

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1075263	<b>(X3) Date Survey Completed</b>  08/07/2018
<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 August, 07 2018. 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>D6017</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2017 CAP (College of American Pathology) Proficiency Testing(PT) documents and an interview with the laboratory's general supervisor, the laboratory director failed to ensure Proficiency Testing results were submitted within the timeframes established by the PT program. Findings include: 1.) A review of the 2017 CAP PT records revealed Event #2 of the Toxicology survey received a score of 0% "Failure to Participate" because results were not submitted to CAP on a timely basis. 2.) An interview with the laboratory's General Supervisor, at approximately 04: 00 pm on August 07, 2018 in the conference room confirmed the laboratory failed to submit Toxicology CAP PT results before the cut off date.</p>