

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D1087365	<b>(X3) Date Survey Completed</b> 12/09/2024
<b>Name of Provider or Supplier</b> Nashville Pain And Wellness Center Pllc	<b>Street Address, City, State</b> 7105 Ramsey Way, Dickson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observations, a review of the laboratory policy, and staff interviews, the laboratory failed to follow safety procedures when the laboratory space used for performing patient urine toxicology testing and the office kitchen were in the same location. The findings include: 1. Observation of the laboratory on 12/09/2024 at 8:45 a.m. revealed the Sciex 4000 Q Trap LC/MS/MS instrument (serial number AR21970805), ThermoScientific Indiko Plus instrument (serial number 864000090718), reagents, and patient urine samples for toxicology testing. During the observation, the laboratory had an open room divider curtain, which allowed the kitchen and laboratory space to be continuous. 2. A review of the laboratory policy titled "Overview and General Laboratory Safety," section "General Laboratory Safety Procedures," revealed that eating and drinking in the laboratory area was prohibited. 3. The survey findings were confirmed by an interview with the technical supervisor and testing person two on 12/09/2024 at 9:15 a.m. Word Key: LC/MS/MS- Liquid chromatography/Tandem mass spectrometry</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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</p>

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:

Citation One Based on observation of the laboratory, a review of laboratory procedures, a lack of records, and staff interviews, the laboratory failed to follow its procedure for annual pipette calibration for pipettes used to prepare patient samples and reagents for toxicology testing in 2024. The findings include: 1. Observation of the laboratory preparation room on 12/09/2024 at 9:30 a.m. revealed four single-tip pipettes and one multi-tip pipette used to prepare reagents and samples for toxicology testing. 2. A review of the laboratory procedure titled "Pipettes" revealed the laboratory was required to perform annual pipette calibration. 3. Documentation of pipette calibrations for 2024 was unavailable on the survey date (12/09/2024). 4. The survey findings were confirmed in an interview with the technical supervisor on 12/09/2024 at 1:00 p.m. Citation Two Based on observation of the laboratory, a review of laboratory procedures, a lack of records, and staff interviews, the laboratory failed to follow its procedure for annual centrifuge calibration for the centrifuge used to process patient samples for toxicology testing in 2024. The findings include: 1. Observation of the laboratory preparation room on 12/09/2024 at 9:30 a.m. revealed the Thermo Scientific Heraeus Megafuge 8 Centrifuge used to process patient samples for toxicology testing. 2. A review of the laboratory procedure titled "Centrifuge and Calibration Maintenance" revealed that the laboratory was required to perform annual centrifuge calibration. 3. Documentation of centrifuge calibration for 2024 was unavailable on the survey date (12/09/2024). 4. The survey findings were confirmed in an interview with the technical supervisor on 12/09/2024 at 1:00 p.m.