Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2223245	07/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Joint And Spine Pain Center North, The	311 Landrum Place Ste 100, 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 performed on 07/09/2024, the laboratory was found out of compliance with the following conditions: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
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 observation of the laboratory, review of the laboratory's policies, lack of records, and staff interview, the laboratory failed to follow the maintenance procedure for centrifuge revolution per minute (RPM) calibration check that was used to process patient urine samples for liquid chromatography with tandem mass spectrometry (LC-MS/MS) testing in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 07/09/2024 at 8:30 a.m. revealed an Eppendorf Centrifuge 5430 used to process patient urine samples for high-complexity LC-MS/MS urine drug screens and confirmatory testing. 2. A review of the laboratory procedure titled "Confirmation Analysis of Drugs and Metabolites in Human Urine by LC-MS/MS" in section 6, "Sample Preparation Procedure," step 9 revealed "Centrifuge at 16,000-26,000g for 15 minutes." 3. A review of the "LC-MS/MS Laboratory Maintenance" laboratory policy revealed that RPM calibration and documentation were required "at least once a year." 4. The laboratory could not provide centrifuge calibration documentation for 2022,

	2023, or 2024 on the survey date (07/09/2024). 5. The survey findings were confirmed in an interview with the technical supervisor and laboratory assistant on 07/09/2024 at 12:00 p.m. Word Key- g- Relative Centrifugal Force or g Force
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 a review of the laboratory's personnel records, the Department of Health and Human Services Centers for Medicare and Medicaid Laboratory Personnel Report (CLIA) (Form CMS-209), and staff interviews, the laboratory assistant (one of one) that performed testing personnel duties did not meet the minimum education requirements for performing high-complexity LC-MS/MS patient testing in 2022, 2023, and 2024. (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 a review of the laboratory's personnel records, a review of Form CMS-209, and staff interviews, the laboratory assistant (one of one) who performed testing duties did not meet the minimum education requirements for high-complexity LC-MS /MS patient urine drug screen and confirmatory testing in 2022, 2023, and 2024. The findings include: 1. A review of the laboratory's personnel records revealed the following: A. The laboratory assistant job description position included pre-analytical sample preparation duties. B. The competency assessments for the laboratory assistant included reagent preparation, quality control dilution, calibration pipetting, and patient sample pipetting preparation. C. The laboratory assistant did not have documented education that met the minimum requirement for high-complexity testing. 2. A review of the Form CMS-209 revealed the laboratory assistant was not listed as a testing person. 3. An interview on 07/09/2024 at 12:00 p.m. with the technical supervisor and the laboratory assistant confirmed that the laboratory assistant's duties included preparing reagents, diluting quality controls, pipetting calibration material, and pipetting dilution buffer to aliquoted samples following incubation for LC-MS/MS drug screens and confirmatory testing.