100 mg/dL. c. The manufacturer's instructions indicate this is for a qualitative assay with a cut-off of 100 mg/dL. 10. There was no data included in the validation packet for controls, or any evaluation of accuracy and precision. EtG 11. The laboratory failed to validate the assay on the Architect c4000 according to the manufacturer's instructions and did not perform a full validation for the changes made to the assay. a. The manufacturer's instructions indicate that the assay is to be calibrated using either the 0 and the 500 or the 0 and the 1000 ng/mL reagents for a qualitative assay. b. The manufacturer's instructions indicate that if the assay is to be used in a semi-quantitative manner that a five-point calibration using 0, 100, 500, 1000, and 2000 ng/mL is to be performed. c. The laboratory validated and currently uses a calibration curve using 0, 625, and 1000 ng /mL. d. There were no positive or negative controls included in the validation documentation. 12. There were no specimen correlation results included in the validation documentation. Opiates 13. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 1000, 2000, 4000, and 6000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 300, 1000, 2000, and 4000 ng/mL. c. The documented test parameters, which were for an Olympus AU400 did not include information regarding which calibrators were to be used. Accuracy and precision for the original validation were not verified above 375 ng/mL. Oxycodone 14. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 100, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 100, 300, and 500 ng/mL. c. The validation does not match the documented test parameters, which were for an Olympus AU400 and indicated the calibrators were to be 0, 100, 300, 500, and 800 ng/mL. 15. There were no positive or negative controls included in the validation documentation. 16. There were no specimen correlation results included in the validation documentation. PCP 17. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 13, 25, 50, and 100 ng/mL. b. The laboratory is currently using a calibration curve of 0, 13, 25, 75, and 100 ng/mL. c. There were no positive or negative controls included in the validation documentation. Propoxyphene 18. The laboratory failed to validate the calibration plan currently in use on the Architect c4000. a. The laboratory validated a calibration curve using 0, 150, 300, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 150, 300, 500, and 800 ng/mL. c. The validation does not match the documented test parameters, which were for an Olympus AU400 and indicated the calibrators were to be 0, 150, 300, 600, and 1000 ng/mL. Creatinine 19. The laboratory failed to validate urine creatinine on the Architect c4000 using an assay that could meet the laboratory's documented normal patient range of 20-400 mg/dL. a. The "low creatinine" assay for urine was validated on the Architect c4000 using calibrators of 2 and 20 mg/dL. The manufacturer's instructions from the validation packet indicate that the assay has a reportable range of 0-200 mg/dL when using the 0, 2, and 20 mg/dL calibrators. b. The laboratory failed to validate accuracy and precision above 22 mg/dL. c. No sensitivity or specificity studies were performed. pH 20. The laboratory failed to validate the calibration curve used in production on the Architect c4000. a. The calibration curve documented in the validation was 3, 9, and 11. b. The curve used in production was 3, 4.5, 9, and 11. 21. There was no specimen correlation results included in the validation documentation. Urine Screening - AU480 22. No coversheet indicating the acceptability criteria for these assays on the AU480 was included with the validation packet. 23. No coversheet or other indication of the director's approval for these assays on the AU480 was included with the validation packet. 24. The laboratory failed to include reference intervals for any of the analytes included in the validation packet for the AU480. 25. The laboratory failed to perform sensitivity, specificity or interference testing on FDA approved assays that were modified when compared to the manufacturer's instructions. 6-AM 26. The laboratory failed to validate 6-AM on the AU480 in accordance with the cut-off level of 300 ng/mL with the calibration plan as established by the laboratory. a. The laboratory validated 6-AM screening in urine on the AU480 using a semi-quantitative method with a calibration curve using 0, 5 and 20 ng/mL. b. The manufacturer's instructions indicate that the assay is to be calibrated using 0, 5, 10, 15, and 20 ng/mL for a semi-quantitative assay or at 10 ng/mL for a qualitative assay. c. There was no documentation that this assay was accurate at 300 ng /mL, as none of the correlation samples were above 300 ng/mL. Ethyl Alcohol and quantitative Alcohol 27. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory uses a qualitative ethyl alcohol screening with a cut-off calibrator of 100 mg/dL. b. The laboratory validated a semi-quantitative method with calibrators at 0, 40, 100, 200, 300, and 400 mg/dL for use with the quantitative alcohol assay (qAlc). c. No validation using only the 100 mg/dL cut-off calibrator were included. 28. The laboratory failed validate the qualitative screening assay with an appropriate calibrator, as a 100 mg/dL calibrator would not be able to detect presumptive positives at the laboratory's cut-off of 0.02% or 20 mg/dL. 29. The laboratory failed to confirm that the correlation samples were accurate. a. Eleven of 20 correlation specimens were greater than the plus or minus 20% accuracy described in the "Analytical Method Validation" procedure. MDMA (ecstasy) 30. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a calibration curve using 0, 150, 300, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 300, and 1000 ng/mL. 31. The laboratory failed to confirm that the urine MDMA results on the AU480 correlated with the existing method on the Architect c4000. a. Ten of 20 specimen results had results with a difference of over 20% from the original value, which is the allowable difference indicated by the "Analytical Method Validation" procedure. b. Zero of the 20 specimens were positive on the original method. c. One of the 20 specimens changed from a negative result on the original method to a positive result on the new method. The laboratory reports screening presumptive positives at levels greater than 500 ng/mL. Opiates 32. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a calibration curve using 0, 300, 1000, and 2000 ng/mL. b. The laboratory verbally indicated they were using a calibration curve of 0, 300, 1000, 2000, and 4000 ng/mL (Siemens Emit levels 0,1, 2, 3, and 5) in a phone interview on August 4, 2025, at approximately 2:00 PM PDT. c. The calibration documentation provided by email on August 5, 2025, indicates that 4 levels of calibration are used, but the levels are not marked on the document. d. The manufacturer's instructions indicate that calibrators at 0, 300, 1000, and 2000 ng/mL should be used for the Opiate 300 semi-quantitative method. 33. The laboratory failed to confirm that the urine opiate results on the AU480 correlated with the existing method on the Architect c4000. a. Three of 20 specimen results were excluded. The comments indicate the three results were greater than the reportable range. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. b. Three of seventeen of the remaining results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. c. One of the seventeen remaining points which was negative (266 ng/mL) on the original method was positive (1,504 ng/mL) on the new method when evaluated using the 300 ng/mL cut-off. Oxycodone 34. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a calibration curve using 0, 100, 300, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 100, 300, and 500 ng/mL. 35. The validation indicated that it was for the Emit II semi-quantitative assay with a cut-off of 100 ng/mL. The laboratory reports screening presumptive positives at levels greater than 150 ng/mL. 36. The laboratory failed to confirm that the urine oxycodone results on the AU480 correlated with the existing method on the Architect c4000. a. The correlation coefficient (r-value) between the two methods was 0.2650, indicating almost no correlation between the two sets of results. Five of 20 specimen results were excluded. b. The comments indicate the five results were greater than the reportable range. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. c. Fifteen of fifteen of the remaining results were negative when compared to the 150 ng /mL cut-off, so accuracy of the semi-quantitative method could not be confirmed. Propoxyphene 37. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a calibration curve using 0, 150, 300, and 500 ng/mL. b. The laboratory testing personnel indicated they were using a calibration curve of 0, 150, 300, 500, and 800 ng/mL (Siemens Emit levels 0, 2, 3, 4, 5) in a phone interview on August 4, 2025, at approximately 2:00 PM PDT. 38. The "Urine - Drugs & Cut-offs" policy indicates that there is no screening available for propoxyphene. The manufacturer's instructions indicate the qualitative cut-off calibrator is 300 ng/mL. 39. There were no correlation samples above the manufacturer's cut-off of 300 ng/mL to demonstrate that the assay was accurate for client samples on the AU480. Creatinine 40. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a linear range using 0, 2, 20, and 100 mg/dL. b. The laboratory is currently using a calibrators at 0, 2, and 20 mg/dL 41. The laboratory failed to validate that the urine creatinine assay on the AU480 could meet the laboratory's documented normal patient range of 20-400 mg/dL. a. The manufacturer indicates that the assay has a reportable range of 0-300 mg/dL when using the 0, 2, 20, and 100 mg/dL calibrators. 42. The laboratory failed to verify accuracy and precision above 300 mg/dL. a. One of 20 correlation samples was above 300 mg/dL, however, the difference in results between the two methods was greater than the 20% difference in accuracy allowed by the "Analytical Method Validation" procedure. Specific Gravity 43. The laboratory failed to validate that the urine specific gravity assay on the AU480 could meet the laboratory's documented normal patient range of 1.005 - 1.030. a. Five of 20 specimen results were excluded. The comments indicate that four of the results are greater than the manufacturer's reportable range of 0.9950 - 1.0250 and one was less than the reportable range of 0.9950 - 1.0250. The "Analytical Method Validation" procedure did not indicate that points outside the reportable range should be tested or that they could be excluded. b. Two of the excluded results were below the upper limit of the normal patient range (1.030). These results were 1.0280 and 1.0260. Oxidants 44. The laboratory failed to validate the calibration plan currently in use on the AU480. a. The laboratory validated a linear range using 0, 50, 75, and 100 ug/mL. b. The laboratory is currently using a cut-off calibrator of 50 ug/mL. 45. The laboratory failed to confirm that the correlation samples were accurate. a. The correlation coefficient (r-value) for the comparative samples was -1.19, indicating an inverse correlation. b. Zero of 20 samples tested on the original method had results greater than zero. c. Two of the 20 samples had results of 12 or greater on the AU480. These results were greater than the 20% difference in accuracy allowed by the "Analytical Method Validation" procedure. Urine Screening - AU5810 46. The laboratory failed to include any appropriate acceptability criteria for semi-quantitative tests on the AU5810 with the EP Evaluator packet for this validation packet. The coversheet indicated that the acceptability criteria for correlation samples was qualitative agreement, rather than a semi-quantitative metric. 6-AM 47. The laboratory failed to validate 6-AM on the AU5810 in accordance with the cut-off level of 300 ng/mL established by the laboratory and documented in the "Urine - Drugs & Cut-off Levels" policy. a. The laboratory validated 6-AM screening in urine on the AU5810 using a semi-quantitative method with a calibration curve using 0, 5, 10, 15, and 20 ng/mL. b. There was no documentation that this assay was accurate at 300 ng/mL, as none of the correlation samples were above 300 ng/mL. 48. The laboratory failed to confirm that the urine 6-AM results correlated with the existing method on the AU480. a. None of the correlation samples were above 300 ng/mL. b. One of the twenty correlation samples was positive (10 ng/mL) on the original method and negative (4 ng/mL) on the new method. The manufacturer's instructions indicate that the cut-off calibrator is 10 ng/mL for a qualitative assay c. Four of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Amphetamine 49. The laboratory validated amphetamine screening in urine on the AU5810 using a semi-quantitative method with a calibration curve from 300 - 2000 ng/mL. a. The indicated cut-off for the semi-quantitative method (1000 SQ) was 1000 ng/mL per the manufacturer's instructions. b. The laboratory reports screening presumptive positives at levels greater than 500 ng/mL. c. The manufacturer's instructions indicate that calibrators at 0, 300, 500, and 1000 ng/mL should be used for a semi-quantitative method with a cut-off of 500. 50. The validation indicated the analytical measurement range (AMR) for urine amphetamine on the AU5810 was 90,000 - 2,000,000 ng/mL. a. The manufacturer's instructions indicated that the semi-quantitative AMR was 90 - 2000 ng/mL. b. The analytical range of 90,000 - 2,000,000 ng/mL was not validated. 51. The laboratory failed to confirm that the urine Amphetamine results correlated with the existing method on the AU480. a. One of the twenty correlation samples was positive (1,356 ng/mL) on the original method and negative using the 1000 ng/mL cut-off (927 ng/mL) on the new method. These results do not match qualitatively, as the coversheet indicated they should. b. Two of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Ethyl Alcohol and quantitative ethyl alcohol 52. The laboratory failed to validate or verify the calibration plan currently in use for qualitative ethyl alcohol on the AU5810. a. A phone interview conducted on August 4, 2025, at approximately 2:00 PM PDT, with the testing personnel, confirmed that the laboratory runs a qualitative ethyl alcohol assay using a 100 mg/dL calibrator and a semi-quantitative assay. b. There was no validation or verification of the ethanol assay on the AU5810 using only a cut-off calibrator of 100 mg/dL. c. The laboratory validated a semi-quantitative method with calibrators at 0, 40, 100, 200, 300, and 400 mg/dL for use with the quantitative alcohol assay (qAlc). 53. The laboratory failed validate the qualitative screening assay with an appropriate calibrator, as a 100 mg/dL calibrator would not be able to detect presumptive positives at the laboratory's cut-off of 0.02% or 20 mg/dL. The cut-off is documented in the "Urine - Drugs & Cut-off Levels" policy. 54. The laboratory failed to confirm that the correlation samples were accurate. a. None of the correlation samples used for the method comparison were above the cut-off of 20 mg/dL or 0.02%. b. One of twenty results was greater than 20% from the original value. Twenty percent is the maximum allowable difference in accuracy as indicated by the "Analytical Method Validation" procedure. 55. The laboratory failed to establish a consistent and accurate reference interval or cut-off to interpret ethyl alcohol in oral fluid specimens. a. The report indicated that the cut-off was 20 mg/dL. b. The policy titled "Oral Fluid-Drugs & Cut-Off Levels" indicates that the cut-off was 0.2%, which would be equivalent to 200 mg/dL. c. Percent ethyl alcohol is typically used for blood alcohol concentrations and not for oral fluids. No instructions for conversion between the two units were available. Fentanyl 56. The laboratory failed to validate the fentanyl assay on the AU5810 in the same manner as they run the assay. a. The laboratory performs fentanyl screening as a qualitative assay (positive or negative results) with a cut-off calibrator at 1 ng/mL and reports screening presumptive positives at levels greater than 1 ng/mL. b. The manufacturer indicates that the fentanyl assay is qualitative (positive or negative results). c. Instead of performing a verification, the laboratory performed a quantitative validation for the assay, including a linearity plot. 57. The laboratory failed to include analytical range (reportable range), which is required for quantitative assays, on the EP Evaluator documents. MDMA (ecstasy) 58. The laboratory failed to validate the calibration plan currently in use on the AU5810. a. The laboratory validated a calibration curve using 0, 150, 300, 500, and 1000 ng/mL. b. The laboratory is currently using a calibration curve of 0, 300, and 1000 ng/mL. 59. The laboratory failed to confirm that the urine MDMA results correlated with the existing method on the AU480. a. Four of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Opiates 60. The laboratory failed to validate the calibration plan currently in use on the AU5810. a. The laboratory validated a calibration curve using 0, 300, 1000, and 2000 ng/mL. b. The laboratory testing personnel verbally indicated they were using a calibration curve of 0, 300, 1000, 2000, and 4000 ng/mL (Siemens Emit levels 0,1, 2, 3, and 5) in a phone interview on August 4, 2025, at approximately 2:00 PM PDT. c. The calibration documentation provided by email on August 5, 2025, indicates that 4 levels of calibration are used, but the levels are not marked on the document. d. The manufacturer's instructions indicate that calibrators at 0, 300, 1000, and 2000 ng/mL should be used for the Opiate 300 semi-quantitative method. 61. The laboratory failed to confirm that the urine opiates results correlated with the existing method on the AU480. a. Four of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the Analytical Method Validation SOP. Oxycodone 62. The laboratory validated an oxycodone screening assay in urine on the AU5810 using a semi-quantitative method using a calibration curve of 0, 100, 300, and 500 ng/mL. a. The validation and the manufacturer's instructions indicated that this calibration set was for the Emit II semi-quantitative assay with a cut-off of 100 ng/mL. b. The laboratory reports screening presumptive positives at levels greater than 150 ng/mL, per the "Urine - Drugs & Cut-off Levels" policy. 63. Sensitivity studies were not performed to determine that the assay could adequately differentiate positives and negatives, since there is no calibration point at 150 ng/mL. Propoxyphene 64. The laboratory failed to validate the calibration plan currently in use. a. The laboratory validated a calibration curve using 0, 150, 300, and 500 ng/mL. b. The laboratory testing personnel indicated they were using a calibration curve of 0, 150, 300, 500, and 800 ng/mL (Siemens Emit levels 0, 2, 3, 4, 5) in a phone interview on August 4, 2025, at approximately 2:00 PM PDT. 65. The "Urine - Drugs & Cut-offs" policy indicates that there is no screening available for propoxyphene. The manufacturer's instructions indicate the qualitative cut-off calibrator is 300 ng/mL. 66. The laboratory failed to confirm that the urine propoxyphene results on the AU5810 were accurate and/or correlated with the existing method on the AU480. a. There were no correlation samples above the cut-off of 300 ng/mL to demonstrate that the assay was accurate for client samples on the AU5810. b. Two of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. THC/Cannabinoids 67. The laboratory validated cannabinoid (THC) screening in urine on the AU5810 using a semi-quantitative method with a calibrators at 0, 20, 50, 100, and 200 ng/mL. a. The manufacturer's instructions indicate that the 0, 50, 100 and 200 ng/mL calibrators should be used for a cut-off of 50 ng/mL and that the 0, 20, 50, and 100 ng/mL calibrators should be used for a cut-off of 20 ng/mL. b. The "Urine - Drug & Cut-Off Levels" policy indicates the laboratory cut-off is 25 ng/mL. There was no documentation of a sensitivity study to determine if the laboratory could differentiate true positives from true negatives at 25 ng/mL. There was no indication that the calibration curves can be combined for a 25 ng/mL cut-off. c. The patient reports indicate screening presumptive positives at levels greater than 50 ng/mL. 68. The laboratory failed to confirm that the urine THC results on the AU5810 correlated with the existing method on the AU480. a. One of twenty correlation samples was negative (23 ng/mL) on the original method and was positive (26 ng/mL) on the new method, when evaluated using the 25 ng/mL cut-off. These results do not match qualitatively, as the coversheet indicated they should. There was no further documentation regarding why this result was acceptable. b. Two of twenty correlation results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the "Analytical Method Validation" procedure. Creatinine 69. The laboratory failed to validate urine creatinine on the AU5810 using an assay that could meet the laboratory's documented normal patient range of 20-400 mg/dL. a. No correlation samples had a concentration of greater than 264 mg/dL to demonstrate that the assay was accurate up to 400 ng /mL. b. The analytical range indicated in the validation packet is 1.00 - 200.00 mg/dL. The manufacturer indicates that the "low creatinine" assay has a reportable range of 0-

300 mg/dL when using the 0, 2, 20, and 100 mg/dL calibrators. 70. The laboratory failed to validate the calibration plan currently in use on the AU5810. a. The laboratory validated the linear range using 0, 2, 20, 50, 100, 200, and 300 mg/dL. b. The laboratory was using the following calibrators at the time of survey: 0, 2, and 20 mg/dL. Oxidants 71. The laboratory failed to validate the calibration plan currently in use on the AU5810. a. The laboratory validated a linear range using 0, 50, 75, and 100 ug/mL, indicating the assay is semi-quantitative. b. The laboratory is currently using a cut-off calibrator of 50 ug/mL, which would be used for a qualitative assay. c. The laboratory indicated that they are performing a qualitative assay for oxidants. 72. The laboratory failed to confirm that the urine oxidant results on the AU5810 correlated with the existing method on the AU480. a. The laboratory failed to include any client samples for correlation that were above the cut-off calibrator of 50 ng/mL. The "Urine - Drugs & Cut-off Levels" does not indicate the appropriate cut-off for oxidants. b. Two of twenty results were over 20% from the original value. Twenty percent is the maximum allowable difference in accuracy indicated by the Analytical Method Validation SOP. 73. The laboratory failed to determine and document the acceptable level of oxidants in client urine specimens. Specific Gravity 74. The laboratory failed to adequately validate that the urine specific gravity assay on the AU5810 using the laboratory's documented normal patient range of 1.005 - 1.030. a. The validation documentation indicated that the highest calibrator was 1.020. The laboratory testing personnel confirmed this was the highest calibrator used in production in a phone interview on August 4, 2025, at approximately 2:00 PM PDT. b. The validation documentation and the manufacturer's instructions indicated that the urine creatinine analytical range on the AU5810 was 0.9950 - 1.0250. LC-MS/MS Validations EPP validation on the API3000 - 09/2016 Accuracy and Precision 75. The laboratory failed to document the accuracy and precision using all control values that were run for the study. 76. The Analytical Method Validation SOP for Accuracy and Precision states that the laboratory should "Analyze controls as described in the analytical SOP in a minimum of five runs on five separate days." a. There is no indication in the validation policy, or the procedure titled "Extended Urine Confirmation for Pain Management Drugs v2" that control points may be excluded. The analytical policy indicates that acceptable controls are "within 20% of assigned values." b. The policy does not indicate that points may be excluded or what to do if points are excluded. c. There was no documentation to explain why the following control points were excluded from the study. 77. The following low control points were excluded: a. Three of eleven low control points were excluded from 6-MAM and Noroxycodone. b. Two of eleven low control points were excluded from Buprenorphine, Hydromorphone, Oxymorphone, and Zolpidem. c. One of eleven low control points was excluded from 7-aminoclonazepam, Amphetamine, Benzoylecgonine (BZE), Clonazepam, Codeine, Desmethyldoxepin, and Diazepam. 78. The following high control points were excluded: a. Three of eleven high control points were excluded from 6-MAM, Mephedrone, and Oxymorphone. b. Two of eleven high control points were excluded from EDDP, Gabapentin, Hydrocodone, Hydromorphone, Norbuprenorphine, and Noroxycodone. c. One of eleven low control points was excluded from 7-aminoclonazepam, Amphetamine, Benzoylecgonine (BZE), Buprenorphine, Carisoprodol, Clonazepam, Codeine, Desmethyldoxepin, Diazepam, Doxepin, Meprobamate, Methamphetamine, Methylone, Midazolam, Morphine, Nordiazepam, O-Desmethyl-cis-Tramadol, Oxazepam, Oxycodone, and Zolpidem. Sensitivity 79. The laboratory failed to include documentation of how the sensitivity (lower limit of detection) for each analyte in the assay was determined. 80. No calibration documentation was included or reviewed in the validation packet for the Expanded Pain Panel on the API 3000. Specificity 83. The laboratory failed to include documentation of testing interfering substances for each analyte in the assay. a. The

Analytical Method Validation SOP indicates that, "An interfering compound is defined as a drug which, under the analysis conditions, has a retention time within 0.1 min of a target analyte, shares the same parent ion 1 mass unit, and has at least one product ion in common, and is identified by the Analyst program as the target analyte." Any other performance characteristic required for test performance. 84. The laboratory failed to document the evaluation of chromatography and ratios between the qualitative and quantitative transitions for all analytes included in the assay. a. The Extended Urine Confirmation for Pain Management Drugs policy indicates that "Chromatograms peaks are clearly resolved from other peaks." b. No chromatography was included with the validation packet. c. The ion ratio is used to determine if the peak being quantified and reported is the target analyte or an interference. d. The policy titled "Extended Urine Confirmation for Pain Management Drugs" indicates that "The MRM (ion) ratio is within the acceptable range (20%). e. There was no documentation of ion ratios included in the validation packet. EPP - Validation for 0.25X standard API 3000 - 7/2018 Accuracy and Precision 85. The laboratory failed to perform the validation for the 0.25X standard being added to the expanded pain panel according to their policy and the information provided on the coversheet for this validation. a. The coversheet indicates that 25 points for the 0.25X standard were used to determine linearity, accuracy and precision. b. The laboratory removed the points listed below and failed to document any additional points. c. The original %CV and accuracy of the new standard were unable to be verified for the analytes with points removed. d. The Analytical Method Validation procedure does not indicate that points may be removed from the validation and does not provide instructions on what to do if points are excluded. 86. Five of twenty-five 0.25X calibration points were excluded from Gabapentin. 87. Three of twenty-five 0.25X calibration points were excluded from Buprenorphine 88. Two of twenty-five 0.25X calibration points were excluded from 6-MAM and Mephedrone. 89. One of twenty-five 0.25X calibration points were excluded from MDA, MDMA, Methamphetamine, Methylone, Norfentanyl, Noroxycodone , Oxycodone, and Oxymorphone. EPP - Modified Sample Prep - 07 /2018 Accuracy and Precision 90. The laboratory failed to evaluate accuracy for this assay according to the Analytical Method Validation procedure. a. The Analytical Method Validation SOP for Accuracy and Precision states that the laboratory should "Analyze controls as described in the analytical SOP in a minimum of five runs on five separate days." b. There is no indication in the validation policy, or the procedure titled "Extended Urine Confirmation for Pain Management Drugs v2" that points may be removed from the validation and these policies do not provide instructions on what to do if points are excluded. c. There was no instruction in the "Extended Urine Confirmation for Pain Management Drugs v2" procedure to determine accuracy of controls or patient samples above the highest retained linearity point. 91. The laboratory only ran the lower four out of five calibrators described in the analytical procedure. The high QC that was intended to validate accuracy was above the highest accurate linearity point for the analytes listed below: a. The highest remaining calibrator (second highest calibrator) was dropped for the following analytes on API3000 #1: 6-AM, Norbuprenorphine, O-Desmethyl Tramadol, and Oxymorphone. b. The highest remaining calibrator (second highest calibrator) was dropped for the following analytes on API3000 #2: EDDP, Flurazepam, MDA , MDMA , Mephedrone , Methadone , Methamphetamine , Nor Fentanyl , O-Desmethyl Tramadol , Oxycodone , Tapentadol, and Tramadol. 92. The laboratory failed to validate the method using the same internal standards as defined by the analytical procedure titled, "Extended Urine Confirmation for Pain Management Drugs." a. The procedure indicates that Carisoprodol is to be paired with Carisoprodol-D7. The laboratory validated it with Meprobamate-D3. b. The procedure indicates that Meperidine is to be paired with Methadone-D3. The laboratory validated it with

Norfentanyl-D5. c. The procedure indicates that Normeperidine is to be paired with Methadone-D3. The laboratory validated it with Norfentanyl-D5. d. The procedure indicates that O-desmethyl (ODM) tramadol is to be paired with Phencyclidine-D5. The laboratory validated it with Norfentanyl-D5. e. The procedure indicates that Tapentadol is to be paired with Phencyclidine-D5. The laboratory validated it with Norfentanyl-D5. f. The procedure indicates that Tramadol is to be paired with . The laboratory validated it with Phencyclidine (PCP)-D5. g. The procedure indicates that Zolpidem is to be paired with Nordiazepam-D5. The laboratory validated it with Norfentanyl-D5. 93. The laboratory failed to use appropriate internal standards when developing the Extended Pain Panel. Internal standards are added to the sample to normalize for loss or gain of signal due to extraction and matrix effects. The follow analytes used internal standards that were either from a differing drug class or had significantly different molecular structure and retention time. These differences can cause the internal standard to behave in a manner that is significantly different from the analyte of interest. The following drugs used inappropriate internal standards: a. Buprenorphine, which is an opioid, was paired with Nordiazepam-D5. Nordiazepam is a benzodiazepine. Stable labeled isotopes of buprenorphine are available. a. Gabapentin, which is an anticonvulsant, was paired with Benzoylecgonine-D3. Benzoylecgonine (cocaine metabolite) is a stimulant. Stable labeled isotopes of gabapentin are available. b. ODM Tramadol, which is an opioid analgesic, was paired with PCP-D5. PCP is a dissociative anesthetic. Stable labeled isotopes of tramadol are available. c. Tapentadol, which is an opioid analgesic, was paired with PCP-D5. PCP is a dissociative anesthetic. Stable labeled isotopes of tapentadol are available. d. Tramadol, which is an opioid analgesic, was paired with PCP-D5. PCP is a dissociative anesthetic. Stable labeled isotopes of tramadol are available. e. Zolpidem, which is a sedative-hypnotic, was paired with Nordiazepam-D5. Nordiazepam is a benzodiazepine. Stable labeled isotopes of zolpidem are available. Integra Assist - Validation - 07/1/2021 Accuracy and Precision 94. The laboratory failed to assess the use of the automated liquid handler in sample preparation as compared to manual pipetting in a using a method appropriate to the assay. Qualitative analysis (presence /absence) was used for a method used to report quantitative (numeric) results. a. The "Analytical Method Validation" procedure indicated that accuracy should be within 20% of the target value. 95. The laboratory failed to analyze all analytes included in the method. The following analytes were not included in the validation documentation: 6-MAM, 7-aminoclonazepam, Benzoylecgonine, Clonazepam, Desalkylflurazepam, Desipramine, Desmethyldoxepin, Doxepin, Flunitrazepam, Flurazepam, lmipramine, MDA, MDMA, Meperidine, Mephedrone, Methylone, Normeperidine, PCP, and Tapentadol. EPP - Carryover Data - 01/2018 96. The laboratory failed to assess carry-over from samples with concentrations above the analytical measurement range according the "Analytical Method Validation" procedure. The procedure indicates that, "Carryover is evaluated by analyzing a blank (zero standard) after the highest standard." 97. The documented carryover studies were performed using the high QC which is within the Analytical Measurement Range (AMR) and below the highest standard. EPP - API4000 - 04/2023 98. The laboratory failed to meet the criteria established in the "API 4000(#4) Validation Summary Addendum." 99. The "API 4000(#4) Validation Summary Addendum" indicated that Interday accuracy and precision was to be evaluated over four days. There was no documentation of this evaluation. 100. The "API 4000(#4) Validation Summary Addendum" indicated that linearity was to be evaluated over four days. There was no documentation of this evaluation. 101. The "API 4000(#4) Validation Summary Addendum" indicated that all samples must meet the criteria in the analytic procedure. There was no documentation of evaluation of retention time, relative retention time, chromatography, or ion ratios as describe in the "Extended Urine

Confirmation for Pain Management Drugs" procedure. 102. The summary addendum indicates that "7 Repetitions of each QC Level (Low/High) will be run for Intraday Accuracy and Precision. a. A review of the "EPP Precision Day 1" document indicates that "6 of 6" values, rather than the seven replicates that were indicated, were used to determine accuracy and precision for all analytes evaluated. b. A review of the "EPP Precision Day 2" document found QC points were excluded from Dextromethorphan, Ritalinic Acid, and Hydromorphone. i) There was no indication that points could be excluded or what to do when they were excluded. c. A review of the "EPP Precision Day 3" document indicates that Norfentanyl 2 (the qualitative ion transition) QC at 500 ng/mL had no values used to determine precision and accuracy. i) The "Mean Calculated Con, Std. Deviation, % CV, Number of Values Used, and Mean Accuracy" columns all indicated "N/A". i). A Norfentanyl 1 (the quantitative ion transition) QC at 500 ng/mL was not included in this study. d. A review of the "EPP Precision Day 4" document indicates that "5 of 5" values, rather than the seven replicates that were indicated, were used to determine accuracy and precision for all analytes evaluated. e. A review of the "LCMS4 EPP Validation Correlation" document revealed significant discrepancies between the 28 of 80 analytes assessed on the original instrument (LCMS1) and the new instrument (LCMS4). f. The acceptance criteria included inappropriate qualitative criteria for an assay that is used to report quantitative results. i) Accuracy of 16 of 84 positive analyte results was greater than the 20% difference established in the API 4000(#4) Validation Summary Addendum. ii) Accuracy for 47 of 84 positive analyte results could not be determined because the values were greater than the upper limit of linearity (ULOL). Analytes affected include 1) Cotinine: 23 of 24 results were greater than the ULOL 2) Gabapentin: eight of nine results were greater than the ULOL 3) Dextrorphan: two of two results were greater than the ULOL 4) Fluoxetine: one of two results were greater than the ULOL 5) Naltrexone: one of one results were greater than the ULOL 6) Norbuprenorphine: one of four results were greater than the ULOL 7) Noroxycodone: one of one results were greater than the ULOL 8) OPC-3373: one of one results were greater than the ULOL 9) Oxycodone: one of one results were greater than the ULOL 10) Oxymorphone: one of one results were greater than the ULOL 11) Temazepam: one of four results were greater than the ULOL 12) Venlafaxine: one of one results were greater than the ULOL iii) Accuracy for three results on LCMS4 could not be determined because the result on LCMS4 was less than the lower limit of detection and the result was positive on LCMS1. 1) Lorazepam in specimen 136362 was detected at 610.3 ng/mL on LCMS1 and not detected on LCMS4. 2) 7-aminoclonazepam in specimen 136369 was detected at 52.3 ng/mL on LCMS1 and not detected on LCMS4. 3) Trazadone in specimen 136231 was detected at 102 ng/mL on LCMS1 and not detected on LCMS4. Urine Barbiturates and THC - 08/2018 103. The laboratory failed to include a precision study for phenobarbital, butalbital, and THC. The coversheet did not indicate any criteria for evaluating precision. 104. The laboratory failed to perform five linearity runs for phenobarbital and butalbital on API 3000 Serial number D5700011. The coversheet indicated that linearity would be tested for five days. Only four linearities were included. 105. The laboratory failed to perform five acceptable linearity runs for THC on API 3000 Serial number D5700011. The linearity run on August 24, 2018, did not meet acceptability criteria from the analytical procedure as the lowest calibrator was greater than 20% from its target value. 106. The laboratory failed to perform five acceptable linearity runs for THC on API 3000 Serial number D11890305. The linearity run on August 7, 2018, did not meet acceptability criteria from the analytical procedure as the ion ratios were unacceptable for the lowest two calibrators. 107. The laboratory failed to validate the same transition ions for butalbital on the two instruments (D5700011 and D11890305). The transition ions were manually lined out and switched for butalbital on D11890305. a. If the transitions had remained as the same as the original program indicated, 0 of 20 replicates for Butalbital would have passed for accuracy when evaluating the UTAK QC. 108. The laboratory excluded points as "outliers" even though these points were within the +/- 20% accuracy criteria. No documentation to explain this was included with the validation. a. One of 4 butalbital UTAK QC points on 8/7/2018 was excluded as an "outlier." The point was 288 ng/mL. The range for the UTAK qc (250) was 200-300 ng/mL. b. The THC data evaluation contained 2 points that were 11 ng/mL. One of the two points was excluded as an outlier; however, the other point was not excluded. The acceptable range (+/-20%) was (7.2-10.8 ng/mL) c. The laboratory failed to include any external patient samples for correlation that were positive for Phenobarbital. Two of 32 samples were positive for butalbital. Thirty of 32 samples were positive for THC. Urine Ethyl Glucuronide (EtG) and Ethyl Sulfate (EtS) on the 5500 - 10/2019 109. The laboratory failed to use the criteria, as indicated on the coversheet to determine accuracy and precision. a. The laboratory excluded two of nine low QC points for EtS and two of nine high QC points for EtS. b. The laboratory excluded two of nine high QC points for EtG. c. One of the nine low QC points for EtG failed to meet the acceptability criteria of being with 20% of the target value. d. There was no indication that points could be excluded or what to do if points were excluded on the coversheet or in the "Analytical Method Validation" procedure. 110. The laboratory failed to confirm the accuracy of EtG and EtS with correlation samples. a. Samples ETB-06, 1832S, 1849S were above the upper limit of linearity for EtS and accuracy could not be determined. b. Samples 1832S, 1849S, 1946S had unacceptable chromatography for EtS and EtG. The peaks were not clearly resolved from neighboring peaks. c. Samples 1832S, 1849S, 1946S had unacceptable ratios for EtS, as determined by the analysis software. d. Samples ETB-06 and 1832S were above the upper limit of linearity for EtG and accuracy could not be determined. Campbell beta-glucuronidase - 08/2018 111. The laboratory failed to include instrument data for this validation so the results could not be confirmed. 112. The laboratory failed to use the industry standard for drug hydrolysis studies, which is codeine-glucuronide. The laboratory used morphine-glucuronide. B-One beta-glucuronidase - 07/2021 113. The laboratory failed to maintain the same criteria used in the previous hydrolysis study for Campbell beta-glucuronidase. The previous study indicated the results were to be within 10% of the target while this study allowed a 30% difference from the target. There was no procedure available on how to perform the validation. 114. The laboratory failed to use the industry standard for drug hydrolysis studies, which is codeine-glucuronide. The laboratory used morphine-glucuronide. 115. The laboratory failed to use samples that could be quantitatively assessed and allowed qualitative assessment. The laboratory reports quantitative results for the extended pain panel in urine. a. Eleven of 15 target analytes had no passing values b. Twenty-five of 47 positive analyte targets were above the upper limit of linearity and could not be assessed for accuracy. c. One of 47 "positive" analyte targets was below the limit of detection and could not be assessed for accuracy but was included in the study. d. Seven of 21 remaining usable points failed to pass per the accuracy criteria of being within 30% of the target value. e. Two of 15 target analytes are not substantially glucuronidated during metabolism and are not appropriate targets for this study. Oral Fluids - 02/2024 116. The laboratory failed to validate the oral fluid confirmation method using the correct calibrator concentrations. A review of the procedure used for the validation of oral fluids on the LC-MS/MS found that the calculated concentrations of the calibrators did not match the nominal targets for the calibrators for all analytes included in the validation. The examples below are not an exhaustive list. a. The 6-MAM calibrator level 1 at the final dilution in matrix had a calculated concentration of 0.57 ng/mL. The target concentration was 1.25 ng/mL. b. The Alprazolam calibrator level 2 at the final dilution in matrix had a

	calculated concentration of 2.27 ng/mL. The target concentration was 5 ng/mL. c. The Amphetamine calibrator level 3 at the final dilution in matrix had a calculated concentration of 28.41 ng/mL. The target concentration was 50 ng/mL. d. The BZE calibrator level 4 at the final dilution in matrix had a calculated concentration of 11.36 ng/mL. The target concentration was 25 ng/mL. e. The Buprenorphine calibrator level 5 at the final dilution in matrix had a calculated concentration of 11.36 ng/mL. The target concentration was 25 ng/mL. f. The Clonazepam calibrator level 6 at the final dilution in matrix had a calculated concentration of 56.82 ng/mL. The target concentration was 125 ng/mL. g. The Cocaine calibrator level 7 at the final dilution in matrix had a calculated concentration of 113.64 ng/mL. The target concentration was 250 ng/mL. 117. The laboratory failed to validate the updated method using the corrected calculations found in the T-008v02 version of the "Oral Fluid LC/MS-MS" procedure. 118. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to retain all documentation, including the original instrument data, for all validations and verifications performed by the laboratory. Findings include: Urine Screening Architect c4000 1. The laboratory failed to include any original results for the patient correlation data to be compared to the results from the Architect c4000. Therefore, the correlation data could not be evaluated or verified. 2. The laboratory failed to include any evaluation of the linearity data for EtG, oxycodone, methadone, creatinine, pH, oxidants, and specific gravity on the Architect c4000, although there were instrument results. Urine Screening AU5800 3. The laboratory failed to include the instrument data with the EP Evaluator data analysis. The values used for the validation /verifications on this instrument could not be verified. Confirmation EPP validation - 09/ 2016 4. The laboratory failed to include instrument data that documented the calibration, chromatography and ion ratios for this validation. EPP - Desipramine numbers - 11/2016 5. The laboratory failed to include any data for this validation of desipramine, except for a single page with the final summary of accuracy and precision. No instrument data including calibration, controls, chromatography, and ion ratios was included for desipramine. EPP - Validation for 0.25X standard API 3000 - 7 /2018 6. The laboratory failed to include instrument data that documented the original run information, including the values for the excluded calibration points, chromatography, and ion ratios for this validation. EPP - Mod Prep ISTD notes - 07 /2018 7. The laboratory failed to document the change of internal standards for carisoprodol and MDA from what the procedure specified (Meprobamate-D3 and

	Amitriptyline-D3, respectively) to Carisoprodol-D7 and Methamphetamine-D5. 8. The laboratory failed to include instrument data that documented the original run information, including the values for the excluded points, chromatography, and ion ratios for this validation. Integra Assist - Validation - 07/1/2021 9. The laboratory failed to include instrument data of any kind for this validation. The only data provided was from LIS reports. EPP - API4000 - 04/2023 10. The "API 4000(#4) Validation Summary Addendum" indicated that Interday accuracy and precision was to be evaluated over four days. There was no documentation of this evaluation. 11. The "API 4000(#4) Validation Summary Addendum" indicated that linearity was to be evaluated over four days. There was no documentation of this evaluation. 12. The "API 4000(#4) Validation Summary Addendum" indicated that all samples must meet the criteria in the analytic procedure. There was no documentation of evaluation of retention time, relative retention time, chromatography, or ion ratios as describe in the "Extended Urine Confirmation for Pain Management Drugs" procedure. Campbell beta-glucuronidase - 08/2018 13. The laboratory failed to include instrument data of any kind for this validation. The only data provided was a single page with a summary table. B-One beta-glucuronidase - 07/2021 14. The laboratory failed to include instrument data of any kind for this validation. The only data provided was a summary table and LIS reporting data. Oral Fluids - 02/2024 15. The laboratory failed to include instrument data of any kind for this validation. The only data provided was summary tables generated by the laboratory. 16. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) (d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the procedure manual included all relevant information for specimen testing and reporting. Findings include: 1. The laboratory failed to ensure that controls were made from a separate stock solution from the calibrators. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. a. A review of the procedure titled "Extended Urine Confirmation for Pain Management" found that the controls were prepared from the same stock solution as the calibrators used for this assay. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. b. A review of the procedure titled "Urine Confirmation for Ethyl Glucuronide and Ethyl Sulfate" found that the controls were prepared from the same stock solution as the calibrators used for this assay. c. A review of the procedure titled " Urine Confirmation for THC-COOH and Barbiturates by LC-MS/MS" found that the controls were prepared from

	the same stock solution as the calibrators used for this assay. d. A review of the procedure titled "Oral Fluid LC-MS/MS Confirmation" found that the controls were prepared from the same stock solution as the calibrators used for this assay. 2. On-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, confirmed that controls were made from the same stock solution as the calibrators. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited at the CLIA recertification survey on March 6, 2024.
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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, a review of the instrument validations, a review of the control procedures being used, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure an adequate written quality assessment program was established and maintained to detect and correct errors in the analytic systems of the laboratory. Findings include: 1. The laboratory QA system failed to detect the unavailability of current and correct written procedures for all tests, assays, and examinations performed by the laboratory and that the existing procedures were not followed by the laboratory personnel. (refer to D5401, D5403, and D5407) 2. The laboratory QA system failed to detect that all unmodified, FDA-approved tests were not completely and appropriately verified. (refer to D5421) 3. The laboratory QA system failed to detect that all modified FDA-approved tests, non-FDA approved tests, and laboratory developed tests (LDT) were not completely and appropriately validated. (refer to D5423) 4. The laboratory QA system failed to detect that all activities related to validations and verification were not documented. (refer to D5427) 5. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited at the CLIA recertification survey on March 6, 2024.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 the laboratory's policies and procedures, a review of patient reports, a review of the test menu, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure that the patient reports indicated the test report date. Findings include: 1. The laboratory failed to indicate the test report date on patient reports. a. The oral fluid testing report for accession number 249888 (collected on 7/2/2025) did not have a report date. b. The urine testing report for accession number 234162 (collected on 2/20/2025) did not have a report date. The confirmation testing was performed on 2/27/2025. c. The urine testing report for accession number 234160 (collected on 2/24/2025) did not have a report date. The confirmation testing was performed on 2/27/2025. d. The urine testing report for accession number 234119 (collected on 2/20/2025) did not have a report date. The confirmation testing was performed on 2/27/2025. e. The urine testing report for accession number 234110 (collected on 2/20/2025) did not have a report date. The confirmation testing was performed on 2/27/2025. 2. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited in the CLIA recertification survey on April 7, 2022.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu, a review of patient reports, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the normal ranges and/or cut-off levels were consistent between the patient reports and the established laboratory cut-off policies. 1. The reference interval (cut-off) for THC screening in oral fluids on the patient report was documented as less 8 ng/mL. The published cut-off in "Oral Fluid - Drugs & Cut-off Levels" was documented as 10 ng/mL. 2. The reference interval (cut-off) for buprenorphine confirmation on LC-MS/MS in oral fluids on the patient report was documented as less 5.0 ng/mL. The published cut-off in "Oral Fluid - Drugs & Cut-off Levels" was documented as 2.5 ng/mL. 3. The reference interval (cut-off) for benzodiazepine screening in urine on the patient report was documented as less 200 ng/mL. The published cut-off in "Urine - Drugs & Cut-off Levels" was documented as 300 ng/mL. 4. The reference interval (cut-off) for opiate screening in urine on the patient report was documented as less 200 ng/mL. The published cut-off in "Urine - Drugs & Cut-off Levels" was

	documented as 300 ng/mL. 5. The reference interval (cut-off) for THC (marijuana) screening in urine on the patient report was documented as less 50 ng/mL. There was no published cut-off for THC (marijuana) in "Urine - Drugs & Cut-off Levels." There was a published cut-off of 25 ng/mL for THC metabolite in "Urine - Drugs & Cut-off Levels." 6. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: [Director] was not met. The director failed to: - ensure that responsibilities delegated to the technical supervisor were properly performed (D6079) - ensure that testing systems developed and used for all laboratory testing provide quality laboratory services in for all phases of testing (D6082) - ensure that appropriate verification procedures are used for unmodified, FDA-approved tests(D6086) - ensure that all corrective action for unacceptable and/or unsatisfactory proficiency testing results were reviewed and approved (D6092) -ensure that all quality control and quality assessment plans were established and maintained to detect and correct failures in quality (D6093) - ensure that appropriate validation procedures are used for modified, FDA-approved, non-FDA approved tests, and laboratory developed tests (LDT) used by the laboratory (D6095) - ensure there was a written and approved procedure manual available for all tests performed by the laboratory (D6106)
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, a review of training and competency documentation, on-site interviews with the laboratory operations director and testing

	personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the procedure manual included all relevant information for specimen testing and reporting. Findings include: 1. The laboratory director failed to ensure that responsibilities delegated to the technical supervisor were properly performed. a. The laboratory director failed to ensure that the selection of test methodology was appropriate to the clinical use of the results. (Refer to D6114) b. The laboratory director failed to ensure that appropriate verification and validation of the testing procedures used by the laboratory were performed. (Refer to D6115) c. The laboratory director failed to ensure that an appropriate quality control program was established for the testing performed. (Refer to D6117) d. The laboratory director failed to ensure that annual competency assessments were performed and documented for all testing personnel. 12 These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. (D6114, D6115, D6120)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory director failed to ensure that all phases of laboratory testing were providing quality services. Findings include: 1. The laboratory director failed to ensure that there were written procedures for all testing processes performed by the laboratory and that the testing personnel followed the written procedures. (Refer to D5401) 2. The laboratory director failed to ensure that the written procedures for testing processes performed by the laboratory contained all relevant information for testing, including calibrators and controls. (Refer to D5403) 3. The laboratory director failed to ensure that all changes to written procedures for testing processes performed by the laboratory were documented and approved prior to use. (Refer to D5407) 4. The laboratory director failed to ensure that appropriate verification and validation of the testing procedures used by the laboratory were performed. (Refer to D5421 and D5423) 5. The laboratory director failed to ensure that an appropriate quality control program was established for the testing performed. (Refer to D5425) 6. The laboratory director failed to ensure that all processes performed for the verification and validation of the testing procedures used by the laboratory were documented. (Refer to D5427) 7. The laboratory director failed to ensure that test reports contained all required information. (Refer to D5805) 8. The laboratory director failed to ensure that the cut-offs on the test reports agreed with the documented cut-off policies for the laboratory. (Refer to D5807) 9. These findings

	were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory failed to ensure the procedure manual included all relevant information for specimen testing and reporting. Findings include: 1. The laboratory director failed to ensure that complete and adequate verifications were performed according to the "Analytical Method Validation" procedure for non-modified FDA approved assays. (refer to D5421) 2. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited in the CLIA recertification survey on October 27, 2016.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the laboratory's proficiency testing documentation, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025,, the laboratory director failed to ensure that corrective action plans for unacceptable or unsatisfactory proficiency testing (PT) were developed, approved, and followed. Findings include: 1. The laboratory director failed to review and approve the corrective action plans for unacceptable or unsatisfactory PT events. 2. The director failed to approve the correction action and investigation documentation for the Urine Drug Adulterant/Integrity (DAI)-B 2023 PT event performed in August 2023. 3. The director failed to ensure that corrective action was determined and followed when the investigation found that the following results for DAI-B 2023 were unacceptable. a. The original result for pH on sample DAI-05 was 11.2. CAP indicated that the correct results were between 11.4 and 12.9. b. The conclusion indicated that the analytical range was up to 11 and that the result should have been entered as greater than 11;

however, the validation performed on the AU480 indicated that the analytic range was from 2 to 12. c. The investigation documentation did not address the pH results being out of range. 4. The director failed to approve the correction action and investigation documentation for the Urine Drug Adulterant/Integrity (DMPM)-B 2024 PT event performed in August 2024. 5. The director failed to ensure that corrective action was determined and followed when the investigation found that the following results for DAI-B 2023 were unacceptable. a. The original result for Oxymorphone on sample DMPM-07 was 856.2. CAP indicated that the correct results were between 86.3 and 364.0. b. The investigation form noted that the sample had a high bias, but did not have any reason for the error. 6. The director failed to approve the correction action and investigation documentation for the Oral Fluid Drugs of Abuse (OFD)-D 2024 PT event performed in December 2024. 7. The director failed to ensure that corrective action was determined and followed when the investigation found that the following results for OFD-D 2024 were unacceptable. a. The original result for Alprazolam on sample OFD-18 was 74. CAP indicated that the correct results were between 21 and 62. b. The investigation form noted that the low QC had a high bias, but did not have any reason for the error. c. The remainder of the PT sample OFD-18 had been used in a validation study and was not repeated. No indication of the results from the validation study were included. 8. The director failed to approve the correction action and investigation documentation for the 202401 in-house spiked blind PT event performed in November 2024. 9. The director failed to ensure that corrective action was determined and followed when the investigation found that the following results for SB2 were unacceptable. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for EDDP on sample SB2 was 56.3 for a target of 75 ng/mL, resulting in a -26% difference. c. The investigation form noted that the QC had a high bias, but did not have any reason for the error or any corrective action for the laboratory to follow. 10. The director failed to approve the correction action and investigation documentation for the 202402 in-house spiked blind PT event performed in November 2024. 11. The director failed to ensure that corrective action was determined and followed when the investigation found that there were unacceptable results for 202402-A, 202402-B, 202402-D, and 202402-E. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for PCP on sample 202402-A was 36.3 for a target of 50 ng/mL, resulting in a -27% difference. c. The original result for Naltrexone on sample 202402-B was 94.3 for a target of 75 ng/mL, resulting in a 26% difference. d. The original result for Alpha-hydroxymidazolam on sample 202402-B was 56.1 for a target of 75 ng/mL, resulting in a -25% difference. e. The original result for Cotinine on sample 202402-D was 184.6 for a target of 150 ng/mL, resulting in a 23% difference. f. The original result for Methylone on sample 202402-E was 196.5 for a target of 150 ng/mL, resulting in a 31% difference. g. The investigation form noted that the samples passed when rerun, but did not have any reason for the error or any corrective action for the laboratory to follow. 12. The director failed to ensure that corrective action was determined and followed when the investigation found that there were unacceptable results for the 202401 in-house spiked blind PT event performed in April 2024. a. Acceptable results were to be within 20 percent of the target concentration according to the "Proficiency Testing" procedure. b. The original result for Amitriptyline on sample 202401-A was 374 ng/mL for a target of 500 ng/mL, resulting in a -25% difference. c. The original result for Mephedrone on sample 202401-C was 1047 ng /mL for a target of 500 ng/mL, resulting in a 109% difference. d. The original result for Methylone on sample 202401-C was 802 ng/mL for a target of 500 ng/mL, resulting in a 60% difference. e. The original result for Paroxetine on sample 202401-D was 382 ng/mL for a target of 500 ng/mL, resulting in a -24% difference. f. The

	original result for Aripiprazole 202401-F was 29 ng/mL for a target of 50 ng/mL, resulting in a -42% difference. g. The original result for Cyclobenzaprine 202401-G was 331 ng/mL for a target of 500 ng/mL, resulting in a -34% difference. h. The original result for Phencyclidine 202401-D was 67 ng/mL for a target of 100 ng/mL, resulting in a -33% difference. i. These samples were sent to an external laboratory for testing. i) The results of the in-house spiked blind failed to be confirmed for Aripiprazole, Paroxetine, and Mephedrone. ii) The corrective action indicated that the laboratory would only report qualitative results forAripiprazole, Paroxetine, and Mephedrone. j. No cause of failure for any of the analytes or further corrective action was determined. 13. The director failed to review and approve the corrective action plan for the unacceptable results of EDDP for 2024-01 Spiked Blind confirmation of accuracy. a. The original result for EDDP was 55.63 ng/mL for a target of 75 ng/mL. b. EDDP showed a low QC bias at the time of testing, however, no investigation into cause of low QC bias was performed and documented. 14. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, the laboratory director failed to ensure that an appropriate quality control program was established for the testing performed. Findings include: 1. The laboratory failed to ensure that controls were made from a separate stock solution from the calibrators. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. a. A review of the procedure titled "Extended Urine Confirmation for Pain Management" found that the controls were prepared from the same stock solution as the calibrators used for this assay. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. b. A review of the procedure titled "Urine Confirmation for Ethyl Glucuronide and Ethyl Sulfate" found that the controls were prepared from the same stock solution as the calibrators used for this assay. c. A review of the procedure titled " Urine Confirmation for THC-COOH and Barbiturates by LC-MS/MS" found that the controls were prepared from the same stock solution as the calibrators used for this assay. d. A review of the procedure titled "Oral Fluid LC-MS/MS Confirmation" found that the controls were prepared from the same stock solution as the calibrators used for this assay. 2. The laboratory operations director and testing personnel confirmed that controls were made with the same stock solutions as the calibrators in on-site interviews between June 24, 2025 and June 26, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory director failed to ensure that appropriate verification and validation of the testing procedures used by the laboratory were performed. Findings include: 1. Complete and adequate validations were not performed according to the "Analytical Method Validation" procedure for modified FDA approved assays or for assays that were not approved by the FDA. (refer to D5423) 2. Qualitative validations were performed for quantitative assays. (refer to D5423) 3. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the laboratory director failed to ensure there was a procedure manual available to all testing personnel. Findings include: Screening 1. The laboratory director failed to ensure that there was a procedure for screening oral fluids for toxicology analytes on the AU480. 2. The laboratory director failed to ensure that there was a procedure for screening urine specimens for toxicology analytes on the AU480. 3. The laboratory director failed to ensure that there was a procedure for screening urine specimens for toxicology analytes on the AU5810. General 4. The laboratory director failed to ensure that staff received and had access to the procedures for testing. The reporting scientist indicated by email received on August 7, 2025, that they had not received a copy of the "Extended Urine Confirmation for Pain Management Drugs" procedure until August 7, 2025. The reporting scientist was hired on June 28, 2024. 5. The laboratory director failed to ensure that there was a procedure available for the process of verifying un-modified FDA approved test methods, including both qualitative and semi-quantitative assays (such as those used in screening). 6. The laboratory director failed to ensure that there was a procedure indicating how to convert urine and blood screens for ethyl alcohol from mg/dL to percentages. The initial screening cut-off for ethyl

	alcohol in urine and blood is 0.02%. This converts to 20 mg/dL. 7. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024. This is a repeat deficiency cited in the CLIA recertification survey on March 6, 2024.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: [Technical Supervisor] was not met. The technical supervisor failed to: - provide ensure that test methodology was appropriate for the clinical use of the test results (D6114) - ensure that test procedures are appropriately verified or validated prior to use (D6115) - ensure that annual competency was performed for all testing personnel (D6120)
D6114	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(1) (b) The technical supervisor is responsible for-- (b)(1) Selection of the test methodology that is appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and and client results, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the technical supervisor failed to select appropriate test methodology for the clinical use of the test results. Findings include: 1. The assay for gabapentin has a linear range of 25 - 1000 ng/mL. Nine of nine patient results reviewed indicate that all the patient results were above 79,000 ng/mL. These results report as >1000 ng/mL and cannot be used to accurately determine the concentration of concentration of gabapentin in the urine for evaluation of compliance. 2. The assay for pregabalin has a linear range of 25 - 1000 ng/mL. Nine of nine patient results reviewed indicate that all the patient results were above 71,000 ng/mL. These results report as >1000 ng/mL and cannot be used to accurately determine the concentration of pregabalin in the urine for evaluation of compliance. 3. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.

D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025, the technical supervisor failed to ensure that appropriate verification and validation of the testing procedures used by the laboratory were performed. Findings include: 1. Complete and adequate verifications were not performed according to the "Analytical Method Validation" procedure for non-modified FDA approved assays. (refer to D5421) 2. Complete and adequate validations were not performed according to the "Analytical Method Validation" procedure for modified FDA approved assays or for assays that were not approved by the FDA. (refer to D5423) 3. Qualitative validations were performed for quantitative assays. (refer to D5423) 4. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, and also through email communications with the laboratory operations manager, owner, and testing personnel between July 1, 2025 and August 6, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, , the technical supervisor failed to ensure that an appropriate quality control program was established for the testing performed. Findings include: 1. The laboratory failed to ensure that controls were made from a separate stock solution from the calibrators. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. a. A review of the procedure titled "Extended Urine Confirmation for Pain Management" found that the controls were prepared from the same stock solution as the calibrators used for this assay. Controls made from the same solution as the calibrators cannot detect errors in the preparation of calibration material. b. A review of the procedure titled "Urine Confirmation for Ethyl Glucuronide and Ethyl Sulfate" found that the controls were prepared from the same stock solution as the calibrators used for this assay. c. A review of the procedure titled

	" Urine Confirmation for THC-COOH and Barbiturates by LC-MS/MS" found that the controls were prepared from the same stock solution as the calibrators used for this assay. d. A review of the procedure titled "Oral Fluid LC-MS/MS Confirmation" found that the controls were prepared from the same stock solution as the calibrators used for this assay. 2. The laboratory operations director and testing personnel confirmed that controls were made with the same stock solutions as the calibrators in on-site interviews between June 24, 2025 and June 26, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records, a review of the test menu and instruments used for testing, on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025, the technical supervisor failed to ensure that annual competency assessments were performed and documented for all testing personnel. Findings include: 1. The technical supervisor failed to perform and document an annual competency assessment in 2024 for one of eight testing personnel performing screening using the AU480. 2. The technical supervisor failed to perform and document an annual competency assessment in 2024 for one of eight testing personnel performing screening using the Architect c4000. 3. The technical supervisor failed to perform and document an annual competency assessment in 2025 for one of eight testing personnel performing confirmation testing using the ABSciex. TP8 had their last annual competency assessment on March 27, 2024. 4. These findings were confirmed in on-site interviews with the laboratory operations director and testing personnel between June 24, 2025 and June 26, 2025. The laboratory performs approximately 1,800,000 chemistry tests per year, based on the CMS-116 submitted in March 2024.