

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2009330	<b>(X3) Date Survey Completed</b> 06/13/2023
<b>Name of Provider or Supplier</b> North Lakes Pain Consultants	<b>Street Address, City, State</b> 1020 Riverwood Court Ste 105, Conroe, TX	
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>D0000</b>	An announced validation survey was performed on 06/13/2023. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory chemistry analyzer records and confirmed in interview, the laboratory failed to document two of two 6- month calibration verifications on all</p>

required analytes on the Indiko Plus chemistry analyzer. (Phencyclidine, Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Oxycodone) Findings were: 1. Review of the calibration records for the following seven analytes for the Indiko Plus chemistry analyzer (Phencyclidine, Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Oxycodone) revealed the assay used 2 or less calibrators. 2. Review of the laboratory records for the Indiko Plus chemistry analyzer (SN864000092386) revealed no documentation of two of two 6-month calibration verification in 2022 for Phencyclidine, Amphetamine, Benzodiazepine, Cocaine, Methadone, Opiate, Oxycodone. 3. Review of the CMS116 signed on 06/07/2023 revealed the laboratory performed 200,000 toxicology tests annually. 4. An Interview with the laboratory manager on 06/13/2023 at 1130 hours in the office confirmed the above findings.