

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1093361	(X3) Date Survey Completed 11/19/2020
Name of Provider or Supplier Indiana Pain & Spine Clinic	Street Address, City, State 6915 Fir Road, Granger, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to verify the accuracy of one of twenty-two tests (buprenorphine) performed on the Liquid Chromatography Mass Spectrometry (LCMS) analyzer during 2019. Findings included: 1. Review of accuracy verification documentation for 2019 indicated the following: a. The laboratory performed a comparison with "From Pain To Wellness" laboratory (FPTW) twice for their accuracy verification activities during 2019 for buprenorphine. The laboratory director reviewed the comparison test results on 4-3-2019 for the accuracy verification performed on 3-18-2019. b. During the March, 2019 comparison, the laboratory noted: "There is a discrepant results (sic) for...Buprenorphine," and indicated the laboratory would only report qualitative results "until the issue is resolved." 2. Review of patient records indicated the following: a. Patient #10 had quantitative test results for buprenorphine reported on 3-26-2019 (1037 nanograms per milliliter (ng/mL)); 4-24-2019 (446 ng/mL); and 5-1-2019 (277 ng/mL). b. Patient #11 had quantitative test results for buprenorphine reported on 5-1-2019 (226 ng/mL). c. Patient #12 had quantitative test results for buprenorphine reported on 3-26-2019 (663 ng/mL). 3. In interview on 11-19-2020 at 3:05 PM, SP1, Laboratory Director, acknowledged the buprenorphine accuracy verification was not acceptable during the March, 2019 accuracy verification event. SP1 further acknowledged they reviewed and signed the accuracy verification report on 4-3-2019. SP1 indicated the corrective action was to only report qualitative test results (positive or negative) for buprenorphine until new standards were performed on 5-8-2019 and the results were within acceptable limits. At 3:57 PM on the same date, SP1 acknowledged the laboratory did not follow their corrective action plan and reported quantitative test</p>

results (concentration) for buprenorphine for Patients #10, #11, and #12 between 4-3-2019 and 5-8-2019. On 4:13 PM on the same date, SP1 indicated the previous accuracy verification for buprenorphine was performed in October, 2018, reviewed on 12-6-2018, and was acceptable. SP1 indicated the laboratory did not review patient test reports for accuracy of buprenorphine testing between October, 2018 and May 8, 2019 as part of their corrective action. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I), signed by the laboratory director on 11-7-2020 indicated the laboratory performed 2000 buprenorphine tests annually on the LCMS 3200 Q-Trap analyzer.