

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1075263	<b>(X3) Date Survey Completed</b>  02/15/2021
<b>Name of Provider or Supplier</b>  Ellis Pain Management	<b>Street Address, City, State</b>  1500 Langford Drive, Bldg 200, Watkinsville, GA	
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>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 15, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 proficiency test (PT) document review and staff interview, the laboratory failed to verify the accuracy of any unregulated test or procedure as required. 1. PT document review revealed no split sample verification documentation for urine specific gravity was available at the time of survey for 2018 (November and December), 2019, 2020, and 2021 thus far. 2. An interview in the conference room on 2/15/2021 at approximately 2:00 p.m. confirmed the lack of verification for urine specific gravity for the aforementioned time periods.</p>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p>

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical supervisor (TS) failed to evaluate TP performance at least annually after the first year as required. Findings include: 1. TP competency document review revealed there was no 2020 annual TP competency documents available at the time of survey for Staff #5 (CMS 209). 2. An interview with a technical consultant in the conference room on 2/15/2021 at approximately 1:30 p.m. confirmed the aforementioned missing 2020 annual TP competency documents.