Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2120720	10/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Center For Pain Control	10176 W 400 N, Suite A, Michigan City, 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
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 document review, observation, and interview, the laboratory failed to: 1) include step by step procedures for two of two analyzers (Carolina Chemistries CLC 480 (also called the BioLis 24i) and the Liquid Chromatography / Mass Spectrometer (LC/MS) (refer to D5403)); 2) ensure the laboratory director approved, signed, and dated 11 of 11 procedures reviewed (refer to D5407); 3) establish criteria for water quality that was consistent with the manufacturer's instructions for one of one analyzer reviewed (Carolina Chemistries CLC 480) (refer to D5413); 4) include analytical sensitivity and analytical specificity for one of one Liquid Chromatography / Mass Spectrometry (LC/MS) analyzer, determine cut-off values based on performance specifications for one of one LC/MS analyzer, verify performance specifications after the relocation of one of one Carolina Chemistries CLC 480 analyzer (refer to D5423); and 5) perform quality control (QC) procedures established by the laboratory for six of ten patients reviewed (refer to D5445).
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 document review and interview, the procedure manual failed to include step by step procedures for two of two analyzers (Carolina Chemistries CLC 480 (also called the BioLis 24i) and the Liquid Chromatography / Mass Spectrometer (LC /MS)). Findings included: 1. Review of procedure manual indicated there were no procedures for the CLC 480 or the LC/MS. 2. Review of patient records indicated the following patients had toxicology testing performed on the CLC 480 and/or the LC /MS, as follows: a. Patient #1 had testing performed on the CLC 480 (5-19-2020). b. Patient #2 had testing performed on the CLC 480 and the LC/MS (9-1-2020). c. Patient #3 had testing performed on the CLC 480 and the LC/MS (6-30-2020). d. Patient #4 had testing performed on the CLC 480 and the LC/MS (6-11-2020). e. Patient #5 had testing performed on the CLC 480 and the LC/MS (7-14-2020). f. Patient #6 had testing performed on the CLC 480 and the LC/MS (6-11-2020). g. Patient #7 had testing performed on the CLC 480 and the LC/MS (10-15-2020). h. Patient #8 had testing performed on the CLC 480 and the LC/MS (10-15-2020). i. Patient #9 had testing performed on the CLC 480 and the LC/MS (10-15-2020). j. Patient #10 had testing performed on the CLC 480 and the LC/MS (6-18-2020). 3. On 10-14-2020 at 10:10 AM, approved procedures for the CLC 480 and LC/MS were requested from SP2, Testing Person. Requested procedures were not provided prior to exit. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory's estimated annual volume for the LC/MS was 156,000 tests and the laboratory's annual test volume for the CLC 480 was 60,000 tests.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on document review and interview, the current laboratory director failed to approve, sign, and date 11 of 11 procedures reviewed ("Specimen Collection: Requisitions and Patient Identification," "Specimen Collection: Non-DOT Urine Drug Testing," "Specimen Labeling," "Specimen Rejection," "Required Quality Control," "Test Reports," "Reference Lab Testing," "Test Tracking," "Proficiency Testing,"

	"Laboratory Incident Management and Error Corrective Action," and "Qualitative and Semi-Quantitative Drugs (sic) Testing"). Findings included: 1. Review of procedure manual indicated the following procedures were not approved, signed, and dated by the current laboratory director: a. "Specimen Collection: Requisitions and Patient Identification" b. "Specimen Collection: Non-DOT Urine Drug Testing" c. "Specimen Labeling" d. "Specimen Rejection" e. "Required Quality Control" f. "Test Reports" g. "Reference Lab Testing" h. "Test Tracking" i. "Proficiency Testing" j. "Laboratory Incident Management and Error Corrective Action" k. "Qualitative and Semi-Quantitative Drugs (sic) Testing" 2. In interview on 10-13-2020 at 1:45 PM, SP1, Medical Doctor, acknowledged the above procedures were not approved, signed, and dated by the current laboratory director. 3. Review of the CMS 116 Clinical Improvement Amendments (CLIA) Application for Certification received on August 31, 2020 for a laboratory director change indicated the change was effective July 20, 2020.
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 document review, observation, and interview, the laboratory failed to establish criteria for water quality that was consistent with the manufacturer's instructions for one of one analyzer reviewed (Carolina Chemistries CLC 480). Findings included: 1. Review of BioLis 24i (Carolina Chemistries CLC 480) read: "Alkaline Wash...To make 2 liters of 2% alkaline wash, pour 1960 mL of DI H2O and 40 mL or (sic) alkaline wash solution and gently mix." 2. Review of "Carolina Liquid Chemistries Fast Detergent 1 Alkaline Washing Solution" read: "Preparation: Dilute to 2% with DI H2O..." 3. On 10-13-2020 at 3:00 PM, while on tour with SP2, Testing Person, the CLC 480 analyzer was observed to have a water tank designated for deionized (DI) water. 4. On 10-13-2020 at 3:00 PM, SP2 indicated the water used to fill the DI water tank on the CLC 480 was "Great Value Distilled Water." 5. On 10-14-2020 at 10:10 AM, SP2 indicated the "Great Value Distilled Water" was substituted for DI water when mixing the alkaline wash solution for the CLC 480. 6. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory's annual test volume for the CLC 480 was 60,000 tests.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

	applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on document review, observation, and interview, the laboratory failed to: 1) establish performance specifications for one of one liquid chromatography / mass spectrometry (LC/MS) analyzer; 2) determine cut-off values based on performance specifications for one of one LC/MS analyzer; and 3) verify performance specifications after the relocation of one of one Carolina Chemistries CLC 480 analyzer. Findings included: 1. On 10-13-2020 at 3:00 PM, while on tour with SP1, Medical Doctor, and SP2, Testing Person, an LC/MS analyzer was observed in the laboratory and the Carolina Chemistries CLC 480 analyzer was observed in a different room from the previous survey conducted on 2-6-2019. 2. In interview on 10-14-2020 at 3:45 PM, SP1 indicated they were unsure how the cut off values for the LC/MS were determined. SP1 further indicated the LC/MS performance specifications was performed in March, 2020, but SP1 was unable to locate the documentation. Documentation of the performance specifications and cut off value determination for the LC/MS was requested. The documentation was not provided prior to exit. 3. In interview on 10-15-2020 at 2:15 PM, SP1 confirmed the laboratory moved the CLC 480 analyzer from the previous laboratory room to the current laboratory room and indicated the analyzer was moved in early November, 2019. Upon request for documentation that performance specifications were not affected by the move, SP1 indicated they were unsure if the performance specifications were affected after the analyzer was moved. Documentation of performance specifications verification after the analyzer was moved was not provided prior to exit. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory's estimated annual volume for the LC/MS was 156,000 tests and the laboratory's annual test volume for the CLC 480 was 60,000 tests.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to perform quality control (QC) procedures established by the laboratory for six of ten patients reviewed (Patients #1 through #6). Findings included: 1. Review of "Required Quality Control" policy/procedure, effective 11-30-2018, read: "At least 2 levels of controls must be tested and verified as acceptable prior to patient testing..." 2. Review of patient test reports indicated the following: a. Patient #1 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing

performed on 5-19-2020. b. Patient #2 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing performed on 9-1-2020. The patient also had buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing performed on 9-1-2020. c. Patient #3 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing performed on 6-30-2020. The patient also had buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing performed on 6-30-2020. d. Patient #4 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing performed on 6-11-2020. The patient also had buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing performed on 6-11-2020. e. Patient #5 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing performed on 7-14-2020. The patient also had buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing performed on 7-14-2020. f. Patient #6 had amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing performed on 6-11-2020. The patient also had buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing performed on 6-11-2020. 3. Review of QC documentation indicated the following: a. There was no QC documentation for amphetamine, benzodiazepine, buprenorphine, cocaine, opiates, oxycodone, and urine creatinine screening testing on 5-19-2020, 6-11-2020, 6-30-2020, 7/14/2020, and 9/1/2020, when patient testing was performed. b. There was no QC documentation for buprenorphine, clonazepam, diazepam, codeine, morphine, hydromorphone, hydrocodone, oxycodone, oxymorphone, amphetamine, methamphetamine, norbuprenorphine, methadone, fentanyl, norfentanyl, tramadol, o-desmethyltramadol, 7-aminoclonazepam, alprazolam, alpha-hydroxyalprazolam, nordiazepam, temazepam, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), benzoylecgonine, and 6 acetylmorphine confirmation testing on 6-11-2020, 6-30-2020, 7-14-2020, and 9-1-2020, when patient testing was performed. 4. In interview on 10-14-2020 at 12:30 PM, SP2, Testing Person, confirmed there was no documentation of QC for the above dates, when

	patients are tested. 5. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory's estimated annual volume for the LC/MS was 156,000 tests and the laboratory's annual test volume for the CLC 480 was 60,000 tests.
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 document review, observation, and interview, the laboratory director failed to: 1) ensure proper ventilation conditions for two of seven chemicals reviewed; and proper conditions for waste disposal for five of seven chemicals reviewed (refer to D6083); 2) ensure proper chemical storage for one of four chemicals observed; hand washing was performed in a clean sink for one of one hand washing sinks observed; the eye wash station was located at a clean sink for one of one eye wash station observed; and the safety shower was located within an appropriate distance for one of one safety showers observed (refer to D6084); 3) maintain a quality assessment (QA) program from July 2020 to date of survey (refer to D6094); 4) ensure patient test results were reported only when the Liquid Chromatography / Mass Spectrometry (LC /MS) test system was functioning properly for 1 of 5 patient LC/MS test reports reviewed (refer to D6097); and 5) ensure one of one testing person (SP2) received training and demonstrated they could perform all testing operations prior to testing patients' specimens on the Carolina Chemistries CLC 480 analyzer (refer to D6102).
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on document review, observation, and interview, the laboratory director failed to ensure: 1) proper ventilation conditions for two of seven chemicals reviewed (acetonitrile, formic acid-free acid) and 2) proper conditions for waste disposal for five of seven chemicals reviewed (acetonitrile, formic acid-free acid, amphetamine assay, benzodiazepine assay, and cocaine metabolite assay). Findings included: 1. Review of Safety Data Sheets (SDS) indicated the following: a. SDS for acetonitrile read: "Harmful if inhaled..." and "Avoid breathing dust/fumes/gas/mist/vapor/spray..." and "Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits..." and "May be harmful if inhaled..." and "Conditions to Avoid...exposure to moist air or water..." and "Material that cannot be saved for recovery or recycling should be managed in an appropriate and approved waste facility..." b. SDS for formic acid-free acid read: "Do not breathe dusts or mists..." and "Do not allow product to reach sewage system..." c. SDS for amphetamine assay read: "Do not empty into drains. Avoid release to the environment..." d. SDS for benzodiazepine assay read: "Do not empty into drains. Avoid release to the environment..." e. SDS for cocaine metabolite assay read: Do not

	empty into drains. Avoid release to the environment..." 2. On 10-13-2020 at 3:00 PM, during laboratory tour while accompanied by SP1, Medical Doctor, and SP2, Testing Person, there was no chemical hood to avoid inhalation nor was there a chemical waste disposal receptacle observed. 3. On 10-13-2020 at 3:00 PM, SP2 acknowledged there was no chemical hood in the laboratory. SP2 further indicated the laboratory should have a chemical hood. 4. On 10-14-2020 at 9:26 AM, SP2 indicated chemical waste was disposed by pouring it down the drain in the dirty sink.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, document review, and interview, the laboratory director failed to ensure 1) proper chemical storage for one of four chemicals observed (acetonitrile); 2) hand washing was performed in a clean sink for one of one hand washing sinks observed; 3) the eye wash station was located at a clean sink for one of one eye wash station observed; and 4) the safety shower was located within an appropriate distance for one of one designated safety showers observed. Findings included: 1. Review of Safety Data Sheets (SDS) indicated the following: a. SDS for acetonitrile read: "Incompatibility With Various Substances: strong oxidizing agents, strong reducing agents, strong acids..." and "Skin Contact: Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes..." b. SDS for Creatinine Reagent read: "Skin Contact: Immediately flush with copious amounts of water for 15 minutes." 2. Review of package insert for the Carolina Liquid Chemistries "Fast Detergent 1" read: "Skin Contact: Flush immediately with cold water..." 3. On 10-13-2020 at 3:00 PM, while on tour of the laboratory, accompanied by SP1, Medical Doctor, and SP2, Testing Person, the following was observed: a. Three unopened four liter (L) bottles of acetonitrile and one opened four L bottle of acetonitrile were observed in the flammable cabinet, stored with one opened 500 milliliter (mL) bottle of formic acid-free acid. b. The laboratory was observed to have one sink supplied with soap and paper towels, available for hand washing. Additionally, the sink faucet contained an eye wash station. On the back of the sink was an orange sign which read: "Dirty Sink." 4. On 10-14-2020 at 10:20 AM, a shower was observed in the facility. To reach the shower from the laboratory, one would be required to exit the laboratory doorway and turn right. Then, walk approximately 35 feet and turn left; walk approximately 15 feet to a door way; turn right and enter the doorway; then walk approximately 20 feet, through another doorway and into a bathroom which contained the shower. 5. In interview on 10-13-2020 at 3:00 PM, SP2 acknowledged acetonitrile and formic acid-free acid were stored together in the flammable cabinet. 6. In interview on 10-14-2020 at 10:20 AM, SP2 indicated the shower mentioned above was used as the laboratory's designated safety shower. SP2 acknowledged the shower was too far from the laboratory to provide immediate access for flushing skin which came in contact with the above mentioned chemicals.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to maintain a quality assessment (QA) program from July 2020 to date of survey. Findings included: 1. Review of "Quality Assessment Manual" indicated the following: a. A document titled "Quality Assessment," effective date unknown, which did not indicate how often QA reviews were to be completed. b. A document titled: "Quality Assurance Review Standard Operating Procedure (SOP)" effective date unknown, which did not indicate how often QA reviews were to be completed. 2. Review of QA documentation indicated the July, August, and September, 2020 QA was not completed. 3. In interview on 10-15-2020 at 1:49 PM, SP1, Medical Doctor, indicated QA documentation from July, August and September had not been completed.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure patient test results were reported only when the Liquid Chromatography / Mass Spectrometry (LC/MS) test system was functioning properly for 1 of 5 patient LC/MS test reports reviewed (Patient #2). Findings included: 1. Review of patient test reports indicated the following patients had drug testing performed using a LC/MS test system: Patient #2 (9-1-2020) 2. Review of correlation study performed during an unknown timeframe indicated the following results: Test Name Lab Result Ref. Lab Result _____ Bup 18.5 30.5 NorB 283.4 77.3 HydroC 85 62.3 HydroM 40.3 27.4 Ref. = Reference; Bup = buprenorphine; NorB = norbuprenophine; HydroC = hyrdocodone; HydroM = hydromorphone 3. Review of email communication, dated 8-5-2020, from laboratory director read: "Our Results (for all analytes) are beyond 2 STD's!" and "We need to get Expert help for LC/MS! Have a Good expert look at it and correct all the issues once for all!" 4. In interview on 10-15-2020 at 11:40 AM, SP1, Medical Doctor, indicated the above correlation study was performed on 8-4-2020. SP1 was unsure how closely the results should correlate, but thought a correlation of 10% or 20% was adequate. 5. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory's estimated annual volume for the LC/MS test system was 156,000 tests.
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 document review, observation, and interview, the laboratory director failed to ensure one of one testing person (SP2) received training and demonstrated they could perform all testing operations prior to testing patients' specimens on the Carolina Chemistries CLC 480 analyzer. Findings included: 1. Review of "Quality Assessment Manual" indicated a document titled "Quality Assessment," effective date unknown, which read: "An employee may not test in areas of the laboratory until training has been completed and competency reviewed by the Laboratory Director or qualified designee..." 2. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 10-13-2020, indicated SP2, hire date 9-23-2020, was the laboratory's only testing person. 3. On 10-14-2020 at 10:10 AM SP2 was observed performing quality control and patient testing on the Carolina Chemistries CLC 480 (also called the BioLis 24i) analyzer. 4. Review of patient test reports indicated SP2 performed patient testing using the Carolina Chemistries CLC 480 analyzer as follows: a. Patient #7 (10-15-2020). b. Patient #8 (10-15-2020). c. Patient #9 (10-15-2020). 5. In interview on 10-13-2020 at 12:14 PM, SP1, Medical Doctor, indicated there was no documentation of training on the Carolina Chemistries CLC 480 for SP2.