Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2082447	06/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Interventional Pain Management Services	2730 S St Peters Pkwy, Suite 200, Saint Peters, MO	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of proficiency records for 2020, 2021 and to date June 21, 2022, review of patient reports and interview with the technical supervisor (TS), the laboratory failed to establish a means to verify the accuracy of 5 of 5 non-regulated analytes for urine drug screen testing twice a year. Findings: 1. Review of laboratory procedure"Quality Management Plan" states, "All testing performed by the laboratory is monitored by proficiency testing." 2. Review of proficiency records for 2020, 2021 and to date June 21, 2022, showed the laboratory failed to enroll to prove accuracy on the non-regulated analytes in urine drug screen testing which include creatinine, alcohol, benzodiazepine, opiate and tetrahydrocannabinol (THC) since patient testing started in March 2020. 3. Review of patient results confirmed the laboratory reports out the 5 non-regulated analytes of urine drug screen testing which are creatinine, alcohol, benzodiazepine, opiate and THC. 4. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to establish a means to verify the accuracy of 5 of 5 non-regulated analytes for urine drug screen testing twice a year.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of College of American Pathologists proficiency testing (PT) for 2020, 2021, 2022 and interview with the technical supervisor (TS), the laboratory failed to ensure the individual testing or examining the samples and the laboratory director attested to the routine integration of the samples into the patient workload using the laboratory's routine methods for four of four PT events. Findings: 1. Review of 2020 PT showed no attestion for event DMPM-B. 2. Review of 2021 PT showed no attestion for DMPM-A and DMPM-B. 3. Review of 2022 PT showed no attestion for DMPM-A. 4. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to ensure the individual testing or examining the samples and the laboratory director attested to the routine integration of the samples into the patient workload using the laboratory's routine methods.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists proficiency testing (PT) for 2020, 2021, 2022 and interview with the technical supervisor (TS), the laboratory failed maintain a copy of all instrumentation data printouts for four of four PT events. Findings: 1. Review of 2020 PT showed no instrument data printouts for event DMPM-B. 2. Review of 2021 PT showed no instrument data printouts for events DMPM-A and DMPM-B. 3. Review of 2022 PT showed no instrument data printouts for event DMPM-A. 4. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed maintain a copy of all instrumentation data printouts.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of procedures, observation of freezer, review of manufacturer's

	instructions, observation of internal standards and calibrators, review of pipette function checks and biosafety cabinet, review of Carolina quality control (QC) records, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow procedure for storage of urine specimens (Refer to D5401); the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for Cerilliant urine drug testing internal standards stored in freezer #3 (Refer to D5413); the laboratory failed to ensure the laboratory's internal standards and calibrators were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to perform and document function checks for one Eppendorf 1000 pipette, and the laboratory biosafety cabinet (Refer to D5435); and the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of procedures, observation of freezer and interview with the technical supervisor (TS), the laboratory failed to follow procedure for storage of urine specimens. Findings: 1. Review of "IPMS Urine Drug Testing Method by LC-MS/MS" procedure states "Once the urine has been ran for the LCMS the aliquot is taken, each specimen should be frozen and kept for 6 months thereafter". 2. Observation of urine freezer showed no urine specimens from January 2022 to April 2022. 3. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to follow procedure for storage of urine specimens.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of freezer #3, review of package insert for Cerilliant urine drug testing internal standards, review of laboratory temperature logs from April 2021 to date June 21, 2022 and interview with the technical supervisor (TS), the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for Cerilliant urine drug testing internal standards stored in freezer #3 for 21 of 149 testing days. Findings: 1. Observation of freezer # 3 showed Cerilliant urine drug testing internal standards labeled "currently in use". 2. Review of package insert for Cerilliant urine drug testing internal standards states, "Long term stability has been

	assessed for Freezer storage (-10 degrees Celsius to -25 degrees Celsius) conditions. 3. Review of laboratory temperature logs from April 2021 to date June 21, 2022 showed freezer #3 with the an acceptable temperature range of -10 degrees Celsius to -25 degrees Celsius. The laboratory failed to meet the acceptable temperature range for 21 of 149 testing days. 4. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for Cerilliant urine drug testing internal standards stored in freezer #3.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory freezer, and interview with the technical supervisor (TS), the laboratory failed to ensure the laboratory's internal standards and calibrators were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory freezer showed Cerilliant chemistry internal standards and calibrators still in use: MDMA lot #FE02211702 exp: 04/2022 benzoylegonine D3 lot #FE03291703 exp: 05/2022 nordiazepam lot #FE12231502 exp: 01/2021 hydrocodone lot # FE04291601 exp: 05/2021 methanol lot #FN07251703 exp: 10 /2021 pregabalin lot #FE05041703 exp: 06/2021 nicotine lot #FN05131604 exp: 05 /2021 methamphetamine lot #FE1214602 exp: 03/2022 meprobamate lot #FE06151605 exp: 07/2021 MDMA lot #FE06241606 exp: 07/2021 MDA lot #FE03161701 exp: 04/2022 benzoylegonine D3 lot #FE01061604 exp: 01/2021 amphetamine lot #FE04061701 exp: 06/2021 EDDP perchlorate lot #FN06281604 exp: 07/2021 methadone lot #FE12071601 exp: 01/2022 cyclobenzaprine lot #FN02031705 exp: 02/2022 oxycodone lot #FE01181701 exp: 03/2022 noroxycodone hci lot #FE02091701 exp: 03/2022 temazapam DT lot #FE11301602 exp: 01/2022 6 acetylmorphine lot #FE02161701 exp: 03/2022 THC lot #FE07211503 exp: 09/2020 2. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to ensure the laboratory's internal standards and calibrators were not used when they had exceeded their expiration date.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the lack of maintenance documentation and interview with the technical

	supervisor (TS), the laboratory failed to perform and document function checks for one Eppendorf 1000 pipette, and the laboratory biosafety cabinet for 2020, 2021, and to date June 21, 2022. Findings: 1. Lack of maintenance documentation showed the laboratory failed to perform and document the function checks for one Eppendorf 1000 pipette in use for patient testing, and for the laboratory biosafety cabinet. 2. Interview with the TS on June 21, 2022 at 1:00 PM confirmed, the laboratory failed to perform and document function checks for one Eppendorf 1000 pipette, and the laboratory biosafety cabinet for 2020, 2021, and to date June 21, 2022.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Carolina quality control (QC) records, the lack of documentation for the parameters of acceptable QC and interview with the technical supervisor (TS), the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Carolina QC records showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the chemistry analyzer for the analytes: creatinine, alcohol, benzodiazepine, opiate and THC. 2. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
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 Carolina verification procedures, proficiency testing, procedures, and interviews, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to verify normal values for creatinine are appropriate for the laboratory's patient population (Refer to D6086); the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory

	(Refer to D6092); and the laboratory director failed to ensure an approved procedure is available to all personnel responsible for any aspect of the testing process and failed to approve the laboratory procedures (Refer to D6106).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of Carolina verification procedures and interview with the technical supervisor (TS), the laboratory director failed to ensure the verification procedure for the Carolina verified the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings: 1. Review of the Carolina verification procedure showed no verification for normal values for creatinine. 2. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory director failed to verify normal values for creatinine are appropriate for the laboratory's patient population.
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 College of American Pathologists proficiency testing (PT) for 2020, 2021, 2022 and interview with the technical supervisor (TS), the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory for three of four proficiency testing events. Findings: 1. Review of 2020 PT showed no corrective action plan for: DMPM-B methadone result unacceptable alpha-hydroxyalprazola result unacceptable methylenedioxyamphetam result unacceptable methulenedioxymethamph result unacceptable oxymorphone result unacceptable norfentanyl result unacceptable 2. Review of 2021 PT showed no corrective action plan for: DMPA-A methadone result unacceptable Delta-9-thc-cooh result unacceptable 3. Review of 2022 PT showed no corrective action plan for: hydromorphone code 20 (Response was not formally graded due to insufficient peer group data.) alprazolam result unacceptable norfentanyl result unacceptable oxymorphone result unacceptable methylenedioxyamphetam result unacceptable 4. Interview on June 21, 2022 at 1:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

	This STANDARD is not met as evidenced by: Based on review of procedures, observation of freezer and interview with the technical supervisor (TS), the laboratory director failed to ensure an approved procedure is available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the "IPMS Urine Drug Testing Method by LC-MS /MS" procedure showed no approved cut-offs for Agilent Tech 6460 Triple Quad LC /MS instrument the following analytes: 6-monoacetylmorphine, amphetamine, methamphetamine, trazodone, 7-aminoclonazepam, alprazolam, hydroxyalprazolam, oxazepam, temazepam, lorazepam, diazepam, clonazepam, nordiazepam, buprenorphine, norbuprenorphine, COOH-THC, benzoylecgonine, fentanyl, norfentanyl, pregabalin, ketamine, norketamine, methadone, EDDP, MDMA, MDA, carisoprodol, meprobamate, cyclobenzaprine, nicotine, zolpidem, codeine, morphine, hydrocodone, dihydrocodeine, hydromorphone, naltrexone, oxycodone, oxymorphone, noroxycodone, phencyclidine, tapentadol, tramadol, amitriptyline, and nortriptyline. 2. Review of "Carolina EasyRA, CLC Urine Drug Testing (UDT), Instrumentation, Preventative Maintenance and Daily Start-up" procedure showed no approved cut-offs for the Carolina screening instrument for the follow analytes: Alcohol, benzodiazepine, opiate and THC. 3. Observation of the freezer showed an unlabeled frozen LC/MS plate with patient specimens. Interview with the TS confirmed the plate was from 6/3/22 and was kept because of instrument issues. The laboratory could not provide a procedure pertaining to freezing an unlabeled plate with patient specimens. 4. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the laboratory director failed to ensure an approved procedure is available to all personnel responsible for any aspect of the testing process. 44735 Based on review of laboratory procedures and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure an approved laboratory procedure manual was available for 39 of 39 laboratory procedures. Findings: 1. Review of laboratory procedures showed no LD approval of procedures. 2. Interview with the TS on June 21, 2022 at 1:00 PM confirmed the LD failed to approve the laboratory procedures.