Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2197233	09/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Stl Diagnostic, Llc	5203 Chippewa St, Saint Louis, MO	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced complaint and initial survey was completed on September 21, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. 493.1100 Condition: Facility Administration 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1441 Condition: Laboratory Director 42 C.F.R. 493.1447 Condition: Laboratory Technical Supervisor 42 C.F.R. 493.1487 Condition: Testing Personnel
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of COVID-19 testing area, Direct RT qPCR SARS-CoV-2 completed by BioRad CFX 96 real time system procedure and interviews, the laboratory failed to maintain a unidirectional workflow process to prevent contamination for COVID-19 PCR testing (Refer to D3005).
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a

	uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation of COVID-19 testing area, interviews with laboratory staff, Direct RT qPCR SARS-CoV-2 completed by BioRad CFX 96 real time system procedure and interview with the testing personnel (TP) #1, the laboratory failed to maintain an uni-directional workflow. Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination of patient specimens, and consists of separate areas for reagent preparation, pre-amplification, and post-amplification. Findings: 1. Observation of the COVID-19 testing area showed: The COVID-19 testing area has 3 distinct rooms. One room with one door going out into the hall, patient specimens are stored in this room, which was referred to as "PCR dirty room". Across the hall is the "PCR clean room", this is where master mix is made, the clean room has two doors one going to the hall with the "PCR dirty room" right across the hall, and one door going into a separate room that has the BioRad CFX 96 analyzer in it. In order to get to the analyzer you have to walk through the "PCR clean room". 2. Interview with TP #1 on September 12, 2023 at 4:00 PM stated "I prepare patient specimens in the PCR dirty room", this is the room across the hall from the PCR clean room. "I go into to the clean area and make master mix after I prepare patient specimens because they have to sit 5 minutes. Then I walk across the hall with the master mix into the dirty room, prepare the plates and then walk across the hall through the clean room to the room with the analyzer to perform patient testing." 3. Interview on September 13, 2023 at 12:00 PM with the TP #1 confirmed the laboratory failed to have an uni-directional workflow to include separate areas to prevent contamination of patient specimens.
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 observation of the laboratory refrigerator, freezer, and room temperature reagents, review of quality control (QC) package inserts, review of the performance verification procedures for the Siemens Viva Pro E toxicology analyzer, patient results, performance verification procedures for the LC/MS, review of Siemens Viva Pro E quality control (QC) records, Agilent 6460 Triple Quad LC/MS QC, the lack of documentation for the parameters of acceptable QC, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow SARS COVID 19 procedure and failed to follow urine toxicology specimen storage procedure (Refer to D5401); the laboratory failed to follow manufacturer's instructions for Siemens Syva Emit reagents (Refer to D5411); the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the Bio-Speedy Direct RT- qPCR SARS-CoV-2 testing kits stored in freezer #7 (Refer to D5413); the laboratory failed to label reagents and identify preparation and expiration

	dates (Refer to 5415); the laboratory failed to ensure the laboratory's reagents, quality control material and calibrators were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to verify performance specifications prior to reporting patient test results for the Siemens Viva Pro E System chemistry analyzer (Refer to D5421); the laboratory failed to perform and document function checks for the laboratory's pipettes, centrifuges and the laboratory biosafety cabinet (Refer to D5435); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469); and the laboratory's procedure cut off value for Gabapentin and Pregabalin did not match the cut off value on the patient test reports (Refer to D5807).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of SARS COVID 19 procedure, review of COVID 19 patient reports, and interviews with testing personnel (TP) #1 and TP # 4, the laboratory failed to follow SARS COVID 19 procedure for 9 patients on September 6, 2023. Findings: 1. Review of "Bio-Speedy Direct RT-qPCR SARS-CoV-2" procedure states "Specimens can be stored at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70 degrees Celsius or lower, ship overnight to the laboratory on dry ice." 2. Interview with TP #1 on September 13, 2023 at 9:30 AM stated "I did not know we had to freeze COVID 19 specimens. We do not have a freezer that goes to -70". 3. Review of patient reports showed the following patient COVID 19 testing performed on 9/6/23 when patient specimens were not stored at -70 degrees Celsius: Patient A specimen obtained on 8/31/23 at 10:30 AM. Specimen should have been froze on 9/3/23. Patient B specimen obtained on 8/30/23. Specimen should have been froze on 9/2/23. Patient C specimen obtained on 8/30/23. Specimen should have been froze on 9/2/23. Patient D specimen obtained on 9/1/23 at 12:00 PM. Specimen should have been froze on 9/4/23. Patient E specimen obtained on 9/1 /23 at 9:45 AM. Specimen should have been froze on 9/4/23. Patient F specimen obtained on 9/1/23 at 9:30 AM. Specimen should have been froze on 9/4/23. Patient G specimen obtained on 8/31/23 at 3:30 PM. Specimen should have been froze on 9/3 /23. Patient H specimen obtained on 8/31/23 at 4:00 PM. Specimen should have been froze on 9/3/23. Patient I specimen obtained on 8/31/23 at 2:30 PM. Specimen should have been froze on 9/3/23. The laboratory could not provide the number of COVID-19 patient's resulted on September 6, 2023. 4. Interview with TP #1 and TP #4 on September 13, 2023 at 10:30 AM confirmed the laboratory failed to follow SARS COVID 19 procedure for 9 patients.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of Siemens Syva Emit reagent package inserts, observation of Siemens Viva Pro E urine toxicology analyzer, review of patient reports, and interview with the testing personnel (TP) #3 and TP #4, the laboratory failed to follow manufacturer's instructions for reagent storage for seven of seven reagents. Findings: 1. The laboratory had no package inserts available on day of survey and printed them while the surveyors were onsite. 2. Review of creatinine, pH, cocaine, opiate, amphetamine, benzodiazepine, and barbiturate Siemens Syva Emit reagent package inserts states "When not in use, store the reagents at 2-8 degrees Celsius, upright and with screw caps tightly closed. Improper storage of reagents can affect assay performance." 3. Observation of Siemens Viva Pro E toxicology screening analyzer showed 23 reagent bottles were on board without screw cap. Observation of 4 of 23 uncapped bottles on board showed: pH lot #52 expiration 5/3/24 wrote on bottle with no screw cap. Barbiturate R1 lot #52 expiration 4/5/25 wrote on bottle with no screw cap. Creatinine R1 lot #51 expiration 1/6/25 wrote on bottle with no screw cap. Cocaine R1 lot #54 expiration 4/28/24 wrote on bottle with no screw cap. The laboratory was unable to provide the number of patients tested, date and time of last toxicology screening performed before September 13, 2023. 4. Interview with TP #3 on September 13, 2023 at 11:00 AM stated "the bottles stay on the analyzer at all times and we do not cap them". 5. Review of patient reports showed on March 28, 2023 toxicology screening was performed including the analyte methadone. A toxicology patient report from September 5, 2023 does not have the analyte methadone on it. The laboratory was unable to provide the date they stopped testing methadone. The laboratory was unable to provide Siemens Syva Emit reagent package insert for methadone. 6. Interview with the TP #3 and TP #4 on September 13, 2023 at 12:00 AM, confirmed the laboratory failed to follow manufacturer's instructions.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the package insert for the Bio-Speedy Direct RT- qPCR SARS-CoV-2 testing kit, review of laboratory temperature logs from October 2022 to date September 13, 2023 and interview with the technical supervisor (TS) #1, the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the Bio-Speedy Direct RT- qPCR SARS-CoV-2 kits stored in freezer #7 for 240 of 240 testing days. Findings: 1. Review of package insert for the Bio-Speedy Direct RT- qPCR SARS-CoV-2 testing kit states, "Storage -20 degrees Celsius." 2. Review of laboratory temperature logs from October 2022 to date September 13, 2023 showed freezer #7 with an unacceptable temperature range for 240 of 240 testing days. 3. The laboratory was unable to provide the number of COVID-19 tests performed from October 2022 to date September 13, 2023 while the

	Bio-Speedy Direct RT- qPCR SARS-CoV-2 testing kit was stored at an unacceptable temperature. 4. Interview with the technical supervisor #1 on September 13, 2023 at 12:00 PM confirmed the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the Bio-Speedy Direct RT- qPCR SARS-CoV-2 testing kits stored in freezer #7.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the freezer reagents, and interview with the testing personnel (TP) #1, the laboratory failed to label reagents and identify preparation and expiration dates. Findings: 1. Observation of the freezer showed four small brown bottles with no open date, no expiration date, and no label identifying the contents. 2. Interview with the TP #1 on September 13, 2023 at 12:30 PM confirmed the laboratory failed to label reagents and identify preparation and expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory's refrigerators, freezers and counters and interview with the technical supervisor (TS) #1, the laboratory failed to ensure the laboratory's reagents, quality control material and calibrators were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory refrigerators showed reagents, quality control material and calibrators still in use: 1 box of Siemens Syva Emit II Plus Cannabinoid Assay, lot # 9N3186L-N6 expiration date 06/18/2022 1 box Siemens Syva Emit II Plus Specific Gravity Validity Test, lot # 3T898Ul-P4 expiration date 11/30/2022 1 box of Siemens Syva Emit II Plus Specific Gravity Validity Test, lot # 3T898Ul-P1 expiration date 03/04/2022 1 box of Siemens Syva Emit II Plus Specific Gravity Validity Test, lot # 3T898Ul-N3 expiration date 06 /30/2021 1 box of Siemens Syva Emit II Plus Buprenorphine Assay, lot # 10872260-P1 expiration date 07/13/2022 1 box of Siemens Syva Emit II Plus Oxycodone Assay, lot # 11275150-P2 expiration date 01/14/2022 1 box of Siemens Syva Emit Ethyl Alcohol Negative Calibrator, lot # 9K028UL-P2 expiration date 06/11/2023 1 box of Siemens Syva Emit Ethyl Alcohol 100 mg/dL Calibrator, lot # 9K058UL-P2 expiration date 06/11/2023 1 box of Siemens Syva Emit Ethyl Alcohol Low Control, lot # 9K048UL-P1 expiration date 06/11/2023 1 box of Siemens Syva Emit Ethyl Alcohol High Control, lot # 9K078UL-P1 expiration date 06/11/2023 1 box of Siemens Syva Emit Oxycodone Negative Control 100, lot # 11275166-P1 expiration date 02/26/2022 1 box of Siemens Syva Emit Oxycodone Positive Control 100, lot #

	11275168-P1 expiration date 02/26/2022 1 box of Siemens Syva Emit 2000 Valproic Acid Calibrators, lot # 4G048UL-N3 expiration date 03/03/2022 1 vial of Siemens Syva Emit Creatinine Validity Calibrator 400, lot # 3T158UL-P1 expiration date 09/07 /2021 1 vial of Siemens Syva Emit Creatinine Validity Calibrator 100, lot # 3T148UL-N5 expiration date 07/17/2021 1 vial of Siemens Syva Emit pH Validity Calibrator 9.0, lot # 3T488UL-N4 expiration date 09/23/2021 1 vial of Siemens Syva Emit pH Validity Calibrator 2.0, lot # 3T388UL-N4 expiration date 09/23/2021 1 vial of Siemens Syva Emit pH Validity Calibrator 12.0, lot # 3T478UL-N4 expiration date 09 /23/2021 1 vial of Siemens Syva Emit pH Validity Calibrator 11.0, lot # 3T458UL-N4 expiration date 09/23/2021 1 vial of Siemens Syva Emit pH Validity Calibrator 4.5, lot # 3T498UL-N4 expiration date 09/23/2021 1 vial of Siemens Syva Emit Validity Calibrator/Control, lot # 3T128UL-N3 expiration date 12/02/2022 1 box of ARK-Tramadol Cut Off Calibrator, lot # W013207 expiration date 11/30/2021 1 box of ARK- Tramadol Control, lot # W013263 expiration date 11/30/2021 1 box standards chemical kit with low/high concentration PPG's lot # MOO7278 expiration date 6/16 /2021 1 box standards chemical kit with low/high concentration PPG's lot # M205637 expiration date 2/1//2023 2. Observation of the laboratory freezers showed reagents, quality control material and calibrators still in use: 1 box Direct RT-qPCR SARS-CoV-2 lot #2b11216N7PAC7R-TK1 expiration date 12/2022 1 box Direct RT-qPCR SARS-CoV-2 lot #2b11224EIN8R-TK10 expiration date 12/2022 1 7-6-L expiration date 8/26/2021 3. Observation of the laboratory counters showed reagents, quality control material and calibrators still in use: 2 bottles of J.T. Baker Hydrochloric Acid, 0.1 N Volumetric Solution batch #0000290004 expiration date 08/23/2023 2 bottles of J.T. Baker Sodium Hydroxide Acid, 0.1 N Volumetric Solution batch #0000277134 expiration date 01/20/2023 1 bottle of J.T. Baker Sodium Hydroxide Acid, 0.1 N Volumetric Solution batch #0000286075 expiration date 06/23/2023 1 bottle of J.T. Baker Sodium Hydroxide Acid, 0.1 N Volumetric Solution batch #0000281659 expiration date 04/14/2023 1 bottle of J.T. Baker Hydrochloric Acid, 0.1 N Volumetric Solution batch #0000288058 expiration date 07/21/2023 1 bottle of J.T. Baker Hydrochloric Acid, 0.1 N Volumetric Solution batch #0000287155 expiration date 07/08/2023 2 boxes COVID-19 Rapid Antigen Test INDIC AID lot # 21SO123 expiration date 5/23/2022 1 bottle EliTech Group for Viva Drug testing systems Lot #220288 expiration date 8/31/2023 4. The laboratory performs approximately 400,000 toxicology tests per year and approximately 1200 COVID tests per year. 5. Interview with the technical supervisor #1 on September 13, 2023 at 12:00 PM confirmed the laboratory failed to ensure the laboratory's reagents, quality control material and calibrators were not used when they had exceeded their expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance specifications procedures for the Siemens Viva Pro E System urine drug screening analyzer, patient results, and interview with the

	technical supervisor (TS) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Siemens Viva Pro E System chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: creatinine, and pH prior to the beginning of patient testing in 2021. 2. The laboratory was unable to provide the number of patient tests performed on the Siemens Viva Pro E System chemistry analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 3. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results on the Siemens Viva Pro E System urine drug screening analyzer.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of maintenance documentation and interview with the technical supervisor (TS) #1, the laboratory failed to perform and document function checks for the laboratory's pipettes, centrifuges and the laboratory biosafety cabinet for 2021, 2022, and to date September 13, 2023. Findings: 1. Review of the laboratory procedure "Pipette Procedure" states, "The pipettes should be calibrated once a year." 2. Lack of maintenance documentation showed the laboratory failed to perform and document the function checks for the following pipettes: one Dragonmed 10-100 microliter pipette serial # AP21117 in 2021, 2022 and to date September 13, 2023 one Finnpipette II 100 - 1000 microliter pipette serial # KU13483 in 2022 and to date September 13, 2023 one Finnpipette II 10 -100 microliter pipette serial # KU11698 in 2022 and to date September 13, 2023 one Fisher Elite 10- 100 microliter pipette serial # LU10650 in 2022 and to date September 13, 2023 one Four E's Scientific 100 - 1000 microliter pipette serial # 21393092 in 2021, 2022 and to date September 13, 2023 one Four E's Scientific 0.5 - 10 microliter pipette serial # 1121798 in 2021, 2022 and to date September 13, 2023 one CE 0.5 - 10 microliter pipette serial # CU0345952 in 2021, 2022 and to date September 13, 2023 3. Review of the laboratory procedure "Centrifuge Procedure" states, "Rpm check should be performed yearly and documented." 4. Lack of maintenance documentation showed the laboratory failed to perform and document the function checks for the following centrifuges: one Thermo Scientific Sorvall ST16 centrifuge in 2021, 2022 and to date September 13, 2023 one Eppendorf 5424 centrifuge in 2021, 2022 and to date September 13, 2023 5. Review of the laboratory procedure "Biological Level II Safety Cabinet" states, "The cabinet and the hoods should be calibrated by the vendors once a year." 6. Lack of maintenance documentation showed the laboratory failed to perform and document the function checks for the The Baker Company SterilGARD III Advance biosafety cabinet, serial

	# 93695 in 2021, 2022 and to date September 13, 2023. 7. The laboratory performs approximately 400,000 toxicology tests per year and approximately 1200 COVID tests per year. 8. Interview with the technical supervisor #1 on September 13, 2023 at 12:00 PM confirmed, the laboratory failed to perform and document function checks for the laboratory's pipettes, centrifuges and the laboratory biosafety cabinet.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Siemens Viva Pro E toxicology quality control (QC) records, and interview with the testing personnel (TP) #4, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Siemens Viva Pro E toxicology QC records showed the laboratory did not establish, document, and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC. 2. Review of Siemens Viva Pro E analyzer showed creatinine level 3 QC range of 2-6 mg/dL. The laboratory could not provide documentation for establishment of the QC range. 3. Review of Siemens Viva Pro E analyzer showed creatinine level 4 QC range of 19.55-26.45 mg /dL. The laboratory could not provide documentation for establishment of the QC range. 4. Review of Siemens Viva Pro E analyzer showed pH level 3 QC range of 8.67-11.73. The laboratory could not provide documentation for establishment of the QC range. 5. Review of Siemens Viva Pro E analyzer showed pH level 2 QC range of 3.06-4.14. The laboratory could not provide documentation for establishment of the QC range. 6. The laboratory was unable to provide the number of patient tests performed on the Siemens Viva Pro E System chemistry analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 7. Interview with the TP #4 on September 13, 2023 at 10:00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5807	TEST REPORT CFR(s): 493.1291(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 review of laboratory procedures, review of patient test reports for urine drug confirmation testing and interview with the technical supervisor (TS) #1, the laboratory failed to ensure the procedure cut off values matched the cut off value on the patient test report for two of 46 analytes. Findings: 1. Review of the laboratory procedure "Method 1 Pain Panel Drugs in Urine by LC/MSMS" states the cut-off value for "Gabapentin as 500 ng/mL and Pregabalin as 500 ng/mL." 2. Review of the patient test reports for urine drug confirmation testing showed the cut-off value for Gabapentin as 200 ng/mL and Pregabalin as 200 ng/mL. 3. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed that the laboratory's procedure cut off value for Gabapentin and Pregabalin did not match the cut off value on the patient test reports.
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 review SARS COVID-19 procedure, review of "Pre-Analytical Procedure" for urine toxicology review of Agilent 6460 Triple Quad LC/MS procedure, review of academic credentials, review of Agilent 6460 Triple Quad LC/MS analyzer quality control (QC), review of Siemens Viva Pro E toxicology screening analyzer quality control (QC), procedures, lack of available delegation of duties for the technical supervisors, and interviews, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that patient toxicology screening provide quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analytes pH and creatinine (Refer to D6082); laboratory director failed to ensure laboratory personnel were performing SARS COVID-19 patient specimens according to manufacturer's instructions to ensure accurate and reliable test results (Refer to D6087); the laboratory director failed to ensure the urine toxicology confirmation QC program is maintained to identify failures in quality as they occur (Refer to D6093); the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for five analytes (Refer to D6095); the laboratory director failed to ensure TP #4 was qualified prior to patient testing (Refer to D6102); the lab director could not provide an approved written procedure for the Siemens Viva Pro E System and for cut-off values for urine drug screening testing (Refer to D6106); and the laboratory director failed to specifically delegate in writing the responsibilities and duties of each technical supervisor (Refer to D6107).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 observation of toxicology urine specimens, review of "Pre-Analytical Procedure" for urine toxicology, review of Siemens Syva package inserts, and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure that patient toxicology screening provides quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analytes pH and creatinine. Findings: 1. Observations on day of survey September 13, 2023 at 10:00 AM revealed 7 bags of patient urine toxicology samples waiting to be tested at room temperature. Bag #1 approximately 10 patient urine specimens in a bag dated September 12, 2023 Bag #2 approximately 12 patient urine specimens in a bag dated September 11, 2023 Bag #3 approximately 10 patient urine specimens in a bag dated September 11, 2023 Bag #4 approximately 10 patient urine specimens in a bag dated September 12, 2023 Bag #5 approximately 10 patient urine specimens in a bag dated September 12, 2023 Bag #6 approximately 9 patient urine specimens in a bag dated September 11, 2023 Bag #7 approximately 9 patient urine specimens in a bag dated September 12, 2023 2. Review of "Pre-Analytical Procedure" for urine toxicology states "If sample is not tested immediately it should be refrigerated until the day of analysis". Interview with TP #1 on September 13, 2023 at 10:30 AM stated "I did not know we have to refrigerate urine toxicology specimens." The laboratory was unable to provide a procedure stating how long patient urine specimens are stable for at room temperature and refrigerated. 3. Review of Siemens Syva creatinine reagent package insert states "Creatinine in urine is stable for 1-2 days when stored at 2-10 degrees Celsius." The laboratory had no package inserts available on day of survey and printed them while the surveyors were onsite. 4. Review of Siemens Syva pH reagent package insert states "Very dilute urine specimens may cause erroneous pH results. Specimens with a creatinine value less than 20 mg/dL or a specific gravity ready less than 1.003 should have a pH value verified by an alternate method, such a pH meter". The laboratory could not provide a procedure for addressing dilute urine specimens. 5. The laboratory was unable to provide the number of patient tests performed on the Siemens Viva Pro E System chemistry analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 6. Interview with the TP #1 on September 13, 2023 at 12:15 PM confirmed the LD failed to ensure that patient toxicology screening provide quality laboratory services for all aspects of test performance, which includes the preanalytic and analytic phases of testing for the analytes pH and creatinine.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of SARS COVID-19 procedure and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure laboratory personnel were performing SARS COVID-19 patient specimens according to manufacturer's instructions to ensure accurate and reliable test results. Findings: 1. Review of Bio-Speedy Direct RT qPCR SARS-CoV-2 manufacturer's instructions stated "Different laboratory coats should be worn pre- and post-PCR.". Interview with TP #1 stated "I did not know that was in the procedure. We do not change lab coats." 2. Review of Bio-Speedy Direct RT qPCR SARS-CoV-2 manufacturer's instructions stated "Master stock reagents should be kept on the cold block during the PCR setup.". Interview

	with TP #1 stated "We do not use cold blocks during PCR setup". 3. Interview with TP #1 on September 13, 2024 at 11:45 AM confirmed the LD failed to ensure laboratory personnel were performing SARS COVID 19 patient specimens according to manufacturer's instructions to ensure accurate and reliable test results.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of "Method 1 Pain Panel Drugs in Urine by LC/MSMS" procedure, review of "Omolon LLC LCMS Toxicology First Review Checklist", review of Agilent 6460 Triple Quad LC/MS analyzer quality control (QC), interview with testing personnel (TP) #4, the laboratory director (LD) failed to ensure the urine toxicology confirmation QC program is maintained to identify failures in quality as they occur for 6 of 23 LC/MS runs. Findings: 1. Review of "Method 1 Pain Panel Drugs in Urine by LC/MSMS" procedure states, "If 2 or 3 out of 3 QC's fail, and there are patient specimens which show the concentrations of the drugs greater that LOD, then corrective action is started as follows: The failed QC's are reanalyzed by the instrument, or re-calibration is performed, or the failed QC is prepared again and reanalyzed by the instrument. After the QC issues are fixed, the positive specimens whose concentrations are greater the LOD of each drug will be reinjected. In addition, the positive specimens which show the concentrations of the drugs greater than LOD can be reanalyzed on the next batch. This corrective action must be documented." 2. Review of "Omolon LLC LCMS Toxicology First Review Checklist" showed TP #4 reviewed LC/MS data and documented to rerun positives on the following dates: 12/12 /2022, 5 patient samples 12/15/2022, 5 patient samples 12/28/2022, 1 patient sample 1 /25/2023, 4 patient samples 2/16/2023, 2 patient samples 8/8/2023, 3 patient samples 3. Review of Agilent 6460 Triple Quad LC/MS analyzer QC showed QC failed on the below dates, patients had potential positive results and no repeat of QC or re-calibration: 12/12/2022 12/15/2022 12/28/2022 1/25/2023 2/16/2023 8/8/2023 4. The laboratory was unable to provide the number of patient tests performed on the Agilent 6460 Triple Quad LC/MS analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 5. Interview with TP #4 on September 13, 2023 at 12:15 PM confirmed the LD failed to ensure the urine toxicology confirmation QC program is maintained to identify failures in quality as they occur.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 review of Siemens Viva Pro E toxicology screening analyzer quality control (QC) and interview with testing personnel (TP) #4, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical

	performance for the Siemens Viva Pro E toxicology screening analyzer for five of five analytes. Findings: 1. Review of Siemens Viva Pro E toxicology screening analyzer QC for cocaine metabolite, opiate, benzodiazepine, barbiturates and amphetamine showed no establishment of acceptable levels of QC. The laboratory could not provide documentation for establishment of the QC ranges. 2. The laboratory was unable to provide the number of patient tests performed on the Siemens Viva Pro E System chemistry analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 3. Interview with TP #4 on September 13, 2023 at 11:00 AM confirmed the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for five analytes.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of academic credentials and interview with the technical supervisor (TS) #1, the laboratory director failed to provide academic credentials to qualify one of four testing personnel prior to patient testing. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing personnel (TP) #4 was qualified to perform high complexity testing. TP #4 is the only testing personnel interpreting LC/MS urine drug confirmation testing data. 2. The laboratory was unable to provide the number of patient tests performed on the Agilent 6460 Triple Quad LC/MS analyzer from 2021 to date September 13, 2023. The laboratory performs approximately 400,000 toxicology tests per year. 3. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed the laboratory director failed to ensure TP #4 was qualified prior to patient testing.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, patient reports and interview with the technical supervisor (TS) #1, the laboratory director (LD) failed to provide an approved written procedure for the Siemens Viva Pro E System or for cut-off values for urine drug screen testing. Findings: 1. Review of the laboratory procedures showed no approved procedure for the Siemens Viva Pro E System or for cut-off values for urine drug screen testing performed on the Siemens Viva Pro E System for the analytes cocaine metabolite, opiate, benzodiazepine, barbiturates, and amphetamine. 2. Review of patient reports showed on March 28, 2023 toxicology screening was performed including the analyte methadone. A toxicology patient report from September 5, 2023 does not have the analyte methadone on it. The

	laboratory was unable to provide the date they stopped testing methadone. The laboratory was unable to provide a procedure with the approved cut-off value for methadone. 3. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed the LD could not provide an approved written procedure for the Siemens Viva Pro E System or for cut-off values for urine drug screen testing.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of available delegation of duties for the technical supervisors and interview with the technical supervisor (TS) #1, the laboratory director failed to specify, in writing, the responsibilities and duties of each technical supervisor engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Findings: 1. No delegation of duties for technical supervisor #1 and #2 were available on September 13, 2023. 2. Interview with the technical supervisor (TS) #1 on September 13, 2023 at 12:00 PM confirmed that the laboratory director failed to specifically delegate in writing the responsibilities and duties of each technical supervisor.
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 review of personnel records and interview with the technical supervisor (TS) #1, the laboratory failed to provide documentation of academic credentials and laboratory training or experience, or both, required to qualify the individual serving as technical supervisor #2 (Refer to D6109).
D6109	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

	This STANDARD is not met as evidenced by: Based on review of academic credentials and interview with the technical supervisor (TS) #1, the laboratory failed to provide academic credentials to qualify one of two technical supervisors. Findings: 1. The laboratory could not provide documentation (academic credentials) to show technical supervisor #2 was qualified to provide technical supervision for the subspecialty, bacteriology for COVID-19 real-time polymerase chain reaction (PCR) testing and for the subspecialty, toxicology for liquid chromatography-mass spectrometry (LC/MS) confirmation drug testing. 2. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed the documents needed to qualify technical supervisor #2 were not available for review.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS) #1, one of four testing personnel did not meet the academic qualifications required to perform high complexity testing (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical

	laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of academic credentials and interview with the technical supervisor (TS) #1, the laboratory failed to provide academic credentials to qualify one of four testing personnel. Findings: 1. The laboratory could not provide documentation (academic credentials) to show testing personnel #4 was qualified to perform high complexity testing. 2. Interview with the TS #1 on September 13, 2023 at 12:00 PM confirmed the documents needed to qualify testing personnel #4 were not available for review.