Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1094692	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pain & Spine Center	5652 N Mesa Street, El Paso, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D5022 - 42 C.F.R. 493.1213 Condition: Toxicology; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor; D6141 - 42 C.F.R. 493.1459 Condition: Laboratories performing high complexity testing; general supervisor; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor observations, temperature records, quality control policies and procedures, quality control records, patient records, and interview with facility personnel, the laboratory failed to meet the requirements for certification in the specialty of Toxicology. The findings included: 1. The laboratory failed to establish and follow procedures for assessing accuracy of analytes twice annually that were reported in quantitative values for 8 of 8 assays. Refer to D5217. 2. The laboratory failed to store specimens at the appropriate temperature prior to testing for 129 of 129 dates reviewed. Refer to D5311. 3. The laboratory failed to monitor the accuracy and precision of quality control materials over time. Refer to D5441. 4. The laboratory failed to ensure that the results of quality control materials were within acceptable limits prior to reporting patient results. Refer to D5481. 5. The laboratory failed to take and document corrective actions when the results of quality control or

	calibrations were outside laboratory established criteria. Refer to D5783. 6. The laboratory failed to take and document corrective actions when the temperatures were unacceptable for the storage of patient specimens. Refer to D5785. This is a REPEAT Deficiency. Deficient practices were cited at D5022 on the inital inspection conducted on 8/19/2016.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing records from 2017, patient test records, and interview with facility personnel, the laboratory failed to verify the accuracy of 8 of 8 assays twice annually for 2017. The findings included: 1. Based on review of American Proficiency Institute (API) records for 2017, the laboratory's performance was evaluated as qualitative measurements (positive and negative results) by the proficiency testing company. 2. Based on review of patient records, the laboratory reported quantitative values. For example, Patient 17963, tested on 7/20/2018, had a hydrocodone result of 344 ng/mL on the patient report. 3. Based on a random review of two (2 of 2) patient reports, the laboratory reported the quantitative values for the following analytes: OxyContin 6-Acetylmorphine Benzodiazepine Cocaine Methadone Opiates Tetrahydrocannabinol (THC) hydrocodone 4. In an interview at 10:21 hours on 7/26/2018 in the Consult Room, the General Supervisor was asked how the laboratory evaluated the accuracy twice annually of the analytes that were reported in quantitative units when the proficiency testing was evaluated as a qualitative result. The General Supervisor stated the proficiency testing company did not provide a program for quantitative result reporting. 5. Based on review of API records, the laboratory did not submit values to API for the analyte hydrocodone. In an interview at 10:22 hours on 7/25/2018 in the Consult Room, the General Supervisor was asked for documentation of assessing the accuracy of hydrocodone twice annually for 2017. The General Supervisor stated, "We compare send out confirmations to patient reports". When asked if the laboratory documented the evaluations twice annually and what criteria for acceptability had been defined by the laboratory, the General Supervisor stated it was an informal evaluation and had not been documented.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observations, assay instructions for use, laboratory environmental records, quality assessment records, and interview with facility personnel, the

	laboratory failed to meet the criteria for storage of patient specimens 129 of 129 days between January 1, 2018 and June 29, 2018. The findings included: 1. Based on surveyor observations at 12:09 hours on 7/25/2018, the surveyor observed thirty-five (35) patient specimens in the freezer that were being stored for future testing. The laboratory document "LABORATORY TEMPERATURE WORKSHEET" defined the acceptable freezer temperature as greater than or equal to -20 degrees Celsius. Previously analyzed patient specimens were stored in the door of the freezer, including specimens analyzed on 6/22/2018 and 6/29/2018. The specimens were stored in the freezer of a Whirlpool model wrt111sfab00. 2. Based on review of toxicology assay instructions for use, the manufacturer defined patient specimen storage requirements as follows: Opiate enzyme immunoassay: "For longer storage, up to 12 months, keep sample frozen (-20C) and then thaw before use." 6-Acetylmorphine enzyme immunoassay: For longer storage, keep sample frozen and then thaw before use. Studies have shown 6-Acetylmorphine analytes in urine are stable at -20C for up to three (3) years." 3. Based on review of quality control records and interview with the General Supervisor at 10:20 hours on 7/25/2018 in the consult room, the laboratory stores patient specimens in the freezer and batches testing on Fridays. For specimens tested on 6/22/2018, patient specimens had been stored at temperatures outside of the acceptable range between 6/19/2018 and 6/22/2018: Date: 6/19/2018 Freezer temperature: -16 C Corrective action recorded: None Date: 6/20 /2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/21/2018 Freezer temperature: -18 C Corrective action recorded: None Date: 6/22/2018 Freezer temperature: -18 C Corrective action recorded: None For patient specimens stored between 6/25/2018 and 6/29/2018, freezer temperatures were outside acceptable limits on the following dates: Date: 6/25/2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/26/2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/27/2018 Freezer temperature: -18 C Corrective action recorded: None Date: 6/28/2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/29/2018 Freezer temperature: -18 C Corrective action recorded: None Between January 1, 2018 and June 29, 2018, 129 of 129 temperatures recorded by the laboratory were outside of the acceptable range for storage of patient specimens. 4. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under "Our QUALITY CONTROL policies were performed as specified", indicates the following quality monitor was met: "All required temperatures were taken and recorded" In the 6 of 6 monthly quality assurance checklists, the laboratory failed to identify that 129 of 129 recorded temperatures were outside of acceptable limits for storing patient specimens. 5. In an interview at 11:09 hours on 7/25/2018 in the laboratory, the General Supervisor stated that the Testing Person had difficulty reading the thermometer in the freezer. This is a REPEAT Deficiency. Deficient practices were cited at D5311 on the initial inspection conducted on 8/19/2016.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

	This STANDARD is not met as evidenced by: Based on surveyor observations, assay instructions for use, laboratory environmental records, quality assessment records, and interview with facility personnel, the laboratory failed follow quality assessment procedures for corrective actions and resolve problems in pre-analytic systems. The findings included: 1. Based on a review of environmental records, assay instructions for use, and interview with facility personnel, 129 of 129 temperatures recorded by the laboratory were outside of the acceptable range for storage of patient specimens between January 1, 2018 and June 29, 2018., Refer to D5311. 2. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under Our QUALITY CONTROL policies were performed as specified, indicates the following quality monitor was met: "All required temperatures were taken and recorded" In the 6 of 6 monthly quality assurance checklists, the laboratory failed to identify that 129 of 129 recorded temperatures were outside of acceptable limits, established by the laboratory, for storing patient specimens. 3. In an interview at 11:09 hours on 7/25/2018 in the laboratory, the General Supervisor stated that the Testing Person had difficulty reading the thermometer in the freezer. This is a REPEAT Deficiency. Deficient practices were cited at D5393 on the initial inspection conducted on 8/19/2016.
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 review of laboratory policies and procedures, quality control records, patient records, and interview with facility personnel, the laboratory failed to define how acceptability criteria for control materials would be determined, what the criteria for acceptable control materials would be, and the corrective actions to take when quality control materials did not meet laboratory established acceptability criteria. The findings included: 1. The laboratory's quality assessment procedure, titled "QUALITY ASSURANCE", under PRINCIPLE, states the following: "This laboratory believes in a strong Quality Assurance program. In order to implement quality assurance in the

	fullest, this laboratory has chosen a number of key indicators to assess periodically and help establish this goal. The entire laboratory staff will review potential problems and document all corrective actions taken to keep the records for at least two years. The quality-assurance system encompasses pre-analytical, analytical, and post analytical factors that can influence results such as: patient preparation, sample collection, sample handling, and storage. Pre-analytical factors are different to monitor and control because most occur outside the laboratory. Next, analytical factors consist of recording and transmission of the patient data to the physician." 2. Based on review of the laboratory's procedure "BioLis 24i Routine Operation", on page 5 of 12, states the following: "Re-run Controls 1. If a control is out of range and needs to be re-run, follow the steps below: 1. Select QC from the main menu. 2. Select current QC 3. Place a check in the box next to the tests that need to be re-run in the ReRun column. 4. Press the Save button. 5. Exit the current QC screen and press Start at the main menu." 3. Based on a review of laboratory policies and procedures, the laboratory failed to define: (a) the process for establishing acceptability criteria for quality control materials (b) the process of monitoring accuracy and precision over time for quality control materials (c) the process for documenting corrective actions taken when quality control results are outside of acceptable limits (d) the remedial process for assessing patient specimens back to the last acceptable quality control values when quality control results are outside of acceptable limits 4. In an interview at 09:55 hours on 7/26/2018 in the Consult Room, when asked about the laboratory's quality control acceptability policy, the General Supervisor stated the laboratory required results to be within two (2) standard deviations of the mean in order to be acceptable. When asked if these criteria were in the laboratory's quality control policy, the General Supervisor stated that it was not written down but understood by testing personnel. In an interview at 10:21 hours on 7/26/2018 in the Consult Room, when asked to explain how the laboratory establishes acceptability criteria for control materials, the General Supervisor stated that laboratory uses the data calculated by the instruments quality control package. When asked if these criteria were in the laboratory's quality control policy, the General Supervisor stated that it was not written down but understood by laboratory personnel. This is a REPEAT Deficiency. Deficient practices were cited at D5403 on the initial inspection conducted on 8/19 /2016.
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 a review of the chemistry analyzer operator's manual, random review of laboratory environmental records, and interview with facility personnel, the laboratory failed to ensure the relative humidity operating requirements were met 13 of 13 days between January 12, 2018 and June 29, 2018. The findings included: 1. Based on review of the operator's manual for the Carolina Liquid Chemistries BioLis 24i, on page 1-11, the document states: "Ambient humidity: 40 - 80 percent (no

	condensation)" 2. Based on a random review of quality control records, patient testing records and environmental records, the instrument was in operation on the following days when relative humidity levels were outside of manufacturer established specifications: 1/12/2018 - 27 percent 1/22/2018 - 26 percent 2/02/2018 -27 percent 2 /09/2018 - 28 percent 3/23/2018 - 24 percent 4/06/2018 -26 percent 4/13/2018 - 22 percent 4/20/2018 - 30 percent 4/27/2018 -28 percent 5/10/2018 - 24 percent 5/25 /2018 - 30 percent 5/31/2018 - 22 percent 6/29/2018 - 34 percent 3. In an interview at 11:09 hours on 7/25/2018 in the laboratory, the General Supervisor stated she was not aware the operating requirements of the Carolina Liquid Chemistries BioLis 24i defined a minimum humidity operating environment requirement. This is a REPEAT Deficiency. Deficient practices were cited at D5413 on the initial inspection conducted on 8/19/2016.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient records, and interview with facility personnel, the laboratory failed to establish and follow quality control procedures that monitored accuracy and precision of test performance over time for 22 of 22 lots of control materials between December 2016 and June 2018. The findings included: 1. Based on review of the laboratory procedure "PAIN AND SPINE CENTER LABORATORY - INTERNAL QUALITY CONTROL", under PRINCIPLE, the document states the following: "Quality Control is a part of the total quality assurance process. QC consists of activities to ensure that each test or instrument is working properly. QC helps you to identify problems with your lab instruments, your reagents, or how the test was performed. Satisfactory QC results will give you confidence that your patient test results are accurate and precise before reporting patient results. Testing lab instrument with controls that have known values. Follow the manufacturer's instructions for test procedures and preventative maintenance. Perform and document and remedial action taken when problems are identified." 2. In an interview at 13:35 hours on 7/25/2018 in the Consult Room, the surveyor requested documentation of assessing the accuracy and precision of control materials over time and the General Supervisor stated that CLIA surveyors in 14 states had never requested documentation of the review of accuracy and precision over time. The General Supervisor stated that Levy-Jennings graphs were reviewed on the instrument periodically and the review was documented on the laboratory's Quality Assurance worksheet, but no other records were created or retained. The General Supervisor stated that she would print a few Levy-Jennings graphs to show inspectors, but did not document performance of accuracy and precision of the quality control material over time. 3. Based on review of quality control records, the

	following lot number of control materials were approved for use by the General Supervisor on 12/12/2016: UDTA-L1 Lot: C1616 Expiration 11/2017 UDTA - L2 lot: C1616 Expiration: 11/2017 UDTB -L1 Lot: C1616 Expiration: 11/2017 UDTB -L2 Lot: C1616 Expiration: 11/2017 EDDP - L1 Lot: 16104002 Expiration: 3/31/2018 EDDP - L2 Lot: 1604004 Expiration: 3/31/2018 The following controls were approved for use on 06/23/2017 by the General Supervisor: pH - L1 Lot: 72549025 Expiration date: 9/2017 pH - L2 Lot: 72745292 Expiration date: 4/2018 Hydrocodone L1 Lot: 1701009 Expiration: 12/19/2018 Hydrocodone -L2 Lot: 1701011 Expiration: 12/19/2018 UDTA - L1 Lot: D1718 Expiration: 12/31/2018 UDTA - L2 Lot: D1718 Expiration: 12/31/2018 UDTB - L1 Lot: D1718 Expiration: 12/31/2018 UDTB - L2 Lot: D1718 Expiration: 12/31/2018 The following controls were approved for use on 1 /25/2018 by the General Supervisor: UDTA -L1 Lot: J1742 Expiration: 12/31/2018 UDTA -L2 Lot: J1742 Expiration: 12/31/2018 UDTB -L1 Lot: J1742 Expiration: 12 /31/2018 UDTB -L2 Lot: J1742 Expiration: 12/31/2018 6-Acetylmorphine: 10 ng/mL Lot: 1609007 Expiration: 9/20/2018 6-Acetylmorphine: 40 ng/mL Lot: 1609100 Expiration: 9/20/2018 Fentanyl Control -Low 1 ng/mL Lot: E32153 Expiration: 12 - 2018 Fentanyl Control -High 4 ng/mL Lot: E32154 Expiration; 12 - 2018 4. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under Our QUALITY CONTROL policies were performed as specified, indicates the following quality monitor was met: "Quality Control results were examined for possible problems" and; "Monthly Levy-Jennings QC charts have been reviewed" The two activities were marked with the tail of a "y" for 6 of 6 months: January 2018, February 2018, March 2018, April 2018, and June 2018. A random review of quality control results from January 2018 through June 2018 indicated quality control values outside of acceptable limits without documentation of corrective action on the following dates: 1/12/2018 1/22/2018 3/23 /2018 5/10/2018 5/25/2018 5/31/2018 6/15/2018 5. During the exit conference at 15: 05 hours on 7/26/2018 in the Consult Room, the General Supervisor stated that Levy - Jennings Charts were reviewed monthly by the General Supervisor and the reviews were documented on the Quality Assurance checklist.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records, patient test records, and interview with facility personnel, the laboratory failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 dates between June 30, 2017 and July 13, 2018. Between June 30, 2017 and July 13, 2018, 582 patient results were tested and reported when at least one level of quality control material was unacceptable. The findings included: 1. Based on review of the laboratory procedure "PAIN AND SPINE CENTER LABORATORY - INTERNAL QUALITY CONTROL", under PRINCIPLE, the document states the following: "Quality Control is a part of the total quality assurance process. QC consists of activities to ensure that each test or instrument is working properly. QC helps you to identify problems with your lab instruments, your reagents, or how the test was performed. Satisfactory QC

results will give you confidence that your patient test results are accurate and precise before reporting patient results. Testing lab instrument with controls that have known values. Follow the manufacturer's instructions for test procedures and preventative maintenance. Perform and document and [sic] remedial action taken when problems are identified." 2. Based on a review of quality control records, the following quality control values were outside of acceptable limits: Review of quality control records for Urine Creatinine Level 1 indicated the laboratory established acceptability criteria defined as 19 to 55. Quality Control values were outside of acceptable limits on the following dates: 7/21/2017: value of 58.3 (HIGH) 09/01/2017: value of 57.0 (HIGH) 10/27/2017: value of 60.2 (HIGH) 1/3/2018: value of 58.3 (HIGH) 5/10/2018: value of 57.5 (HIGH) 5/25/2018: value of 56.6 (HIGH) 7/13/2018: value of 56.3 (HIGH) Based on the worklist for 09/01/2017, the laboratory reported 31 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. Based on the worklist for 10/27/2017, the laboratory reported 63 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. Based on the worklist for 5/10/2018, the laboratory reported 33 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. Based on the worklist for 5/25/2018, the laboratory reported 60 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. Based on the worklist for 7/13/2018, the laboratory reported 63 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. Review of quality control records for Benzodiazepine -Level 1 indicated the laboratory established acceptability criteria defined as 81 to 171. Quality Control values were outside of acceptable limits on the following date: 1/12/2018 value of 218 (High). No corrective action was documented. Forty-two (42) patients were tested on 1/12/2018 for Benzodiazepine. Two patients had values just above the cut-off value of 200 ng /mL: Patient ID: 9631 -Benzodiazepine level of 227 ng/mL Patient ID: 1634 - Benzodiazepine level of 210 ng/mL It could not be determined at the time of the survey if the patients had been prescribed benzodiazepine based on a review of the patients' active medication list. In an interview at 11:05 hours on 7/26/2018 in the Consult Room, the General Supervisor stated that only active medications could be seen on the patients' medication list and not past prescriptions. Review of quality control records for 6-Acetylmorphine Level 1 indicated the laboratory established acceptability criteria defined as 4 -16. Quality Control values were outside of acceptable limits on the following date: 1/22/2018 -Level of 2.4 (LOW). No corrective action was documented. Based on the worklist for 1/22/2018, 51 patient specimens were tested and reported when the 6-Acetylmorphine Level 1 control was low and outside of acceptable criteria. Review of quality control records for 6-Acetylmorphine Level 2 indicated the laboratory established acceptability criteria defined as 20 - 40. Quality Control values were outside of acceptable limits on the following date: 3/23/2018 - 41.6 (outside 3SD). No corrective action was documented. Based on the worklist for 3/23/2018, the laboratory reported 27 patient results when the for 6-Acetylmorphine Level 2 control was high and outside of acceptable criteria. Review of quality control records for Opiates Level 1 indicated the laboratory established acceptability criteria defined as 196 - 292. Quality Control values were outside of acceptable limits on the following dates: 07/21/2017 - unacceptable value of 189 (LOW) with no corrective action documented. 3/23/2018 -low value of 191. No repeat or corrective action documented. Based on the worklist for 3/23/2018, the laboratory reported 27 patient results when the Opiates Level 1 control was low and outside of acceptable criteria. Review of quality control records for Opiates Level 2 indicated the laboratory established acceptability criteria defined as 272 - 402. Quality Control values were outside of acceptable limits on the following date: 6/15/2018 -409 (HIGH). No repeat or corrective action was documented. Based on review of the

	worklist for 6/15/2018, the laboratory reported 57 patient specimens when the Opiates Level 2 control was high and outside of acceptable limits. Review of quality control records for Cocaine Level 1 indicated the laboratory established acceptability criteria defined as 164 - 286. Quality Control values were outside of acceptable limits on the following date: 5/10/2018 unacceptable value of 304 - High. No corrective action was documented. Based on review of the worklist for 5/10/2018, the laboratory reported 32 patient specimens when the Cocaine Level 1 control was high and outside of acceptable limits. Review of quality control records for THC -Level 2 indicated the laboratory established acceptability criteria defined as 50 - 74. Quality Control values were outside of acceptable limits on the following dates: 6/30/2017 value of 49 (LOW). No corrective action taken or documented. 8/18/2017 value of 49 (LOW) no corrective action taken or documented. Based on the worklist for 08/18/2017, the laboratory reported 74 patient results when the THC -Level 2 control was low and outside of acceptable criteria. Review of quality control records for OxyContin Level 1 indicated the laboratory established acceptability criteria defined as 115 - 235. Quality Control values were outside of acceptable limits on the following dates: 10/20 /2017 -Value of 247 (HIGH) is unacceptable. No corrective action is documented. Based on the worklist for 10/20/2017, the laboratory reported 22 patient results when the OxyContin Level 1 control was high and outside of acceptable criteria. 3. In an interview at 15:05hours on 7/256/2018 in the Consult Room, when asked if patient results had been reported on days when quality control values were outside acceptable limits, the General Supervisor stated she was unaware it had been a problem and would follow up with the testing personnel each day of testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the laboratory failed to document corrective actions taken when the results of quality control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018. The findings included: 1. Based on review of the laboratory's procedure "BioLis 24i Routine Operation", on page 5 of 12, states the following: "Re-run Controls 1. If a control is out of range and needs to be re-run, follow the steps below: 1. Select QC from the main menu. 2. Select current QC 3. Place a check in the box next to the tests that need to be re-run in the ReRun column. 4. Press the Save button. 5. Exit the current QC screen and press Start at the main menu." 2. Based on review of the laboratory procedure "PAIN AND SPINE CENTER LABORATORY - INTERNAL QUALITY CONTROL", under PRINCIPLE, the document states the following: "Quality Control is a part of the total quality assurance process. QC consists of activities to ensure that each test or instrument is working properly. QC helps you to identify problems with your lab instruments, your reagents, or how the test was performed. Satisfactory QC results will give you confidence that your patient test results are accurate and precise before

reporting patient results. Testing lab instrument with controls that have known values. Follow the manufacturer's instructions for test procedures and preventative maintenance. Perform and document and remedial action taken when problems are identified." 3. Review of quality control records for Urine Creatinine Level 1 indicated the laboratory established acceptability criteria defined as 19 to 55. Quality Control values were outside of acceptable limits on the following dates: Based on review of the quality control records from 10/27/2017, the Urine Creatinine Level 1 control value was 60.2. This value was outside of the acceptability criteria of 19 to 55. Based on the worklist for 10/27/2017, the laboratory reported 54 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. 1/3 /2018: value of 58.3 5/10/2018: value of 57.5 5/25/2018: value of 56.6 7/13/2018: value of 56.3 Review of quality control records for Benzodiazepine -Level 1 indicated the laboratory established acceptability criteria defined as 81 to 171. Quality Control values were outside of acceptable limits on the following dates: 1/12/2018 - 218. No corrective action documented. 5/31/2018 -217 at 12:34 pm. Repeated value of 143 at 03:40 PM. No corrective action documented. Review of quality control records for Benzodiazepine -Level 2 indicated the laboratory established acceptability criteria defined as 146 - 290. Quality Control values were outside of acceptable limits on the following dates: 1/5/2018 at 09:11 a.m. Value of 141 (unacceptable) repeated at 11:46 am. Repeat value of 220. No corrective action documented. 5/31/2018 unacceptable value of 317 at 12:35 PM. Repeated value of 235 at 03:40 pm. No corrective action documented. Review of quality control records for 6-Acetylmorphine Level 1 indicated the laboratory established acceptability criteria defined as 4 -16. Quality Control values were outside of acceptable limits on the following dates: 1/22/2018 - Level of 2.4 3/16/2018 -unacceptable value of 1.1 at 10:57 a.m., Repeated value within limits at 4.2 at 11:20 am. No corrective action documented. 04/06/2018 - unacceptable value of 3.4 at 10:18 a.m., Repeated value within limits at 8.9 at 11:11 am. No corrective action documented. Review of quality control records for 6-Acetylmorphine Level 2 indicated the laboratory established acceptability criteria defined as 20 - 40. Quality Control values were outside of acceptable limits on the following dates: 3/23/2018 value of 41.6 (outside 3SD). No corrective action. Review of quality control records for Opiates Level 1 indicated the laboratory established acceptability criteria defined as 196 - 292. Quality Control values were outside of acceptable limits on the following dates: 07/21/2017 - unacceptable value of 189 with no corrective action documented. 12/09/2017 at 12:53 PM value of 191, repeated at 02:31pm acceptable at 237 no corrective action documented. 3/23/2018 value of 191. No corrective action documented. 5/10/2018 value of 177 at 02:41 (unacceptable). Repeated value of 196 at 03:08 p.m. No documented corrective action documented. Review of quality control records for Opiates Level 2 indicated the laboratory established acceptability criteria defined as 272 - 402. Quality Control values were outside of acceptable limits on the following dates: 6/15/2018 value of 409. No corrective action documented. Review of quality control records for Cocaine Level 1 indicated the laboratory established acceptability criteria defined as 164 - 286. Quality Control values were outside of acceptable limits on the following dates: 12/09/2017 - At 12:52 PM value of 153 is outside acceptable limits. The control is repeated at 02: 31 p.m. and is within acceptable limits at 196. No corrective action is documented. 5 /10/2018 value of 304 with no corrective action Review of quality control records for Cocaine Level 2 indicated the laboratory established acceptability criteria defined as 322 - 482. Quality Control values were outside of acceptable limits on the following dates: 12/09/2017 - At 12:53 PM value of 320 is outside acceptable limits. The control is repeated at 02:32 p.m. and is within acceptable limits at 366. No corrective action is documented. Review of quality control records for Urine Creatinine Level 1 indicated the laboratory established acceptability criteria defined as 19 - 55. Quality Control

	values were outside of acceptable limits on the following dates: On 7/21/2017 value of 58.3 and no corrective action documented. On 09/01/2017 value of 57.0 and no corrective action documented. On 10/27/2017 value of 60.2 and no corrective action documented. Review of quality control records for THC -Level 2 indicated the laboratory established acceptability criteria defined as 50 - 74. Quality Control values were outside of acceptable limits on the following dates: 6/30/2017: value of 49. No corrective action documented. 8/18/2017 value of 49 no corrective action documented. Review of quality control records for OxyContin Level 1 indicated the laboratory established acceptability criteria defined as 115 - 235. Quality Control values were outside of acceptable limits on the following dates: 7/21/2017 - unacceptable value at 01:12 pm of 275, repeated unacceptable value of 300 on 7/21 /2017 at 02:04 p.m. 10/20/2017 -Value of 247 is unacceptable. No corrective action is documented. 4. In an interview at 15:05hours on 7/256/2018 in the Consult Room, when to provide documentation of corrective actions on days when quality control values were outside acceptable limits, the General Supervisor stated she was unaware it had been a problem and would create a corrective action log.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, temperature records, patient test records, and interview with facility personnel, the laboratory failed to take and document corrective actions when the storage temperatures were outside acceptable limits for the storage of patient specimens 129 of 129 days between January 1, 2018 and June 29, 2018. The findings included: 1. Based on surveyor observations at 12:09 hours on 7/25/2018, the surveyor observed the laboratory storing 35 patient specimens in the freezer. The laboratory document "LABORATORY TEMPERATURE WORKSHEET" defined the acceptable freezer temperature as greater than or equal to -20 degrees Celsius. Previously analyzed patient specimens were stored in the door of the freezer, including specimens analyzed on 6/22/2018 and 6/29/2018. The specimens were stored in the freezer of a Whirlpool model wrt111sfab00. 2. Based on review of toxicology assay instructions for use, the manufacturer defined patient specimen storage requirements as follows: Opiate enzyme immunoassay: "For longer storage, up to 12 months, keep sample frozen (-20C) and then thaw before use." 6-Acetylmorphine enzyme immunoassay: For longer storage, keep sample frozen and then thaw before use. Studies have shown 6-Acetylmorphine analytes in urine are stable at -20C for up to three (3) years." 3. Based on review of quality control records and interview with the General Supervisor at 10:20 hours on 7/25/2018 in the consult room, the laboratory stores patient specimens in the freezer and batches testing on Fridays. For specimens tested on 6/22/2018, patient specimens had been stored at temperatures outside of the acceptable range between 6/19/2018 and 6/22/2018: Date: 6/19/2018 Freezer temperature: -16 C Corrective action recorded: None Date: 6/20 /2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/21/2018 Freezer temperature: -18 C Corrective action recorded: None Date: 6/22/2018 Freezer temperature: -18 C Corrective action recorded: None For patient specimens stored between 6/25/2018 and 6/29/2018, freezer temperatures were outside acceptable limits on the following dates: Date: 6/25/2018 Freezer temperature: -17 C Corrective action

	recorded: None Date: 6/26/2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/27/2018 Freezer temperature: -18 C Corrective action recorded: None Date: 6/28/2018 Freezer temperature: -17 C Corrective action recorded: None Date: 6/29/2018 Freezer temperature: -18 C Corrective action recorded: None Between January 1, 2018 and June 29, 2018, 129 of 129 temperatures recorded by the laboratory were outside of the acceptable range for storage of patient specimens. No corrective actions were documented for any of the 129 of 129 unacceptable temperatures. 4. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under Our QUALITY CONTROL policies were performed as specified, indicates the following quality monitor was met: "All required temperatures were taken and recorded" In the 6 of 6 monthly quality assurance checklists, the laboratory failed to identify that 129 of 129 recorded temperatures were outside of acceptable limits for storing patient specimens and no corrective actions had been taken and documented. 5. In an interview at 11:09 hours on 7/25/2018 in the laboratory, when asked to provide documentation of corrective actions for unacceptable temperatures, the General Supervisor stated that the laboratory did not document corrective actions for unacceptable temperatures and the recorded temperatures may not be accurate due to the testing personnel having difficulty reading the thermometer.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment procedure, policies and procedures, environmental records, quality control records, patient testing records, corrective action records, and interview with facility personnel the laboratory's quality assessment program failed to identify, monitor, correct and evaluate the effectiveness of corrections for problems in analytic systems. The findings included: 1. The laboratory's quality assessment procedure, titled "QUALITY ASSURANCE", under PRINCIPLE, states the following: "This laboratory believes in a strong Quality Assurance program. In order to implement quality assurance in the fullest, this laboratory has chosen a number of key indicators to assess periodically and help establish this goal. The entire laboratory staff will review potential problems and document all corrective actions taken to keep the records for at least two years. The quality-assurance system encompasses pre-analytical, analytical, and post analytical factors that can influence results such as: patient preparation, sample collection, sample handling, and storage. Pre-analytical factors are different to monitor and control because most occur outside the laboratory. Next, analytical factors consist of recording and transmission of the patient data to the physician." 2. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under Our QUALITY CONTROL policies were performed as

	specified, indicates the following quality monitor was met: "Y -All required temperatures were taken and recorded. Y - All necessary remedial action was performed and documented. Y - All quality control/calibrations were performed and were within acceptable limits before test results were reported. Y - Quality control results were examined for possible problems Y - Monthly Levy Jennings QC charts have been reviewed." In the 6 of 6 monthly quality assurance checklists, the laboratory's quality assessment procedures failed to ensure the relative humidity operating requirements were met 13 of 13 days between January 12, 2018 and June 29, 2018. Refer to D5413. In the 6 of 6 monthly quality assurance checklists, the laboratory's quality assessment procedures failed to establish and follow quality control procedures that monitored accuracy and precision of test performance over time for 22 of 22 lots of control materials between December 2016 and June 2018. Refer to D5441. In the 6 of 6 monthly quality assurance checklists, the laboratory's quality assessment procedures failed to ensure patient results were not reported unless quality control results were within established criteria. Refer to D5481. In the 6 of 6 monthly quality assurance checklists, the laboratory's quality assessment procedures failed to identify, monitor, and correct that Testing Personnel failed to document corrective actions taken when the results of quality control materials were outside acceptable limits. Refer to D5783. This is a REPEAT Deficiency. Deficient practices were cited at D5793 on the initial inspection conducted on 8/19/2016.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, quality control program and documentation, patient records, corrective action records, environmental temperature and humidity records, and interview with facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. Based on review of proficiency testing records, quality control records, and interview with facility personnel, the Laboratory Director failed to ensure an approved corrective action plan was followed when the second event of 2017 chemistry proficiency testing results for urine creatinine were unsatisfactory. Refer to D6092. Based on review of laboratory policies and procedures, quality control records, patient testing records, and interview with facility personnel, the Laboratory Director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services. Refer to D6093. Based on review of the laboratory's quality assessment procedure, policies and procedures, environmental records, quality control records, patient testing records, corrective action records, and interview with facility personnel, the Laboratory Director failed to establish and maintain a quality assessment program capable to identify, monitor, correct and evaluate the effectiveness of corrections for problems in all phases of laboratory testing. Refer to D6094. Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the laboratory director failed ensure that all necessary remedial actions were taken and documented whenever signification deviations from the laboratory's established performance were identified. Refer to D6096. This is a REPEAT deficiency. Deficient practices at D6076 were cited on the initial certification inspection on 8/19/2016.

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, quality control records, and interview with facility personnel, the Laboratory Director failed to ensure an approved corrective action plan was followed when the second event of 2017 chemistry proficiency testing results for urine creatinine were unsatisfactory. The findings included: 1. Based on review of the laboratory's procedure "PREPARATION, PROCESSING AND PERFORMANCE OF PROFICIENCY TESTING SPECIMENS", under RESULTS, states the following: "When PT results are received, they should be reviewed promptly. Proficiency results forms are graded by an optical scanner and occasionally and[sic] number can get misread. If this should be the case, you have a certain time period in which you can dispute the error. Please be aware of these time frames. When assessing unacceptable PT results, please consider the following: Technical Ability Specimen handling Instrument function Clerical error" 2. Based on review of the American Proficiency Institute (API) records from the second event of 2017, the laboratory received a score of thirty-three (33) percent for the analyte urine creatinine. Sample: UAD-04 Lab Result: 0.0 Expected Result: 0.0 - 0.6 Grade: Acceptable Sample: UAD-05 Lab Result: 10.0 Expected Result: 5.1 - 7.7 Grade: Unacceptable Sample: UAD-06 Lab Result: 10.3 Expected Result: 5.2 - 7.9 Grade: Unacceptable 3. Based on review of analytic records, API specimens UAD-04, UAD-05, and UAD-06 were tested on 10/27/2017. 4. On the PROFICIENCY TESTING PERFORMANCE EVALUATION worksheet, the laboratory documented the following: "All Analytes Except Crea 100 percent Reviewed Cal and Cntls for PT Testing Day Acceptable No Abnormal Pts Reported Unable to Repeat Crea Due to Samples Being Discarded" 5. Based on review of the quality control records from 10 /27/2017, the Urine Creatinine Level 1 control value was 60.2. This value was outside of the acceptability criteria of 19 to 55. Based on the worklist for 10/27/2017, the laboratory reported 54 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. 6. In an interview at 10: 28 hours on 7/25/2018 in the Consult Room, the General Supervisor stated that she believed the controls were within acceptable limits at the time of testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient testing records, and interview with facility personnel, the Laboratory Director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services. The findings included: 1. Based on review of the laboratory procedure "PAIN AND SPINE CENTER LABORATORY - INTERNAL QUALITY CONTROL", under PRINCIPLE, the document states the following:

	"Quality Control is a part of the total quality assurance process. QC consists of activities to ensure that each test or instrument is working properly. QC helps you to identify problems with your lab instruments, your reagents, or how the test was performed. Satisfactory QC results will give you confidence that your patient test results are accurate and precise before reporting patient results. Testing lab instrument with controls that have known values. Follow the manufacturer's instructions for test procedures and preventative maintenance. Perform and document and [sic] remedial action taken when problems are identified." 2. Based on review of laboratory policies and procedures, quality control records, patient records, and interview with facility personnel, the laboratory director failed to establish quality control procedures that monitored accuracy and precision of test performance over time for 22 of 22 lots of control materials between December 2016 and June 2018. Refer to D5441. 3. Based on review of quality control records, patient test records, and interview with facility personnel, the laboratory director failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D5481. This is a REPEAT deficiency. Deficient practices at D6193 were cited on the initial certification inspection on 8/19 /2016.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment procedure, policies and procedures, environmental records, quality control records, patient testing records, corrective action records, and interview with facility personnel, the Laboratory Director failed to establish and maintain a quality assessment program capable to identify, monitor, correct and evaluate the effectiveness of corrections for problems in all phases of laboratory testing. The findings included: 1. The laboratory's quality assessment procedure, titled "QUALITY ASSURANCE", under PRINCIPLE, states the following: "This laboratory believes in a strong Quality Assurance program. In order to implement quality assurance in the fullest, this laboratory has chosen a number of key indicators to assess periodically and help establish this goal. The entire laboratory staff will review potential problems and document all corrective actions taken to [sic] keep the records for at least two years. The quality-assurance system encompasses pre-analytical, analytical, and post analytical factors that can influence results such as: patient preparation, sample collection, sample handling, and storage. Pre-analytical factors are different [sic] to monitor and control because most occur outside the laboratory. Next, analytical[sic] factors consist of recording and transmission of the patient data to the physician." 2. Based on a review of quality assessment records from January 2018 through June 2018, each form had a "y" with a line drawn down the middle of each row for all quality assessment monitoring procedures. The document "MONTHLY QUALITY ASSURANCE CHECKLIST", under Our QUALITY CONTROL policies were performed as specified, indicates the following quality monitor was met: "Y -All required temperatures were taken and recorded. Y - All necessary remedial action was performed and documented. Y - All quality control/calibrations were performed and were within acceptable limits before test results were reported. Y - Quality control results were examined for possible

	problems Y - Monthly Levy Jennings QC charts have been reviewed." The laboratory's quality assessment procedures failed to identify unacceptable temperatures for storage of patient specimens. Refer to D5393. The laboratory's quality assessment procedures failed to identify unacceptable operating environmental conditions for the BioLis 24i chemistry analyzer, the quality control program failed to monitor the accuracy and precision of control performance over time, and the laboratory failed to ensure that quality control values were within acceptable limits prior to reporting patient test results. Refer to D 5793. This is a REPEAT deficiency. Deficient practices at D6194 were cited on the initial certification inspection on 8/19 /2016.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever signification deviations from the laboratory's established performance were identified. The findings included: 1. The laboratory director failed to ensure a corrective action plan was followed and remedial actions taken for patients when the results of the second event of 2017 proficiency testing scores were unsatisfactory and quality control values on the day of testing were outside acceptable limits. Refer to D6092. 2. The laboratory director failed to ensure the laboratory documented corrective actions taken when the results of quality control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018. Refer to D5481.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's quality control program and documentation, environmental records, corrective action records, patient records, and interview with facility personnel, the Technical Supervisor failed to provide technical supervision of the laboratory. The findings included: 1. Based on review of the laboratory's proficiency testing records, quality control program and documentation, patient records, corrective action records, environmental temperature and humidity records, and interview with facility personnel, the Technical Supervisor failed to provide technical and scientific oversight of the laboratory. Refer to D6112. 2. Based on review of laboratory policies and procedures, quality control records, patient testing records, and interview with facility personnel, the Technical Supervisor failed to ensure a quality control program appropriate for the testing performed was established and the parameters for acceptable levels of analytic performance and ensuring that

	these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results were established and maintained. Refer to D6117. 3. Based on quality control records, patient test records, and interview with facility personnel, the Technical Supervisor failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D6119. 4. Based on review of the laboratory's proficiency testing records, quality control program and documentation, patient records, corrective action records, environmental temperature and humidity records, and interview with facility personnel, the Technical Supervisor failed to identify training needs of personnel performing high complexity testing. Refer to D6120. This is a REPEAT deficiency. Deficient practices at D6108 were cited on the initial certification inspection on 8/19 /2016.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, quality control program and documentation, patient records, corrective action records, environmental temperature and humidity records, and interview with facility personnel, the Technical Supervisor failed to provide technical and scientific oversight of the laboratory. The findings included: Based on review of laboratory policies and procedures, quality control records, patient testing records, and interview with facility personnel, the Technical Supervisor failed to ensure a quality control program appropriate for the testing performed was established and the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results were established and maintained. Refer to D6117. Based on quality control records, patient test records, and interview with facility personnel, the Technical Supervisor failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D6119.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient testing records, and interview with facility personnel, the Technical Supervisor failed

	to ensure a quality control program appropriate for the testing performed was established and the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results were established and maintained. The findings included: 1. Based on review of the laboratory procedure "PAIN AND SPINE CENTER LABORATORY - INTERNAL QUALITY CONTROL", under PRINCIPLE, the document states the following: "Quality Control is a part of the total quality assurance process. QC consists of activities to ensure that each test or instrument is working properly. QC helps you to identify problems with your lab instruments, your reagents, or how the test was performed. Satisfactory QC results will give you confidence that your patient test results are accurate and precise before reporting patient results. Testing lab instrument with controls that have known values. Follow the manufacturer's instructions for test procedures and preventative maintenance. Perform and document and [sic] remedial action taken when problems are identified." 2. Based on review of laboratory policies and procedures, quality control records, patient records, and interview with facility personnel, the Technical Supervisor failed to establish quality control procedures that monitored accuracy and precision of test performance over time for 22 of 22 lots of control materials between December 2016 and June 2018. Refer to D5441. 3. Based on quality control records, patient test records, and interview with facility personnel, the Technical Supervisor failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D5481. 4. Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the Technical Supervisor failed to ensure the laboratory documented corrective actions taken when the results of quality control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018. Refer to D5783.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on quality control records, patient test records, and interview with facility personnel, the Technical Supervisor failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D5481 and D5783.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of the laboratory's proficiency testing records, quality control program and documentation, patient records, corrective action records, environmental temperature and humidity records, and interview with facility personnel, the Technical Supervisor failed to identify training needs of personnel performing high complexity testing. The findings included: The Technical Supervisor failed to identify the training needs of personnel performing high complexity testing. This is evidenced by: a. Testing Personnel failed to document corrective actions when quality control results were outside of acceptable limits. Refer to D5783. b. Testing Personnel failed to document corrective actions when freezer temperatures were outside of laboratory established limits for the storage of patient specimens. Refer to D5785. c. Testing Personnel failed to ensure the results of quality control materials were within acceptable limits prior to reporting patient or proficiency testing results. Refer to D5481.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor observations, temperature records, quality control policies and procedures, quality control records, patient records, and interview with facility personnel, the General Supervisor failed to provide supervision of day to day laboratory operations. The findings included: 1. Based on quality control records, quality assessment records, patient testing records, environmental records, and interview with facility personnel, the General Supervisor failed to provide day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Refer to D6144. 2. Based on quality control records, quality assessment records, patient testing records, environmental records, and interview with facility personnel, the General Supervisor failed to monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. Refer to D6148. This is a REPEAT deficiency. Deficient practices at D6141 were cited on the initial certification inspection on 8/19/2016.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on quality control records, quality assessment records, patient testing records, environmental records, and interview with facility personnel, the General Supervisor failed to provide day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. The findings included: 1. The General Supervisor failed to provide day-to-day supervision of personnel performing high complexity testing. This is evidenced by: a. General Supervisor failed to ensure

	Testing Personnel documented corrective actions when quality control results were outside of acceptable limits. Refer to D5783. b. General Supervisor failed to ensure Testing Personnel documented corrective actions when freezer temperatures were outside of laboratory established limits for the storage of patient specimens. Refer to D5785. c. General Supervisor failed to ensure Testing Personnel evaluated the results of quality control materials to ensure they were within acceptable limits prior to reporting patient or proficiency testing results. Refer to D5481. d. Quality Assessment records complied and approved by the General Supervisor failed to identify any problems in toxicology testing. Refer to D5393 and D5793.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on quality control records, quality assessment records, patient testing records, environmental records, and interview with facility personnel, the General Supervisor failed to monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. The findings included: 1. 1. Based on review of the laboratory's procedure "PREPARATION, PROCESSING AND PERFORMANCE OF PROFICIENCY TESTING SPECIMENS", under RESULTS, states the following: "When PT results are received, they should be reviewed promptly. Proficiency results forms are graded by an optical scanner and occasionally and[sic] number can get misread. If this should be the case, you have a certain time period in which you can dispute the error. Please be aware of these time frames. When assessing unacceptable PT results, please consider the following: Technical Ability Specimen handling Instrument function Clerical error" 2. Based on review of the American Proficiency Institute (API) records from the second event of 2017, the laboratory received a score of thirty-three (33) percent for the analyte urine creatinine. Sample: UAD-04 Lab Result: 0.0 Expected Result: 0.0 - 0.6 Grade: Acceptable Sample: UAD-05 Lab Result: 10.0 Expected Result: 5.1 - 7.7 Grade: Unacceptable Sample: UAD-06 Lab Result: 10.3 Expected Result: 5.2 - 7.9 Grade: Unacceptable 3. Based on review of analytic records, API specimens UAD-04, UAD-05, and UAD-06 were tested on 10/27/2017. 4. On the PROFICIENCY TESTING PERFORMANCE EVALUATION worksheet, the laboratory documented the following: "All Analytes Except Crea 100 percent Reviewed Cal and Cntls For PT Testing Day Acceptable No Abnormal Pts Reported Unable to Repeat Crea Due to Samples Being Discarded [sic]" 5. Based on review of the quality control records from 10/27/2017, the Urine Creatinine Level 1 control value was 60.2. This value was outside of the acceptability criteria of 19 to 55. Based on the worklist for 10/27/2017, the laboratory reported 54 patient results when the urine creatinine level 1 control was high and outside of acceptable criteria. 6. In an interview at 10: 28 hours on 7/25/2018 in the Consult Room, the General Supervisor stated that she believed the controls were within acceptable limits at the time of testing. 7. Based on quality control records, patient test records, and interview with facility personnel, the General Supervisor failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D5481. 8. Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the General Supervisor failed to ensure that testing personnel documented corrective actions taken when the results of quality

	control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observations, temperature records, quality control policies and procedures, quality control records, patient records, and interview with facility personnel, the testing personnel failed to perform and document corrective actions when quality control values were outside of acceptable limits. The findings included: 1. Based on review of laboratory policy, quality control records, patient test records, and interview with facilty personnel, Testing Personnel performing high complexity testing failed to follow laboratory quality control policies and procedures and document all quality control activities between June 2017 and July 2018. Refer to D6177 2. Based on laboratory policies and procedures, quality control records, freezer temperature records, patient test records, and interview with facility personnel, the Testing Person failed to take and document all corrective actions taken for control values outside of acceptable limits and freezer temperatures outside of acceptable storage requirements. Refer to D6181. This is a REPEAT deficiency. Deficient practices at D6168 were cited on the initial certification inspection on 8/19/2016.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control records, patient test records, and interview with facility personnel, Testing Personnel performing high complexity testing failed to follow laboratory quality control policies and procedures and document all quality control activities between June 2017 and July 2018. The findings included: 1. Based on review of the laboratory's procedure "BioLis 24i Routine Operation", on page 5 of 12, states the following: "Re-run Controls 1. If a control is out of range and needs to be re-run, follow the steps below: 1. Select QC from the main menu. 2. Select current QC 3. Place a check in the box next to the tests that need to be re-run in the ReRun column. 4. Press the Save button. 5. Exit the current QC screen and press Start at the main menu." 2. Based on quality control records, patient test records, and interview with facility personnel, the Testing Personnel failed to ensure that the results of quality control materials were acceptable prior to reporting patient test results for 14 days between June 30, 2017 and July 13, 2018. Refer to D5481. 3. Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the Testing Personnel failed to

	document corrective actions taken when the results of quality control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018. Refer to D5783.
D6181	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(6) Each individual performing high complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on laboratory policies and procedures, quality control records, freezer temperature records, patient test records, and interview with facility personnel, the Testing Person failed to take and document all corrective actions taken for control values outside of acceptable limits and freezer temperatures outside of acceptable storage requirements. The findings included: 1. Based on review of the laboratory's procedure "BioLis 24i Routine Operation", on page 5 of 12, states the following: "Re-run Controls 1. If a control is out of range and needs to be re-run, follow the steps below: 1. Select QC from the main menu. 2. Select current QC 3. Place a check in the box next to the tests that need to be re-run in the ReRun column. 4. Press the Save button. 5. Exit the current QC screen and press Start at the main menu." 2. Based on review of laboratory procedures, quality control records, patient test records, and interview with facility personnel, the Testing Personnel failed to document corrective actions taken when the results of quality control materials were outside acceptable limits 14 days between June 30, 2017 and July 13, 2018. Refer to D5783.