Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2001177	05/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Interventional Pain Institute	2700 Lighthouse Point East Suite 402, Baltimore, MD	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and the exit interview with the quality manager (QM), the laboratory failed to retain quality assessment (QA) records for one of ten months reviewed. Findings: 1. Every month the testing person would send a packet of QA documentation to the laboratory director for review. 2. The packet included the liquid chromatography mass spectrometry maintenance log, the Indiko Plus maintenance log, the temperature and humidity log, and the monthly QA review form which documented the review of a different QA monitor each month according to a schedule. 3. The QA records were reviewed from 06/2022 - 03/2023 for a total of 10 months. Records from 07/2022 were not available during the survey. 4. During the exit interview on 05/23/2023 at 2:45 PM, the QM confirmed that the QA records for 07/2022 were not available at the time of the survey.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, review of the procedure, and interview with the quality manager (QM), the laboratory failed to document a self-evaluation of toxicology PT scores that were ungraded by the College of American Pathologists (CAP) PT program. Findings: 1. The laboratory was enrolled with CAP for two annual events (A and B) for Urine Drug Adulterant (DAI) and Drug Monitoring for Pain Management (DMPM) PT programs. 2. The CAP PT program used reason codes when a PT sample was not graded. 3. Reason code [22] was "Result is outside the method/instrument reportable range" and used in the following PT events: a. DMPM-A 2022 for sample DMPM-01 b. DMPM-B 2021 for sample DMPM-06 4. Reason code [26] was "Educational challenge" and used in the following PT events: a. DAI-A 2023 for samples DAI-01 through DAI-03 b. DAI-A 2022 for samples DAI-01 through DAI-03 c. DAI-B 2021 for samples DAI-04 through DAI-06 5. Reason code [27] was "Lack of participant or referee consensus" and used in PT event DMPM-B 2022 for sample DMPM-08. 6. Reason code [30] was "Scientific committee decision" and used in PT event DMPM-A 2022 for sample DMPM-04. 7. Reason code [42] was "No credit assigned due to absence of response" and used in PT event DMPM-B 2022 for sample DMPM-05. 8. Reason code [46] was "Quantitation not appropriate" and was used in PT event DMPM-B 2022 for sample DMPM-05. 9. The laboratory's procedure, SLP 10 Proficiency Testing, stated that ungraded PT challenges "will be reviewed and documented using guidance from Appendix I in the CAP Laboratory Accreditation Manual for listing of PT exception codes and actions." Appendix I was not attached to the procedure. 10. There was no indication on any of the PT documentation that the laboratory's results for samples with ungraded PT results were compared with results listed in CAP's participant summary to verify accuracy. 11. During the survey on 04/25/2023 at 5:00 PM, the QM confirmed that self-evaluations of ungraded CAP PT results were not 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 review of the procedure manual, "Corrective/Preventive Action Request" (CAPA), quality control product insert (PI), referenced stability study, and batch tracking log, and exit interview with the testing person (TP) and quality manager (QM), the laboratory's procedure manual failed to reflect laboratory practice for urine specimen storage and failed to establish urine specimen stability criteria to ensure accurate and reliable results for toxicology testing using liquid chromatography tandem mass spectrometry (LCMSMS). Findings: 1. The laboratory tested urine specimens for drug analytes using LCMSMS. 2. During the exit interview on 05/23 /2023 around 2:30 PM, the TP explained that an aliquot of the patient specimens was pipetted into a deep well plate and then frozen after patients were tested on the LCMSMS. The TP stated that the original specimen containers were stored in the

	refrigerator for up to 7 days. If a retest was required within 7 days of collection, then the original specimen stored in the fridge was used. If it was after 7 days, then the aliquot from the frozen deep well plate was thawed and used for the retest. If another retest was needed, then the deep well plate would be thawed a second time and the specimen aliquot used again. If multiple retests were required, then the deep well plate would be thawed and frozen multiple times. 3. A CAPA dated 06/17/2022 stated that the "Quality team confirmed samples were stable refrigerated for 7 days and frozen for 30 days. Aliquoting specimens and freezing was an approved storage method." 4. The "Specimen Rejection Criteria" (5.5.2) of the procedure titled "Specimen Collection and Handling" (SLP 13) stated "The specimen collection date should be within 7 days of the date it is to be tested at the laboratory. If the storage period exceeds this criteria, specimens may still be tested and reported at the discretion, approval, and instruction of the Supervisor and/or Laboratory Director." 5. The laboratory did not provide a procedure that stated specimens were stable frozen for 30 days or instructed where to obtain a patient specimen when a retest was required. 6. The laboratory provided an article to be referenced for data on urine specimen stability for drug testing. The article included stability data for 30 of the 42 analytes tested by the laboratory. Each analyte was tested at time point 0 and then 2, 3, and 6 months after collection and at storage temperatures of 4 degrees Celsius (C), -20 C, and -20 C with an additional freeze-thaw cycle. Results showed that buprenorphine, norbuprenorphine, methadone, lorazepam, and meprobamate results were outside acceptance criteria at 2 months when stored at -20 C with an additional freeze-thaw cycle indicating that multiple freeze-thaw cycles impacted results accuracy. 7. The PI for the calibrators and quality control reagents used in each batch of testing stated "Freeze-thaw cycles may impact accuracy of results. It is recommended that laboratories perform in-house freeze-thaw testing to determine the maximum cycle number for their assay." 8. The laboratory procedures did not state how many freeze-thaw cycles urine specimens could be subjected to before the accuracy of results were affected. 9. The laboratory utilized a batch tracking log to document patient testing. All patient accession numbers and when they were screened using the Indiko Plus analyzer and confirmed using LCMSMS were documented on the batch tracking log. Review of the batch tracking log showed many instances where patient specimens were retested multiple times. Some example accession numbers are listed below: a. 1801: The specimen was screened on 02/16/2023 and run with LCMSMS on 02/21 /2023, 02/24/2023, 02/27/2023, 02/28/2023, 03/02/2023, and lastly on 03/06/2023 (18 days after the screen). b. 1926: The specimen was screened on 02/27/2023 and run with LCMSMS on 02/27/2023, 02/28/2023, 03/02/2023, 03/06/2023, 03/09/2023, and lastly on 03/13/2023 (14 days after the screen). c. 2250: The specimen was screened on 03/14/2023 and run with LCMSMS on 03/17/2023, 03/23/2023, and lastly on 04/10 /2023 (27 days after the screen). d. 2674: The specimen was screened on 04/04/2023 and run with LCMSMS on 04/11/2023, 04/14/2023, 04/18/2023, 04/28/2023, and lastly on 05/03/2023 (29 days after the screen). 10. The laboratory did not have stability data demonstrating that results for all reported analytes were accurate and reliable after multiple freeze-thaw cycles. 11. During the exit interview on 05/23/2023 at 2:45 PM, the QM confirmed that the laboratory did not have approved procedures describing the specimen storage and retest protocols currently in use and did not have stability data demonstrating that all reported analytes were stable after multiple urine specimen freeze-thaw cycles.
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: I. Based on review of the policy and procedure manuals and interview with the quality manager (QM), the laboratory failed to have written policies and procedures for documenting the lot numbers of the reagents, calibrators and quality control (QC) material used by the laboratory on the "Batch Tracking log" excel worksheet. Findings: 1. Review of the procedure manual showed that there were no written procedures for keeping records of the lot numbers and expiration dates of the reagents, calibration and quality control materials used on the Indiko Plus (toxicology) analyzer. 2. During the exit interview on 05/23/2023 at 2:25 PM, the QM confirmed that the laboratory's procedure manual failed to include written policies and procedures for maintaining the lot numbers and expiration dates of the reagents, calibration and QC materials when they were put into use and the prior lot was discontinued on the "Batch Tracking log" excel worksheet. II. Based on review of the policy and procedure manuals and interview with the testing person (TP), the laboratory failed to have written policies and procedures for documenting the corrective actions taken when there were failures with the Indiko Plus and liquid chromatography tandem mass spectrometry (LC-MS/MS) (toxicology analyzers) on the "Batch Tracking log" excel worksheet. Findings: 1. Review of the procedure manual showed that there were no written procedures for documenting corrective actions taken when there were failures with the Indiko Plus and the LC-MS/MS analyzers. 2. According to the TP the corrective actions and communications to the technical supervisor (TS) are to be recorded on the "Batch Tracking log" excel worksheet since the TS has remote access the information recorded 3. During the survey on 04/25/2023 at 4:15 PM, the TP confirmed that the laboratory's procedure manual failed to include written policies and procedures for documenting corrective actions on the "Batch Tracking log" excel worksheet.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
I. Based on review of the quality control (QC) and calibration records for the Indiko Plus and liquid chromatography tandem mass spectrometry (LC-MS/MS) toxicology analyzers and interview with the testing person (TP), the laboratory failed to ensure calibration and QC materials were not used after their expiration date. Findings: 1. The printed calibration and QC records and the information in the Indiko Plus and LC-MS/MS analyzers failed to include the lot number and expiration date of the QC materials used prior to the current lot in use. 2. During the survey on 04/25/2023 at 4: 15 PM, the TP confirmed that the laboratory's record system failed to include documentation of the lot numbers and expiration dates of the calibration and QC materials in use and when the prior lot was discontinued to show that they were not used past the manufacturer's defined expiration date. II. Based on review of the "Batch Tracking Logs" records for the Indiko Plus and LC-MS/MS toxicology analyzers, and interview with the testing person (TP) and quality manager (QM), the laboratory failed to ensure that the records included the lot numbers (#) and expiration (exp) dates of all the calibrators, buffers, reagents, and quality control (QC) materials used for patient testing to ensure that nothing was used past the expiration date. Findings: 1. According to the TP and QM the "Batch Tracking Log" should include documentation of lot numbers and expiration dates of the calibrators, buffers, reagents and QC materials used in the laboratory. 2. The "Batch Tracker Logs" from July 7, 2022 to May 5, 2023 were reviewed. The "Batch ID" column identifies the LC-MS /MS with a batch ID number that includes the year, month, and day followed by an "A" and the Indiko Plus as "Screens" followed by the month and day. 3. On 02/22 /2022 the new ISTD was documented on the comment section for batch "20220722A1 (repre" and "20220809A." There are no additional records showing that the ISTD had been replaced after the expiration date of 08/2022. 4. Proficiency Testing (PT) is provided by the PT agency twice a year. The only time PT was recorded on the "Batch Tracking Log" was 10/07/2022. Tracking Log." 5. On 10/10/22 "New Creatinine Calibrators (2.0 and 23.0) lot 74588624-5" were documented without an exp date documented. 6. On 10/17/22 "New Negative Uri Cal" was documented on the "Batch Tracking Log." There was no documentation of the new lot # and exp date. 7. The "Batch Tracking Log" from July 7, 2022 to May 5, 2023 showed that the "guard column" on the LC-MS/MS was changed on 08/09/2022, 10/20/2022, 02/27/2023 and there was a post-it note on the analyzer that states "New column 03/04/22." According to the "Attachment 1_Email response notes" document received on 05/23/2023, the "guard column changes are required monthly." The "Batch Tracking Log" shows that the guard column was not documented as being changed six of ten months that were reviewed. 8. On 10/27/2000 "New Cal/QC lot" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 9. On 11/15/2022 "New neg uri calibrator" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 10. On 11/16/2022 "New creatinine 7.5 and 23.0 QCs" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 11. On 12/02/2022 "New Mobile Phase A" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 12. On 12 /16/2022 "New Primary Control Lot 7447839" was documented on the "Batch Tracking Log." There was no new exp date documented. 13. On 01/01/2023 "New Cal /QC lot" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 14. On 01/23/2021 "New Mobile Phase A and Needle Wash Solution" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 15. On 02/02/2023 "New IS Lot 2232015 04/2023" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented on 05/01/2023 once the previous lot expired and anything prior to that date. The records failed to include documentation of new lot # and exp dated each

time the "IS [internal standard]" was changed 16. On 01/26/2023 "Plate needs reprep due to shifting" was documented on the "Batch Tracking Log." The "comment" section did not identify what drug was shifting, which patient specimens need re-prepping, which analytes need to be retested. 17. On 01/30/2023 "Reprep of 20230126A" was documented on the "Batch Tracking Log." There was no "r" behind the batch ID# 20230126A to indicate a repeat analysis. The run was given a new batch ID #- 20230130A. The laboratories protocol of labeling the runs was not followed. 18. On 02/06/2023 "New Primary QC Lot 74478395 exp 12/31/2023" was documented on the "Batch Tracking Log." Primary control is listed on 2-6-2023 and 2-2-2023 with the same lot # and expiration date. The records do not include when the previous Primary QC was started along with the lot # and exp date. 19. On 02/16/2023 "New MPA[Mobile Phase A] and Needle Wash" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented. 20. On 02/27/2023 "Reprep of 20230224A (plus additional samples); New MPB[Mobile Phase B], new guard column; IPA[Isopropyl Alcohol] Flush performed 2/27/23" was documented on the "Batch Tracking Log." Batch "20230224A" is not listed on the "Batch ID" column. There is no documentation showing that there was a run on 02/24/2023. There is no documentation stating why "20230224A" was repeated. 21. On 02/27 /2023 "Reprep of 20230224A (plus additional samples); New MPB, new guard column; IPA Flush performed 2/27/23" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented for the "New MPB" and "new guard column." 22. On 03/02/2023 "Reprep of 20230227A; new needle wash" was documented on the "Batch Tracking Log." The "Batch ID" is listed as "20230227Ar." Review of the "Sample Range" showing that samples (1933-1937) (1940) (1942) were being repeated. This information is not included in the "comment" section. 23. On 03 /07/2023 "New BG QC added to end of plate: New Needle Wash" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented for the "BG QC" and the "New Needle Wash." 24. On 03/20/2023 "New pH 7.0 control lot 74560412" was documented on the "Batch Tracking Log." There was no new exp date documented for the pH 7.0. 25. On 03/20/2023 "New Enzyme Lot E22-08004A; BETA GLUC is in well E1 (accidentally spiked old BG in the B1 cell)" was documented on the "Batch Tracking Log." There was no new exp date documented for the "New Enzyme" and now follow-up for "(accidentally spiked old BG in the B1 cell)." 26. On 03/23/2023 "New MPA; Run did not finish; N2 generator error, needs repair- LCMS down" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented for the "MPA" and no documentation of the storage of the specimens that were not able to be tested due to the LC-MS/MS failure. 27. On 04/10/2023 "First run since LCMS went down 3-23; received chiller from InTech 4-6. All samples stored on plate in Freezer. New MPB prepped 4/6/23" was documented on the "Batch Tracking Log." There was no new lot # and exp date documented for the "MPB" and no documentation of which samples were being stored on the plate in the freezer. 28. On 04/11/2023 "2591-2666 stored in freezer on plate" was documented on the "Batch Tracking Log." There was no documentation stating why the specimens needed to be repeated. The specimens were repeated on 04 /14/2023 on "Batch ID" "20230414A." 29. On 05/01/2023 "Only ran one single sample to test the updated MDC. All results appear to be sending over to LIS [laboratory information system]" was documented on the "Batch Tracking Log." Since there is no "Batch ID" number recorded on the "Batch Tracking Log", this comment is referring to the Indiko screening analyzer. The documentation does not identify whether this is a problem, or this is an annual validation of the LIS. 30. The "Batch Tracking Log" that was provided had 7 pages. The records show that only a screening was performed on 04/28/2023 and there was no LC-MS/MS testing. According to the "Time loaded/Dated added to log" column, "Batch ID"

	"20230428Ar" was released on "5/3/23@11:55am." The records do not show when "20230428A" was originally tested. 31. According to the TP the MPA and MPB buffers and "Needle Wash" solution are good for two months after they are prepared. The TP stated that the buffers and needle wash are routinely prepared monthly because they are depleted before they expired. The "Batch Tracking Log" showed that the MPA buffer was documented as being prepared twice during the ten months reviewed, and the MPB buffer and Needle wash solution were documented as being prepared three times during the ten months reviewed. 32. During the exit interview on 05/23/2023 at 2:20 PM, the TP and QM confirmed that the laboratory's record system failed to include documentation of the lot numbers and expiration dates of the calibration and QC materials in use and when the prior lot was discontinued to show that they were not used past the manufacturer's defined expiration date. 43123 III. Based on review of the batch tracking log and exit interview with the quality manager (QM), the laboratory failed to ensure the enzyme was not tested beyond the stated expiration date for toxicology testing using liquid chromatography tandem mass spectrometry (LCMSMS). Findings: 1. New lot numbers of LCMSMS reagents were documented on the batch tracking log. The batch tracking log was reviewed for the dates 07/06/2022 - 05/05/2023. 2. On 07/25/2022 it was noted that a new enzyme, lot 01003b with an expiration date of 02/2023, was put into use. 3. The next new enzyme, lot E22-08004A, was documented as put into use on 03/20/2023. No expiration date was listed. 4. Batches 20230301Ar, 20230306A, 20230307A, 20230309A, 20230313A, and 20230317A were run after lot 01003b was expired and before lot E22-08004A was put into use. 5. During the exit interview on 05/23/2023 at 2:45 PM, the QM confirmed that batches were documented on the batch tracking log after the enzyme (lot 01003b) was expired and before the next enzyme was put into use. IV. Based on review of the procedure and batch tracking log and interview with the quality manager (QM), the laboratory failed to document the lot number and expiration dates of the individual components used to prepare LCMSMS solvents. Findings: 1. Appendix I of the procedure titled ""Sample Preparation" (SLP 16) stated that the stability for in-house prepared mobile phase A (MPA), mobile phase B (MPB), and needle wash solvents was "6 months or expiration of individual components whichever is first." 2. The laboratory's batch tracking log stated to document new lots of solvents in the "Notes" section of the log. 3. The batch tracking log was reviewed for the dates 07/06/2022 - 05/05/2023. New MPA, MPB, and needle wash solvents were listed on the log, but the date of preparation and lot numbers and expiration dates of the individual components used to prepare each solvent were not documented on the log. 4. During the exit interview on 05/23/2023 at 2:45 PM, the QM confirmed that the laboratory did not document the lot numbers and expiration dates of the individual components of the in-house prepared MPA, MPB, and needle wash solvents to ensure that reagents were not used beyond their expiration.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of maintenance logs, and interview with the quality manager (QM), the laboratory failed to define the acceptable range for the starting binary pump pressure and the corrective actions to be taken if values fell outside the acceptable range. Findings: 1. The laboratory performed toxicology testing using a liquid chromatography mass spectrometry (LCMS) assay developed by the laboratory. 2. The monthly LCMS Maintenance Log included a column to document the daily "Starting Binary Pump Pressure", which was re-labeled as "N2 Pressure (95-120) PSI" in 02/2023. 3. The "Agilent 6400 Series Operation and Maintenance" procedure did not include instructions for checking the pump pressure daily, what the acceptable pressure range was, or what corrective actions to take if the pump pressure was outside the acceptable range. 4. The acceptable range of 95-120 PSI was included on the LCMS Maintenance Logs beginning in 02/2023. 5. The LCMS Maintenance Logs for 08/2022 - 03/2023 were reviewed. 6. Based on an acceptable range of 95-120 PSI, the pump pressure was out of acceptable range on 1 of 5 days recorded in 08/2022, 2 of 6 days recorded in 10/2022, 1 of 6 days recorded in 12/2022, 7 of 8 days recorded in 01/2023, 1 of 9 days recorded in 02/2023, and 1 of 8 days recorded in 03/2023. 7. During the survey on 04/25/2023 at 5:00 PM, the QM confirmed that there were no procedures defining the acceptable daily pump pressure range and what corrective actions should be taken if values were outside the acceptable range.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory failed to document the corrective actions taken when the liquid chromatography tandem mass spectrometry (LC-MS/MS) instrument failed to complete the patient test run. Findings: 1. According to the email correspondence between the TP and the technical supervisor (TS) and comments documented in the "Batch Tracking Log" excel spreadsheet by the TP, the LC-MS/MS analyzer failed to function as required on 03/23/2023. 2. A field engineer was on site on 03/29/23 and 03/30/23 for repairs. The repairs could not be completed so the "chiller" portion of the LC-MS/MS analyzer was sent for repairs on 03/30/23. 3. The "chiller" was received back at the laboratory on 04/06/23 and the TP connected it to the LC-MS/MS analyzer. 4. On 04/07/23 the TP, with the assistance of a remote engineer, performed some tests to adjust the "chiller" and verify that it was working properly. 5. Patients were retested on 04/10/23 and released on 04/11/23. 6. Specimen #2250 was received on 03/14/23 and tested on 03/17/23. Specimen #2250 was flagged by the TS and scheduled to be retested on 03/23/23. Specimen #2250 was on the batch that was tested on 03/23/23 when the LC-MS/MS analyzer failed. Specimen #2250 was not

	retested until 04/10/23 and released on 04/11/23. 7. According to the procedure manual patient specimens are to be tested within 7 days. If not tested within that time frame the specimen is to be frozen. The TP stated that specimen #2250 was frozen after the initial testing on 03/17/23, defrosted and tested again on 03/23/23, and frozen again after the failure of the LC-MS/MS analyzer. The specimen was not tested until 04/10/23. 8. Section 5.8 "Downtime" of the "SLP 6IPI IPI: Control of Nonconformance" procedures requires the laboratory to "Document the event on a non-conformance form." 9. During the survey on 04/25/2023 at 4:15 PM, the TP confirmed that the laboratory's record system failed to include documentation of the extension of the acceptability for specimen #2250 on the non-conformance form.
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 temperature and humidity logs and interview with the quality manager (QM), the laboratory failed to document corrective actions when refrigerator temperatures were out of acceptable range in seven of eight months reviewed. Findings: 1. The monthly "Temperature and Humidity Log" (log) stated "If the temperature is unacceptable, record, adjust and recheck within 2 hours. Record the second temperature. If the adjusted temperature is within range, no further action is required. If the adjusted temperature is unacceptable, move contents to another refrigerator within range until appropriate temperature range achieved. Document all corrective actions." 2. The acceptable temperature range for the refrigerator was listed as 4-8 degrees Celsius (C) until 02/2023 when it was changed to 2-8C. 3. The logs for 08/2022 - 03/2023 were reviewed. 4. The refrigerator was out of acceptable range on 1 of 7 days recorded in 08/2022, 4 of 8 days recorded in 09/2022, 3 of 20 days recorded in 10/2022 and 11/2022, 3 of 21 days recorded in 12/2022, 4 of 19 days recorded in 02/2023, and 1 of 21 days recorded in 03/2023. 5. There were no second temperatures or corrective actions documented on the log on days when the temperature was out of acceptable range. 6. During the survey on 04/25/2023 at 5:00 PM, the QM confirmed that corrective actions were not documented when refrigerator temperatures were out of acceptable range.
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 liquid chromatography mass spectrometry (LCMS) maintenance logs, the temperature and humidity logs, and the batch tracking log, and interview with the quality manager (QM), the laboratory director (LD) failed to assure that quality assessment (QA) activities were monitored to ensure the quality of laboratory services provided. Findings: 1. Every month the testing person would send

	a packet of QA documentation to the laboratory director for review which included the monthly LCMS maintenance logs and temperature and humidity logs. 2. The binary pump pressure was out of acceptable range in 6 of 8 months reviewed (cross-refer to tag D5433). All months were signed as reviewed by the LD. 3. The refrigerator was out of acceptable range with no corrective actions documented in 7 of 8 months reviewed (cross-refer to tag D5785). All months were signed as reviewed by the LD. 4. The batch tracking log showed that various batches and specimens were retested multiple times after 7 days from collection indicating that the specimens had undergone multiple freeze-thaw cycles (cross-refer to tag D5311). There were no procedures defining specimen stability beyond 7 days in refrigerated temperatures or which laboratory personnel were responsible for monitoring the batch tracking log. 5. The batch tracking log showed that the lot numbers and expiration dates were not consistently being recorded when of the calibrators, buffers, reagents, and quality control materials used for patient testing to ensure that nothing was used past the expiration date (cross-refer to tag D5417 I, II, III and IV).
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 the procedure manual and interview with the testing person (TP), the technical supervisor (TS) failed to ensure that the "Lot-to-Lot Verification" procedures were being performed as required for the Indiko Plus and liquid chromatography tandem mass spectrometry (LC-MS/MS) toxicology analyzers. Findings: 1. Section 5.1.2 of the "Lot-to-Lot Verification" procedures states: "Each new lot of calibrator is verified by assaying as patient samples (5x) using the new lot of calibrators and current lot of reagents." 2. Section 5.1.3 of the "Lot-to-Lot Verification" procedures states: "Each new lot of control is verified by analysis (5x) using the current lot of reagents." "Prior to the depletion of a current lot of control material, begin parallel studies with the new lot of controls." 3. Section 5.2.1 of the "Lot-to-Lot Verification" procedures for LC-MS/MS states: "Each new lot of calibrator is verified by assaying as patient samples using the new lot of calibrators and current lot of calibrators." 4. Section 5.2.2 of the "Lot-to-Lot Verification" procedures for LC-MS/MS states: "Each new lot of control is verified by analysis using the current lot of calibrators and QC [quality control]." 5. Section 5.3 of the "Lot-to-Lot Verification" procedures states: "Document the results of the lot-to-lot verification on the batch tracking log in the comments/notes section. Make note of the Lot # and dated entered into production." 6. During the survey on 04/25/2023 at 4:15 PM, the TP confirmed that the laboratory's record system failed to include documentation of the lot-to-lot verification for the Indiko and LC-MS/MS analyzers.