

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2001177	(X3) Date Survey Completed 08/27/2021
Name of Provider or Supplier Interventional Pain Institute	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the quality manager (QM), the laboratory's procedure manual failed to define one of the positive quality control (QC) samples used for toxicology testing on the liquid chromatography tandem mass spectrometry (LC-MS/MS) instrument. Findings: 1. The procedure titled "Sample Preparation" listed the positive QC samples as level 2 (Low), level 4 (Mid), and level 6 (High) and stated that they should be positioned in the last three wells of the first row of the 96-well plate, after the calibrators but before the patient</p>

specimens. The procedure included an example of a plate map depicting the positions of each positive QC. 2. The procedure titled "QC Data Analysis Interface and Verification" defined the acceptability criteria for the Low, Mid, and High QC and stated that the "End QC should be +/- 30% of the calculated concentration of the Mid QC on that batch." The "End QC" was not defined in any other procedure and was not listed in the plate map found in the "Sample Preparation" procedure. 3. The QM stated that the "End QC" was the same as the Mid QC and was positioned after the patient specimens at the end of the 96-well plate. 4. During the exit interview on 08/27/2021 at 3:00 PM, the QM confirmed that the laboratory's procedure did not define the composition of the "End QC" or where it should be positioned on the 96-well plate.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the quality assessment (QA) plan and laboratory records and interview with the testing person (TP) and quality manager (QM), the laboratory failed to perform and document monthly QA Reviews as defined in the written policy. Findings: 1. The policy titled "Quality Assessment Plan" stated that the QA plan "will be implemented by review of the following monitors at the frequency and method of review specified. Quality Assessment Forms for each monitor which are suitable for documenting the review and proficiency testing checklist are part of this plan." 2. The plan defined 5 monitors, the frequency of review for each monitor, a calendar for when each monitor should be reviewed, and a checklist to be completed for each monitor according to the calendar. For each month, a single QA Review checklist for a particular monitor was required to be completed. 3. The plan stated "QA Review forms are signed and dated by the reviewer and laboratory director and retained in the Quality Assessment folder for a minimum of two years." 4. The laboratory began testing patient specimens in January 2020. Review of the QA binder for 2021 showed that a QA Review checklist was filled out for 04/2021 and signed by the laboratory director on 08/03/2021. The TP, who was hired in 03/2021, confirmed that the QA Reviews assigned on the calendar for 05/2021-07/2021 had not been completed or sent to the laboratory director for review. 5. The QM confirmed that prior to the TP's hire in 03/2021, the QA Reviews were not being completed and reviewed by the laboratory director. 6. During the exit interview on 08/27/2021 at 3:00 PM, the TP and QM confirmed that only one of the assigned QA Reviews was performed in 2021 and none were performed in 2020.

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 the proficiency testing (PT) records and interview with the quality

manager (QM), the laboratory director (LD) failed to investigate unacceptable PT results and implement corrective actions to prevent recurrence of unacceptable test results. Findings: 1. The PT records for Urine Drug Adulteration (DAI) from 2020 and 2021 were reviewed for a total of 3 events. 2. The PT agency evaluation for Creatinine and pH quantification during PT event DAI-A 2020 noted that the lab was unable to test. The PT agency evaluation for Creatinine and pH quantification during PT event DAI-B 2020 noted that the results were unacceptable. The PT agency evaluation for Creatinine quantification during PT event DAI-A 2021 noted that the results were unacceptable. The laboratory records failed to include an investigation of the unacceptable results and implement corrective actions. 3. The PT records for Drug Monitoring for Pain Management (DMPM) from 2020 were reviewed for a total of 2 events. 4. PT event DMPM-A 2020 showed that samples DMPM-01 and DMPM-02 received an evaluation stating "Result is outside the method/instrument reportable range" for 1 of the 5 drugs present in DMPM-01 and 1 of the 6 drugs present in DMPM-02. The laboratory records failed to provide an explanation for the missing results. 5. PT event DMPM-A 2020 showed that sample DMPM-03 received an unacceptable grade for 2 of 7 drugs being analyzed in the sample. The laboratory records failed to provide an explanation for the unacceptable results. 6. PT event DMPM-A 2020 showed that results for sample DMPM-04 were not consistent with the medications that the unknown patient was taking. The original evaluation from the PT agency did not indicate that the intended response was correct. This was an educational challenge, but the laboratory is still required to verify that their results were correct. 7. PT event DMPM-B 2020 showed that the lab received an unacceptable grade for the 6 drugs present in sample DMPM-05. Sample DMPM-06 received an unacceptable grade for 3 of the 6 drugs present and "Result is outside method/instrument reportable range" for 3 of the 6 drugs present in the sample. Sample DMPM-07 received an unacceptable grade for 5 of the 6 drugs present and "Result is outside method/instrument reportable range" for 1 of the 6 drugs present in the sample. The laboratory records failed to include an investigation of the unacceptable results. 8. During the survey on 08/27/2021 at 2:30 PM, the QM confirmed that the unacceptable PT results were not investigated and no corrective actions were taken to prevent recurrence.

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:

I. Based on procedure and record review and interview with the quality manager (QM) and testing person (TP), the laboratory director (LD) failed to ensure that the quality control (QC) and calibration records for the Indiko enzyme immunoassay (EIA) toxicology analyzer were reviewed and saved. Findings: 1. Section "6.1 EIA" of the procedure titled "Quality Control" stated that the LD or designee was responsible for monthly review of the Indiko QC to identify and document any failures, biases and trends for all QCs used for drug screening. 2. The QC and calibration records from 2020 and 2021 for the Indiko analyzer were reviewed. 3. The QM stated that the records were to be printed by the TP and sent to the LD for review. When the QM reviewed the records after the previous TP was let go, it was determined that the previous TP did not send the records to the LD for review from January 2020 through

March 2021. 4. The new TP emailed the Indiko QC records to the LD from April 2021 through June 2021, but did not receive confirmation that the LD received or reviewed the QC documentation. 5. In June 2021, the TP discovered that the documents were being sent to an incorrect email address. The TP was given the correct email address for the LD and the QC records from April 2021 through July 2021 were sent to the LD in August 2021 for review. 6. The LD did not review the Indiko QC records monthly, as stated in the procedure, from the time the laboratory opened in January 2020 through August 2021 when they were received from the new TP. The LD never investigated why the records were not being sent by the TPs during this timeframe. 7. During the survey on 08/27/2021 at 2:30 PM, the QM stated that the LD was responsible for initially reviewing the Indiko QC and calibration records and that the QM would be notified if an investigation was needed. 43123 II. Based on review of the procedure manual and interview with the quality manager (QM), the laboratory director failed to perform and document weekly quality control (QC) reviews as defined in the procedure manual. Findings: 1. The procedure titled "Quality Control" stated that for both enzyme immunoassay (EIA) and liquid chromatography mass spectrometry (LCMS) analyzers, the laboratory director or designee would review QC and document any observed failures, biases, trends or shifts in the "Weekly QC log" including any corrective actions taken towards correcting the issues. 2. The QM stated that the laboratory director reviewed the QC on a monthly basis not a weekly basis and there was no "Weekly QC log." 3. During the exit interview on 08/27/2021 at 3:00 PM, the QM confirmed that the laboratory director did not perform a weekly QC review and there was no "Weekly QC log" as defined in the laboratory's "Quality Control" procedure.

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:
The laboratory director failed to ensure that the quality assessment (QA) program was implemented and maintained by failing to review and approve the monthly QA monitor review checklists. Cross-refer to D5791.