

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2166097	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Indiana Neurology And Pain Center	Street Address, City, State 7301 N Shadeland Avenue #1a, Indianapolis, IN	
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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to have an adequate electronic system in place to ensure patient specific data on the test report and quality control records were accurate and documented which system the test was performed for five (PT#1-PT#5) of five patient records ran on two of two analyzers, (Diatron Pictus 700 used for moderate complexity testing and AB Sciex 4500 Liquid Chromatography Mass Spectrometry (LCMS) for high complexity testing) from June 2022 through February 2023. Findings include: 1. Review of patient records (PT#1-PT#5) indicated inadequate labeling for samples ran on both analyzers, Diatron Pictus 700 (Diatron) and AB Sciex 4500 (AB) Liquid Chromatography Mass Spectrometry (LCMS) from June 2022 through February 2023. Patient records for the following was identified to have one of the following mislabeled, or absent identifiers: Patient(s) Date(s) Records Analyzer(s) Error _____ PT#1 6/1/2022 Quality Control Diatron Year Report (QC) absent QC AB System ID absent PT#2 8/29/2022 Test Diatron Birthdate Result incorrect 9/02/2022 QC AB System ID absent PT#3 11/29/2022 Test Diatron Birthdate Result incorrect PT#4 01/12/2023 QC Diatron System ID absent 01/13/2023 QC AB System ID absent PT#5 02/14/2023 QC Diatron System ID absent QC AB System ID absent 2. On 02/16/23 at 2:</p>

20pm, interview with SP-2 (Testing Personnel) stated the facility had problems with setting up the interphase system during installment that led to incorrect data output. 3. Annual Test volume for specialty of Chemistry (Toxicology) is approximately 384,000.