Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2224035	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Revive Medical Group	7150 South Madison Ave, Medical Suite 2, Indianapolis, IN	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to keep food materials away from hazardous reagents in one (nursing area "Revive Lab") of two refrigerators observed. Findings Included: 1. During a tour of the nursing area on 11-28-22 at 2:54 PM, a refrigerator labeled "Revive Lab" was in the room. Inside the refrigerator was "MGC Primary DAU" control set and "Creatinine Detect Test" along with lunch boxes and soda. The refrigerator was labeled "Meds and Medical Only". 2. Review of "DRI Creatinine-Detect Test" stated "This test is for in vitro diagnostic use only. The reagents are harmful if swallowed. The assay components contain .0.09% sodium azide, 0.2% bovine serum albumin (BSA) and 0.5% Drug-specific antibody (Mouse). Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing." 3. During an interview on 11/28/2022 at 3:00 pm

	with office member (nurse), they could not confirm what happens in the room due to laboratory staff leaving earlier in the day. 4. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation, record review, lack of documentation, and interview, the laboratory failed to perform twice annual proficiency testing (PT) for fourteen of fourteen toxicology analytes with testing performed prior to ceasing testing in November 2022. Finding included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology testing. 2. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11 /29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure on the performance of twice annual PT for Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3, 4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 3. Review of proficiency records revealed no documentation of performance of PT twice annually for Amphetamine, Barbiturate, Benzene, Bupropion Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity for 2022. 4. During an interview on 11/29/2022 at 12: 18 PM SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send proof of proficiency testing for the toxicology analytes. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain information for proficiency testing for toxicology analytes. 5.During an interview on 11/28/2022 at 11:24 am, SP#1 (Testing personnel) stated the laboratory had cease testing due to deionized (DI) water problems in November 2022. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, lack of documentation, and interview, the laboratory failed to meet the preanalytic system requirements. The laboratory failed to have a written request or standing order for tests performed on thirty of thirty patients (PT#1-PT#30) on BS-480 Chemistry Analyzer in January 2022 through October

	2022. (Refer to D5301). The laboratory failed to have a system to document date and time urine specimen is received by the lab for 30 (PT#1-PT#30) out of 41 patients reviewed. (Refer to D5313).
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview, the laboratory failed to have a written request or standing order for tests performed on thirty of thirty patients (PT#1-PT#30) on BS-480 Chemistry Analyzer in January 2022 through October 2022. Findings include: 1. Review of patient (PT#1-PT#30) medical records indicated toxicology tests were performed on the BS-480 Chemistry Analyzer ran in 2022 as follows: PT#1 on 09/23/22 and 10/03/22 PT#2 on 10/03/22 PT#3 on 09/23/22, 09/26 /22 and 10/03/22 PT#4 on 09/26/22 PT#5 on 09/26/22 PT#6 on 09/23/22 and 09/26 /22 PT#7 on 09/26/22 PT#8 on 09/26/22 PT#9 on 09/26/22 PT#10 on 09/26/22 PT#11 on 09/26/22 PT#12 on 09/23/22 PT#13 on 09/23/22 PT#14 on 09/23/22 PT#15 on 04 /08/22 PT#16 on 03/29/22 PT#17 on 03/29/22 PT#18 on 02/22/22 PT#19 on 01/28/22 and 02/15/22 PT#20 on 02/11/22 PT#21 on 02/11/22 PT#22 on 02/11/22 PT#23 on 01 /28/22 PT#24 on 01/28/22 PT#25 on 01/28/22 PT#26 on 01/28/22 PT#27 on 01/28/22 PT#28 on 01/28/22 PT#29 on 01/28/22 PT#30 on 01/28/22 2. On 11/28/22 at 12:45 PM, upon request for tests requests or standing order for each patient tested, SP-3 (Owner) was not able to provide referral/ order for patient medical records. 3. On 11 /28/22 at 12:55 PM, SP-4 was provided email information and a copy of patient medical records to forward the referral/order to surveyors by the end of the day, but no referral/orders were received. 4. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on observation, record review, lack of documentation, and interview, the laboratory failed to have a system to document date and time urine specimens are received by the laboratory for 30 (PT#1-PT#30) out of 41 patients reviewed. Findings Included: 1. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure for how urine specimens are received by the laboratory. 2. Review of Patients Records revealed the following: a. PT#23-PT#30 patient reports stated urine specimens were collected on 1/28/2022 but there was no documentation of when they were received by the laboratory with date and time. b. PT#3-PT#11 patient reports stated urine specimens were collected on 9/26/2022 but there was no documentation of when they were received by the laboratory with date and time. c. PT#1, PT#6, PT#12-PT#14 patient reports stated urine specimens were collected on 9/23/2022 but there was no documentation of when they were received by the laboratory with date and time. d. PT#20-PT#22 patient reports stated urine

	specimens were collected on 2/11/2022 but there was no documentation of when they were received by the laboratory with date and time. e. PT#16-PT#17 patient reports stated urine specimens were collected on 3/29/2022 but there was no documentation of when they were received by the laboratory with date and time. f. PT#19 patient report stated urine specimens were collected on 2/15/2022 but there was no documentation of when they were received by the laboratory with date and time. g. PT#2 patient report stated urine specimens were collected on 10/3/2022 but there was no documentation of when they were received by the laboratory with date and time. f. PT#15 patient report stated urine specimens were collected on 4/8/2022 but there was no documentation of when they were received by the laboratory with date and time. g. PT#18 patient report stated urine specimens were collected on 2/22/2022 but there was no documentation of when they were received by the laboratory with date and time. 3. During an interview on 11/28/2022 at 10:27 AM, SP#2 (Owner) stated the laboratory could pull up patients results with orders and receive time from the rehab center in the cloud. The results with orders and receive times were never received. 4. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
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, record review, lack of documentation, and interview, the laboratory failed to meet the analytic systems requirements: 1. The laboratory failed to have a procedure manual that included: urine specimen collection; step by step procedure for how to perform testing for toxicology analytes: Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity, quality control procedure; calibration; reportable ranges; urine specimen labeling; urine specimen storage; criteria for urine specimen acceptability and rejection; and course of action if the toxicology test system becomes inoperable. (Refer to D 5403) 2. The laboratory failed to monitor temperature for one out of two refrigerators that held reagents and calibrators from January 2022 to October 2022 and 41 of 41 patients (PT#1-PT#41) reviewed. (Refer to D5413) 3. The laboratory failed to label reagents and calibrators to indicate expiration date, lot number and identify for the 28 reagents and 3 calibrators in the testing carousel of one of one analyzer (BS-480 Chemistry analyzer). (Refer to D5415) 4. The laboratory failed to remove expired reagents and calibrators in the RCR fridge and expired blood tubes from use during patient testing. (see D5417) 5. The laboratory failed to complete a validation of their BS-480 Chemistry analyzer for the following analytes: Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity before performing patient testing for 41 of 41 patients (PT#1-PT#41) reviewed. (Refer to D5421) 6. The laboratory failed to perform the required daily, weekly and monthly maintenance for BS-480 Chemistry analyzer during patient

	testing 1/28/22 -10/14/2022. (Refer to D5431) 7. The laboratory failed to perform calibration as required by the manufacture on the BS-480 Chemistry Analyzer in January 2022 through October 2022 for twenty-nine of thirty patients (PT#1-PT#24 and PT#26-PT#30) reviewed. (Refer to D5437) 8. The laboratory failed to establish the use of calibrators for fourteen of fourteen toxicology analytes in use on BS-480 and 41 of 41 patients (PT#1-PT#41) reviewed. (Refer to D5439) 9. The laboratory failed to run two levels of toxicology quality controls (QC) at least once each day patient specimens are assayed for fourteen of fourteen analytes tested for 41 of 41 patients (PT#1-PT#41) reviewed from 1/28/2022-10/14/2022. (Refer to D5447)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 observation, record review, lack of documentation, and interview, the laboratory failed to have a procedure manual that included: urine specimen collection; step by step procedure for how to perform testing for toxicology analytes: Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity, quality control procedure; calibration; reportable ranges; urine specimen labeling; urine specimen storage; criteria for urine specimen acceptability and rejection; and course of action if the toxicology test system becomes inoperable. Findings included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology testing. 2. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, revealed there were no procedures for urine specimen collection; step by step procedure for how to perform testing for toxicology analytes: Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity; quality control procedure: calibration; reportable ranges; urine specimen labeling; urine specimen storage; criteria for urine specimen acceptability and rejection; and course of action if the toxicology test system becomes inoperable. 3. During an interview on

	11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send the procedure manual. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain the above listed procedures. 4. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
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 observation, record review, lack of documentation, and interview, the laboratory failed to monitor temperature for one out of two refrigerators that held reagents and calibrators from January 2022 to October 2022 and 41 of 41 patients (PT#1-PT#41) reviewed. Findings included: 1. During a tour of the laboratory room of the on 11-28-22 at 10:00 AM, revealed a "RCR" refrigerator with a blank temperature log for monitoring storage of Toxicology reagents. Toxicology reagents (DRITM Cannabinoid Assay) and calibrators stored in the refrigerator had labels for storage of 2-8 degrees Celsius. 2. Review of BS-480 installation binder revealed no temperature logs for "RCR" refrigerator from January 2022 to October 2022. 3. Review of "DRITM Cannabinoid Assay" stated "The reagents are ready for use. No reagent preparation is required. All assay components when stored properly at 2-8 C, are stable until the expiration date indicated on the label." 4. Review of patient records revealed 41 patients (PT#1-PT#41) were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 5. During an interview on 11/29/2022 at 12:18 PM SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send temperature logs for "RCR" refrigerator. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain temperature logs for RCR refrigerator from January 2022 to October 2022. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
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, record review, lack of documentation, and interview, the laboratory failed to label reagents and calibrators to indicate expiration date, lot

	number and identify for the 28 reagents and 3 calibrators in the testing carousel of one of one analyzer (BS-480 Chemistry analyzer). Findings included: 1. A laboratory tour of the 11/28/2022 at 10:47 AM, revealed the BS-480 Chemistry analyzer had bottles of 28 reagents and 3 calibrators in the testing carousel without lot number, expiration date and reagent name. There was also a storage box with empty bottles used to pour reagents into bottles to load onto the reagent carousel. 2. Review of "BS-480 Chemistry Analyzer Operator's Manual" stated "The system provides the manual and auto check of inventory of biochemical. During the test, the system automatically checks the reagent inventory and displays it on the Reagent/Calibration screen. After the reagents are loaded, it is necessary to perform the inventory check in order to ensure that sufficient reagents are available for analysis. Reagent inventory check is allowed only when the system status is Incubation or Standby. While the system is checking reagent inventory, loading or unloading reagents on the current module is not permitted, and the Utility button is disabled. If your system is equipped with a reagent bar code reader, you may put the bar-coded reagents on the reagent carousel, and the system will scan all reagent positions automatically and obtain reagent information from the bar code label. The bar code scanning is only applied to biochemical reagents. The reagent probe wash solution and physiological saline can only be loaded manually rather than bar code scanning." The laboratory can either load reagents manually or use the barcode on the reagent. 3. Review of "BS-480 instrument reagent log" revealed no written or electronic documentation of the what reagents are currently loaded in the BS-480 Chemistry analyzer. 4. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11 /29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure for reagent and calibrator labeling in the instrument. 5. During an interview on 11/29/2022 at 11:24 AM SP#1 (Testing personnel) confirmed the reagents and calibrators were not labeled with expiration, name and lot number in the reagent and calibrator carousel. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
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, record review and interview, the laboratory failed to remove expired reagents and calibrators in the "RCR" refrigerator and expired blood tubes (expiration dates of 4/3/2022 to 10/31/2022) from use. Findings Included: 1. A tour of the laboratory room of the on 11-28-22 at 10:00 AM, revealed a "RCR" refrigerator that held expired Toxicology reagents. The Toxicology reagents and blood tubes are expired as follows: a) PH -Detect test: reference: 100054 expired 7-31-2022 b) PH - Detect kit: reference: 100054 expired 10/31/2022 c) "MGC Primary DAU Control Set" reference: 1000202 expired 10/31/2022 d) Creatinine- Detect Calibrator kit reference: 100272 expired 4/3/2022 e) Ecstasy calibrator lot 74147692 expired 6/30 /2022 f) MDMA calibrator lot 74147693 expired 7/31/2022 g) Oxycodone Calibrator lot 74110380 expired 10/31/2022 h) 2 Blood tube packages in cabinet expired 4/30 /2022 and 9/10/2022 2. Review of "DRI pH-Detect Test, Calibrators and Controls" package insert stated "The reagent and calibrators are ready for use. No reagent preparation is required. All assay components, when stored properly at 2C to 8C, are

	stable until the expiration date indicated on the label." 3. Review of "DRI Oxycodone Assay" package insert stated "The reagents are ready-to-use. No additional reagent preparation is required. The reagents should be stored refrigerated (2-8C). All assay components, opened or unopened, are stable until the expiration date indicated on their respective labels. Do not use the reagents beyond their expiration dates." 4. Review of "DRI Ecstasy Assay" package insert stated "The reagents are ready for use. No reagent preparation is required. All assay components, when stored refrigerated, are stable until the expiration date indicated on the label." 5. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure on how to handle expired reagents, calibrator and blood tubes. 6. During an interview on 11/28/2022 at 11:24 am, SP#1 (Testing personnel) indicated they did not dispose of reagents because they were waiting for the company to tell them what to do. 7. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
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 observation, record review, lack of documentation, and interview, the laboratory failed to complete a validation of their BS-480 Chemistry analyzer for the following analytes Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity before performing patient testing for 41 of 41 patients (PT#1-PT#41) reviewed. Findings included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology testing. 2. Review of "BS-480 installation" binders revealed no documentation of a validation for Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4 methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 3. Review of patient records revealed 41 patients (PT#1-PT#41) were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen and specific gravity. 4. During an interview on 11/28/2022 at 11:20 am, SP#1 (Testing personnel) confirm three binders were only used in the lab and the binders did not contain a validation for BS-480 Chemistry analyzer. 5. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, record review, lack of documentation, and interview, the laboratory failed to complete a validation of their BS-480 Chemistry analyzer for the following analytes Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity before patient testing for 41 of 41 patients (PT#1-PT#41) reviewed. Findings included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology testing. 2. Review of "BS-480 installation" binders revealed no documentation of a validation for Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4 methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 3. Review of Patient records revealed 41 patients (PT#1-PT#41) were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen and specific gravity. 4. During an interview on 11/28/2022 at 11:20 am, SP#1 (Testing personnel) confirm three binders were only used in the laboratory and the binders did not contain a validation for BS-480 Chemistry analyzer. 5. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review, observation, lack of documentation, and interview, the laboratory failed to perform calibration as required by the manufacture on the BS-480 Chemistry Analyzer in January 2022 through October 2022 for twenty-nine of thirty patients (PT#1-PT#24 and PT#26-PT#30) reviewed. Findings include: 1. Review of patient (PT#1-PT#24 and PT#26-PT#30) medical records indicated "flag" errors (LOW and RRN) for reagents: Amphetamine (AMPH), Benzodiazepine (BENZ), Buprenorphine (BUPR), Methadone (MTD), Opiates (OPI300), Oxycodone (OXY), Cocaine (COC) and Cannabinoids (THC) for twenty-three of twenty-four tested on the BS-480 Chemistry Analyzer for six of ten months (January 2022 through October 2022) reviewed. PT#19, PT#23 thru PT#30 on 01/28/22 for Flags: LOW- BURP,

	MTD, OPI300, OXY, and THC and RRN-BUPR PT#20 thru PT#22 on 02/11/22 for Flags: LOW- BURP and RRN-AMPH and THC PT#19 on 02/15/22 for Flag: LOW-BUPR and RRN-AMPH PT#18 on 02/22/22 for Flag: LOW-BUPR PT#16 thru PT#17 on 03/29/22 for Flag: LOW-BENZ, BURP, MDMA, MTD, OPI300, OXY, and THC PT#15 on 04/08/22 for Flag: LOW- BENZ, MTD, OPI300, OXY, and THC PT#1, PT#3, PT#6, PT#12 thru PT#14 on 09/23/22 for Flag: LOW- AMPH, BARB, BENZ, BURP, COC, MTD, OPI300, and THC PT#3 thru PT#11 on 09/26/22 for Flag: LOW- AMPH, BARB, BENZ, BURP, COC, MDMA, MTD, OPI300, and THC PT#1 thru PT#3 on 10/03/22 for Flag: LOW- AMPH, BARB, BENZ, COC, MTD, OPI300, OXY, and THC 2. "BS-480 Chemistry Analyzer Operator's Manual" issued in 2015, under 17.4.2 Result Flags, Table 17.7 Result flags and corrective actions, and error codes were identified as follow: a. Flag description "LOW" states "probable cause is the sample concentration is lower than the sensitivity indicated on the reagent pack, making response less than that of the lowest-concentration calibrator." The corrective action states, "rerun the test with standard or increased sample volume; for descending calibration curve, rerun the test with diluted sample" on pg. 742. b. Flag description "RRN" states "probable cause is the sample concentration exceeds the high limit of the calibrator concentration." The corrective action states, "rerun the test with diluted sample" on pg. 746. 3. Review of Revive Medical Group policy, "Procedures for Operating Procedures for running Mindray-BS480" under "Calibration" states, "If any of the following chemistry parameters are changed, a calibration is required for "reagent volume (R1/R2/R3/R34) and sample volume." 4. On 11/28/22 at 10:39 AM, during the laboratory tour, expired calibrators were observed in the refrigerator for the following: a. Oxycodone (OXY), LOT: 74147696, EXP: 2022 06 30 b. Ecstasy or Methylenedioxymethamphetamine (MDMA), LOT: 74147692, EXP: 2022 06 30 LOT: 74147693, EXP: 2022 07 31 LOT: 74147694, EXP: 2022 06 30 5. During an interview on 11/29/2022 at 12:18 PM, SP-1 (Testing personnel) and SP-2 (owner 2) stated that they would send calibration records for BS-480. An email was sent by SP-1 on 11/29/2022 at 11:57 PM, it did not contain calibration records for BS-480. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review, lack of documentation, and interview, the laboratory failed to perform the required daily, weekly and monthly maintenance for BS-480 Chemistry analyzer during patient testing 1/28/22 -10/14/2022. Findings included: 1. Review of the "Procedures For Operating Procedures for running Mindray-BS480"given by SP-1(testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, stated "Perform Scheduled Maintenance & Log - Daily, Weekly, Bi-weekly, monthly, three-month, 6 months, and as needed or as required maintenance Check when last maintenance was performed in each time category: Daily Maintenance: " Check probes/mixers/wash wells " Check sample /reagent syringes " Check deionized water " Check waste " Check concentrated /diluted wash solution " Clean electrode tubes Weekly Maintenance: " Clean sample /reagent probe exterior " Clean mixers " Diluted wash " Cuvette check " Photometer check Monthly Maintenance: " Clean wash wells " Clean rotors " Clean wash station " Clean filter core " Clean dust screens " Clean sample injection port " Pump calibration " Air bubble detector calibration " Clean the dust screen of the external vacuum pump 3-month maintenance: " Clean DI water tank " Replace filter core " Replace sample syringe " Replace reagent syringe 6-month maintenance: " Replace lamp " Replace water inlet filter " Replace reference electrode " Replace pump tube" 2. Review of "BS-480 instrument maintenance log" revealed no written or electronic documentation of the maintenance done for the Bs-480 Chemistry analyzer from January 2022-October 2022. 3. Review of Patient records revealed 41 (PT#1-PT#41) patients were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE, 300 Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 4. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send BS-480 instrument maintenance log. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain a BS-480 instrument maintenance log. 5. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run two levels of toxicology quality controls (QC) at least once each day patient specimens are assayed for fourteen of fourteen analytes tested for 41 of 41 patients (PT#1-PT#41) reviewed from 1/28/2022-10/14/2022. Findings Included: 1. Review of "BS-480 Chemistry Analyzer Operator's Manual" stated a "QC run may require more than one control samples. You are recommended to use two control samples, one with normal values (within the reference range) and the other with abnormal values (beyond the reference range). To ensure the system performance, run control samples every time after you

perform a calibration, or change the reagent lot, or maintain and troubleshoot the instrument." 2. Review of the "Laboratories Standard Operating Procedures" given by SP#1(testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure on how QC is performed. 3. Review of "DRI Amphetamines Assay" package insert stated "Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." 4. Review of QC Results revealed the following toxicology QC failures and no QC runs: A. Failures of the following controls on 1/28/2022: Amphetamine (AMPH): controls for (DOAT 4 AMPH) (DOAT 5 AMPH) were not in range. No negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): value for BUPR L1 control was not in range. No negative control. Cocaine (COC): controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): controls for DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): Control for DOAT 4 OXY and DOAT 5 OXY were not in range. No negative control delta-9 tetrahydrocannabinol (THC): no negative control. creatinine (CRET-D): controls for Cret-D 1.3 Cret-D were not range. No negative control potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control. B. Failures of the following controls on 2/11/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range. No negative control. Barbiturate (BARB): the values for controls for DOAT 4 Barb and DOAT 5 Barb were not in range. No negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for control BUPR L1 were not in range. No negative control. Cocaine (COC): the values for controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. Methadone (MTD): the values for controls DOAT 2 MTD and DOAT 3 MTD were not in range. No negative control. OPIATE 300 (OPI300): the values for DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): the values for controls DOAT 4 OXY and DOAT 5 OXY were not in range. No negative control. delta-9 tetrahydrocannabinol (THC): the values for controls for DOAT 4 THC were not in range. No negative control. creatinine (CRET-D): the values for controls Cret-D 1.3 Cret-D and Cret-D 7.5 Cret-D were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control. C. Failures of the following controls on 2/15/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range, and no negative control. Barbiturate (BARB): the values for controls DOAT 4 Barb and DOAT 5 Barb were not in range and no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for controls BUPR L1 and BUPR L2 were not in range, and no negative control. Cocaine (COC): the controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): No negative control. Methadone (MTD): the control values for DOAT 3 MTD were out of range. No negative control OPIATE 300 (OPI300): the values for controls DOAT 2 OPI300 and DOAT 3 OPI

300 were not in range. No negative control. Oxycodone (OXY): the control values for DOAT 4 OXY and DOAT 5 OXY were out of range. No negative control. delta-9 tetrahydrocannabinol: the values for controls for DOAT 4 THC were not in range. No negative control creatinine (CRET-D): the values for controls Cret-D 1.3, Cret-D 7.5 and Cret-D 23 were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control. D. Failures of the following controls on 2/22/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range, and no negative control. Barbiturate (BARB): the values for controls DOAT 4 Barb and DOAT 5 Barb were not in range and no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for controls BUPR L1 and BUPR L2 were not in range, and no negative control. Cocaine (COC): the following controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. Methadone (MTD): the control values for DOAT 2 MTD and DOAT 3 MTD were out of range. No negative control OPIATE 300: the values for controls DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): the values for the controls DOAT 4 OXY and DOAT 5 OXY were not within range. No negative control. delta-9 tetrahydrocannabinol (THC): the values for the control DOAT 4 THC was not in range. No negative control. creatinine (CRET-D): the values for the control Cret-D 1.3 Cret-D and Cret-D 7.5 Cret-D were not in range. No negative control. potential hydrogen (PH-D): no negative control . specific gravity (SG-D): no negative control. E. Failures of the following controls on 3/29/2022: Amphetamine (AMPH): the values for the control DOAT 4 AMPH was not in range. No negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for the controls BUPR L1 and BUPR L2 were not in range and no negative control. Cocaine (COC): no negative control. ethyl alcohol (ETOH): the values for the control ETOH 50 were not in range. No negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): no negative control. Oxycodone (OXY): the values for the controls DOAT 4 OXY were not in range. delta-9 tetrahydrocannabinol (THC): no negative control. creatinine (CRET-D): the values for the controls Cret-D 1.3 Cret-D, Cret-D 7.5 Cret-D, and Cret-D 23 were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control Methadone (MTD): no negative control. F. Failures of the following controls occurred on 4/8/2022: Amphetamine (AMPH): no negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): BUPR L1 BUPR L2 no negative control. Cocaine (COC): no negative control. ethyl alcohol (ETOH): no negative control 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): no negative control. Oxycodone (OXY): no negative control. delta-9 tetrahydrocannabinol (THC) no negative control. creatinine (CRET-D): the control values for Cret-D 7.5 Cret-D were out of range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): no negative control. Methadone (MTD): no negative control. G. Failures of the following controls occurred on 9/23/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD):

	no controls run. H. Failures of the following controls occurred on 9/26/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. I. Failures of the following controls occurred on 10/3/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300: no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. J. Failures of the following controls on 10/14/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): No controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. 5. Review of patients' records revealed the following: a. PT#23-PT#30, PT#19 on 1/28 /2022 received toxicology reports. b. PT#20-PT#22 on 2/11/2022 received toxicology reports c. PT#19 on 2/15/2022 received toxicology reports. d. PT#18 on 2/22/2022 received toxicology reports. e. PT#16-PT#17 on 3/29/2022 received toxicology reports. f. PT#15 on 4/8/2022 received toxicology reports. g. PT#1, PT#6, PT#12-PT#14 on 9/23/2022 received toxicology reports. h. PT#3-PT#11 on 9/26/2022 received toxicology reports. i. PT#1-PT#3 on 10/3/2022 received toxicology reports. j. PT#31-PT#41, 19 on 10/14/2022 received toxicology reports. 6. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) confirmed 2 levels of QC were not performed. 7. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include an identification number on the test report for fourteen of thirty patients (PT#1-PT#14) in September 2022 through October 2022. Findings include: 1. Review of patient

	medical records indicated the name of the patient was present but there were no identification numbers on test results ran on Chemistry Analyzer BS-480 in 2022 for the following: PT#1 on 09/23/22 and 10/03/22 PT#2 on 10/03/22 PT#3 on 09/23/22, 09/26/22 and 10/03/22 PT#4 on 09/26/22 PT#5 on 09/26/22 PT#6 on 09/23/22 and 09 /26/22 PT#7 on 09/26/22 PT#8 on 09/26/22 PT#9 on 09/26/22 PT#10 on 09/26/22 PT#11 on 09/26/22 PT#12 on 09/23/22 PT#13 on 09/23/22 PT#14 on 09/23/22 2. During an interview on 11/29/2022 at 12:18 PM SP-1 (Testing personnel) and SP-2 (owner 2) stated that they would send documentation of patient identification numbers. An email was sent by SP-1 on 11/29/2022 at 11:57 PM, it did not contain information for documentation of patient identification numbers. 3. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director failed to meet the requirements of 42 Code of Federal Regulations 493.1405 and provide overall managment and direction of the laboratory: 1. The laboratory director failed ensure a validation of the BS-480 Chemistry analyzer was completed for the following analytes Amphetamine Barbiturate Benzene Bupropion Cocaine ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity before performing patient testing for 41 of 41 patients (PT#1-PT#41) reviewed. (Refer to D6013) 2. The laboratory director failed to ensure two levels of toxicology quality controls (QC) were run at least once each day patient specimens are assayed for fourteen of fourteen analytes tested for 41 of 41 patients (PT#1-PT#41) reviewed from 1/28/2022-10/14/2022. (Refer to D6014) 3. The laboratory director failed to create a quality assurance policy for pre-analytic, analytic and postanalytical to prevent issues that occurred in toxicology testing. (Refer to D6021) 4. The laboratory director failed to ensure the laboratory performed the required daily, weekly, and monthly maintenance for BS-480 Chemistry analyzer during patient testing 1/28/22 -10/14 /2022. (Refer to D6023)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director

	failed to ensure a validation of the BS-480 Chemistry analyzer was completed for the following analytes Amphetamine Barbiturate Benzene Bupropion Cocaine ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity before patient testing for 41 of 41 patients (PT#1-PT#41) reviewed. Findings included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology testing. 2. Review of "BS-480 installation" binders revealed no documentation of a validation for Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4 methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 3. Review of Patient records revealed 41 patients (PT#1-PT#41) were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE 300, Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 4. During an interview on 11/28/2022 at 11:20 am, SP#1 (Testing personnel) confirm three binders were only used in the laboratory and the binders did not contain a validation for BS-480 Chemistry analyzer. 5. The laboratory director was not available onsite or through email or phone call only owners. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure two levels of toxicology quality controls (QC) were run at least once each day patient specimens are assayed for fourteen of fourteen analytes tested for 41 of 41 patients (PT#1-PT#41) reviewed from 1/28/2022-10/14/2022. Findings Included: 1. Review of "BS-480 Chemistry Analyzer Operator's Manual" stated a "QC run may require more than one control samples. You are recommended to use two control samples, one with normal values (within the reference range) and the other with abnormal values (beyond the reference range). To ensure the system performance, run control samples every time after you perform a calibration, or change the reagent lot, or maintain and troubleshoot the instrument." 2. Review of the "Laboratories Standard Operating Procedures" given by SP#1(testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, revealed no procedure on how QC is performed. 3. Review of "DRI Amphetamines Assay" package insert stated "Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within established ranges, as determined by laboratory procedures and guidelines. If results fall outside of established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control frequency." 4. Review of QC Results revealed the following toxicology QC failures and no QC runs: A. Failures of the following

controls on 1/28/2022: Amphetamine (AMPH): controls for (DOAT 4 AMPH) (DOAT 5 AMPH) were not in range. No negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): value for BUPR L1 control was not in range. No negative control. Cocaine (COC): controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): controls for DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): Control for DOAT 4 OXY and DOAT 5 OXY were not in range. No negative control delta-9 tetrahydrocannabinol (THC): no negative control. creatinine (CRET-D): controls for Cret-D 1.3 Cret-D were not range. No negative control potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1. 015 and SG-D 1.030 were not in range. No negative control. B. Failures of the following controls on 2/11/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range. No negative control. Barbiturate (BARB): the values for controls for DOAT 4 Barb and DOAT 5 Barb were not in range. No negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for control BUPR L1 were not in range. No negative control. Cocaine (COC): the values for controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. Methadone (MTD): the values for controls DOAT 2 MTD and DOAT 3 MTD were not in range. No negative control. OPIATE 300 (OPI300): the values for DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): the values for controls DOAT 4 OXY and DOAT 5 OXY were not in range. No negative control. delta-9 tetrahydrocannabinol (THC): the values for controls for DOAT 4 THC were not in range. No negative control. creatinine (CRET-D): the values for controls Cret-D 1.3 Cret-D and Cret-D 7.5 Cret-D were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control. C. Failures of the following controls on 2/15/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range, and no negative control. Barbiturate (BARB): the values for controls DOAT 4 Barb and DOAT 5 Barb were not in range and no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for controls BUPR L1 and BUPR L2 were not in range, and no negative control. Cocaine (COC): the controls for DOAT 4 COC and DOAT 5 COC were not in range. No negative control. ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): No negative control. Methadone (MTD): the control values for DOAT 3 MTD were out of range. No negative control OPIATE 300 (OPI300): the values for controls DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): the control values for DOAT 4 OXY and DOAT 5 OXY were out of range. No negative control. delta-9 tetrahydrocannabinol: the values for controls for DOAT 4 THC were not in range. No negative control creatinine (CRET-D): the values for controls Cret-D 1.3, Cret-D 7.5 and Cret-D 23 were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control. D. Failures of the following controls on 2/22/2022: Amphetamine (AMPH): the values for controls DOAT 4 AMPH and DOAT 5 AMPH were not in range, and no negative control. Barbiturate (BARB): the values for controls DOAT 4 Barb and DOAT 5 Barb were not in range and no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for controls BUPR L1 and BUPR L2 were not in range, and no negative control. Cocaine (COC): the following controls for DOAT 4

COC and DOAT 5 COC were not in range. No negative control ethyl alcohol (ETOH): no negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. Methadone (MTD): the control values for DOAT 2 MTD and DOAT 3 MTD were out of range. No negative control OPIATE 300: the values for controls DOAT 2 OPI300 and DOAT 3 OPI 300 were not in range. No negative control. Oxycodone (OXY): the values for the controls DOAT 4 OXY and DOAT 5 OXY were not within range. No negative control. delta-9 tetrahydrocannabinol (THC): the values for the control DOAT 4 THC was not in range. No negative control. creatinine (CRET-D): the values for the control Cret-D 1.3 Cret-D and Cret-D 7.5 Cret-D were not in range. No negative control. potential hydrogen (PH-D): no negative control . specific gravity (SG-D): no negative control. E. Failures of the following controls on 3 /29/2022: Amphetamine (AMPH): the values for the control DOAT 4 AMPH was not in range. No negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): the values for the controls BUPR L1 and BUPR L2 were not in range and no negative control. Cocaine (COC): no negative control. ethyl alcohol (ETOH): the values for the control ETOH 50 were not in range. No negative control. 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): no negative control. Oxycodone (OXY): the values for the controls DOAT 4 OXY were not in range. delta-9 tetrahydrocannabinol (THC): no negative control. creatinine (CRET-D): the values for the controls Cret-D 1.3 Cret-D, Cret-D 7.5 Cret-D, and Cret-D 23 were not in range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): the values for controls SG-D1.015 and SG-D 1.030 were not in range. No negative control Methadone (MTD): no negative control. F. Failures of the following controls occurred on 4/8/2022: Amphetamine (AMPH): no negative control. Barbiturate (BARB): no negative control. Benzene (BENZ): no negative control. Bupropion (BUPR): BUPR L1 BUPR L2 no negative control. Cocaine (COC): no negative control. ethyl alcohol (ETOH): no negative control 3,4-methylenedioxymethamphetamine (MDMA): no negative control. OPIATE 300 (OPI300): no negative control. Oxycodone (OXY): no negative control. delta-9 tetrahydrocannabinol (THC) no negative control. creatinine (CRET-D): the control values for Cret-D 7.5 Cret-D were out of range. No negative control. potential hydrogen (PH-D): no negative control. specific gravity (SG-D): no negative control. Methadone (MTD): no negative control. G. Failures of the following controls occurred on 9/23/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. H. Failures of the following controls occurred on 9/26/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. I. Failures of the following controls occurred on 10/3/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300:

	no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): no controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. J. Failures of the following controls on 10/14/2022: Amphetamine (AMPH): no controls run. Barbiturate (BARB): no controls run. Benzene (BENZ): no controls run. Bupropion (BUPR): no controls run. Cocaine (COC): no controls run. ethyl alcohol (ETOH): no controls run. 3,4-methylenedioxymethamphetamine (MDMA): no controls run. OPIATE 300 (OPI300): no controls run. Oxycodone (OXY): no controls run. delta-9 tetrahydrocannabinol (THC): No controls run. creatinine (CRET-D): no controls run. potential hydrogen (PH-D): no controls run. specific gravity (SG-D): no controls run. Methadone (MTD): no controls run. 5. Review of patients' records revealed the following: a. PT#23-PT#30, PT#19 on 1/28 /2022 received toxicology reports. b. PT#20-PT#22 on 2/11/2022 received toxicology reports c. PT#19 on 2/15/2022 received toxicology reports. d. PT#18 on 2/22/2022 received toxicology reports. e. PT#16-PT#17 on 3/29/2022 received toxicology reports. f. PT#15 on 4/8/2022 received toxicology reports. g. PT#1, PT#6, PT#12-PT#14 on 9/23/2022 received toxicology reports. h. PT#3-PT#11 on 9/26/2022 received toxicology reports. i. PT#1-PT#3 on 10/3/2022 received toxicology reports. j. PT#31-PT#41, 19 on 10/14/2022 received toxicology reports. 6. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) confirmed 2 levels of QC were not performed. 7. The laboratory director was not available onsite or through email or phone call only owners. 8. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director failed to create a quality assurance policy for pre-analytic, analytic and postanalytical to prevent issues that occurred in toxicology testing. Findings included: 1. A laboratory tour on 11/28/2022 at 10:28 am, revealed a BS-480 Chemistry analyzer in use for toxicology. 2. Review of the "Laboratories Standard Operating Procedures" given by SP-1(testing personnel) on 11/29/2022 at 11:57 PM in email not signed by laboratory director revealed no procedure to monitor quality assurance. 3. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send the procedure for quality assurance. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain information for quality assurance. 4. The laboratory director was not available onsite or through email or phone call, only owners. 5. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (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 record review and interview, the laboratory director failed to ensure the laboratory performed the required daily, weekly, and monthly maintenance for BS-480 Chemistry analyzer during patient testing 1/28/22 -10/14/2022. Findings included: 1. Review of the Procedures For Operating Procedures for running Mindray-BS480 given by SP-1(testing personnel) on 11/29/2022 at 11:57 PM in email, not signed by laboratory director, stated "Perform Scheduled Maintenance & Log - Daily, Weekly, Bi-weekly, monthly, three-month, 6 months, and as needed or as required maintenance Check when last maintenance was performed in each time category: Daily Maintenance: " Check probes/mixers/wash wells " Check sample/reagent syringes " Check deionized water " Check waste " Check concentrated/diluted wash solution " Clean electrode tubes Weekly Maintenance: " Clean sample/reagent probe exterior " Clean mixers " Diluted wash " Cuvette check " Photometer check Monthly Maintenance: " Clean wash wells " Clean rotors " Clean wash station " Clean filter core " Clean dust screens " Clean sample injection port " Pump calibration " Air bubble detector calibration " Clean the dust screen of the external vacuum pump 3-month maintenance: " Clean DI water tank " Replace filter core " Replace sample syringe " Replace reagent syringe 6-month maintenance: " Replace lamp " Replace water inlet filter " Replace reference electrode " Replace pump tube" 2. Review of "BS-480 instrument maintenance log" revealed no written or electronic documentation of the maintenance done for the Bs-480 Chemistry analyzer from January 2022-Octoober 2022. 3. Review of Patient records revealed 41 (PT#1-PT41) patients were tested from 1/28/2022 -10/14/2022 for the Amphetamine, Barbiturate, Benzene, Bupropion, Cocaine, ethyl alcohol, 3,4-methylenedioxymethamphetamine, OPIATE, 300 Oxycodone, delta-9 tetrahydrocannabinol, creatinine, potential hydrogen, and specific gravity. 4. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send BS-480 instrument maintenance log. An email was sent by SP#1 on 11/29/2022 at 11:57 PM, it did not contain a BS-480 instrument maintenance log. 5. The laboratory director was not available onsite or through email or phone call only owners. 6. Annual test volume for Chemistry subspecialty of Toxicology is approximately 1500.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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 record review and interview, the technical consultant failed to create and perform an initial competency assessment for one (SP#1) out one testing personnel in 2022. Findings included: 1. Review of the "Laboratories Standard Operating Procedures" given by SP#1 (testing personnel) on 11/29/2022 at 11:57 PM in email,

	not signed by laboratory director, revealed no procedure on how competency assessments will be performed. 2. During an interview on 11/29/2022 at 12:18 PM, SP#1 (Testing personnel) and SP#2 (owner 2) stated that they would send an initial competency assessment. 3. Review of competency document provided by SP#1 via email on 11/29/2022 at 11:57 PM, revealed a document titled "Competency Assessment" with employee name "SP#1". The document did not have secure electronic signatures or dates. The document was missing the following: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem-solving skills. Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.