

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2080211	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Comprehensive Pain Specialists, Pllc	Street Address, City, State 5154 Miller Road, Flint, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to establish a policy to assess clinical consultant competency for 2 (January 2021 to January 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Competency Assessments" procedure revealed a lack of process for assessing the competency of the clinical consultant. 2. A review of personnel record for the clinical consultant revealed a lack of assessment for their duties as a clinical consultant. 3. An interview on 1/12/23 at 2:39 pm with the General Supervisor confirmed the laboratory had not established a policy to assess clinical consultant competency.</p>
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 record review and interview with the General Supervisor, the laboratory failed to verify the accuracy of its quantitative urine toxicology testing for 4 (UT-B 2021, UT-C 2021, UT-A 2022, and UT-B 2022) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American</p>

Pathologists Proficiency Testing records revealed the laboratory participated in the qualitative urine toxicology events. No documentation was present to show the laboratory had assessed these analytes for quantitative accuracy for testing events UT-B 2021, UT-C 2021, UT-A 2022, and UT-B 2022. 2. An interview on 1/12/23 at 11:14 am with the General Supervisor confirmed the laboratory had not assessed the urine toxicology analytes tested using proficiency testing for their quantitative accuracy.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory failed to ensure results of quality control testing met the laboratory's acceptability criteria prior to reporting patient results for 2 (9147981 and 914391) of 21 control testing runs reviewed. Findings include: 1. A review of the laboratory's "Quality Control Monitoring" procedure revealed a section titled "Quantitative Analysis" stating, "All positive controls are subject to rejection according to the following Westgard rules, established and monitored per batch by the LIMS in order to judge the acceptability of a batch run and to identify random or systematic error. However, if a control triggers a Westgard warning, but is within 20% of the established mean for that control, the warning may be disregarded. 1-2s, If a single point lies outside of 2 SD from the established, validated mean, consider the following failure rules, in order: a. 1-3s i. One point lies outside of 3 SD from the established, validated mean. b. 2-2s i. (Across runs) 2 consecutive values outside the same 2 SD. ii. (Within run) 2 consecutive values outside the same 2 SD. c. R-4s i. The range (difference) between two controls within a run exceeds 4 SD. ii. 4 consecutive control values on one side of the mean and further than 1 SD from the mean. (This can be within one control across 4 consecutive runs or within 2 controls across 2consecutive runs.) d. 10x i. 10 consecutive values on one side of the mean. (This can be within one control across 10 consecutive runs or within 2 controls across 5 consecutive runs.)" 2. A review of 21 runs of quality control data revealed the following testing runs when quality control had a 2-2s failure and was not within 20% of the mean in September 2022: a. Run 9147981, containing 48 patients, had a 2-2s failure for o-desmethyltramadol for the low control with a result of 357. The mean was 289.7 and the result fell outside of 20%. b. Run 9148391, containing 34 patients, had a 2-2s failure for phenobarbital low control with a result of 320. The mean was 413.9 and the result fell outside of 20%. 3. An interview on 1/12/23 at 2:39 pm with the General Supervisor confirmed the runs above had failed controls for o-desmethlytramadol and phenobarbital.