Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2035674	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pain Institute Of Nashville Plc	1849 Madison St Suite D & Suite F, Clarksville, TN	

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	During a recertification survey conducted on 03/12/24 the laboratory was found out of compliance with the following conditions: 493.1240 Condition: Preanalytic systems 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interview, the facility failed to ensure the laboratory area was protected from physical and electrical hazards. 1. Observation of the laboratory on 03/12/24 at 9:00 am revealed the AB Sciex API 4000 system used for performing patient testing for urine drug screen and confirmation testing. The observed laboratory space contained physical and electrical hazards that included cardboard boxes, mailing envelopes, boxes of decorating items, partially blocked exits, cases of water sitting in the floor next to laboratory equipment, bags of packing peanuts, and other miscellaneous items. 2. During interview on 03/12/24 at 9:30 am, testing person three stated the pharmacy next door was using the laboratory space for storage of pharmacy items. He stated he had no control over what was being stored in the laboratory.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient records, review of laboratory policy and staff interview, the laboratory policy for urine collection did not include specimen stability and transport requirements. Refer to D5311.
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 patient records, review of laboratory policy, and staff interview, the laboratory policy for urine collection failed to include specimen stability and transport requirements. The findings include: 1. Review of patient records for urine drug screen and confirmation revealed the following: Patient ID #702-collected on 06 /28/22, on the specimen batch worklist for 06/30/22, reported on 07/06/22; patient ID # 92-collected on 03/09/23, on the batch worklist for 03/14/23, reported on 03/16/23; patient ID # 1277-collected on 10/13/23, on the batch worklist for 10/19/23, reported on 10/20/23; patient ID# 680-collected on 01/25/24, on the batch worklist for 02/01 /24, reported on 02/05/24. 2. Review of the policy title "Urine Collection" revealed no specimen stability or transport requirements. 3. During an interview on 03/12/24 at 2: 30 pm, testing person three and the laboratory liaison confirmed the laboratory procedure failed to define specimen stability requirements. They further stated the specimen stability studies could not be located.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS 209), patient test reports,staff interview, and review of the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments Application for Certification (Form CMS 116), the

	laboratory failed to maintain the identity of the person performing the final interpretation of patient toxicology results for four of four patients reviewed from 2022, 2023, and 2024, with approximately 17,184 patient toxicology results reported by testing person two using the login and identifier of the technical supervisor. The findings include: 1. Review of Form CMS 209 revealed the technical supervisor was not listed as a testing person. 2. Review of patient test reports revealed the initials of the technical supervisor on the following patient test reports: patient ID #702-collected on 06/28/22, patient ID # 92-collected on 03/09/23, patient ID # 1277-collected on 10/13/23, patient ID # 680-collected on 01/25/24. 3. The lab liaison stated during interview on 03/12/24 at 3 pm that testing person two used the login of the technical supervisor from the time she started releasing results in March 2022 until the date of the survey. 4. Review of Form CMS 116 revealed the laboratory reported an average of 8,592 patients per year for a total of approximately 17,184 patients released by testing person two using the login and identifier of the technical supervisor.
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 observation of the laboratory, review of instrument maintenance logs, education records, and staff interviews, testing person three lacked the necessary science hours to qualify as a high-complexity testing person (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of instrument maintenance logs, education records, and staff interviews, testing person three lacked the necessary science hours to qualify as a high-complexity testing person. The findings include: 1. Observation of the laboratory on 03/12/24 at 9:00 am revealed the high-complexity AB Sciex API 4000 system used for performing patient testing for urine drug screen and confirmation testing. 2. Review of the AB Sciex instrument maintenance logs for June 2022, March 2023, October 2023, and February 2024 revealed maintenance tasks for the AB Sciex instrument initialed by testing person three. 3. Review of testing person three's college transcript revealed a lack of the required science hours for performing high-complexity testing. 4. During an interview on 03/12/24 at 3 pm testing person three confirmed the lack of the required science hours to perform high-complexity testing. 5. A phone interview was conducted with the laboratory owner /testing person two on 03/20/24 at 1:45 pm. Testing person two stated instrument maintenance is performed by testing person three. This confirmed the survey findings.