

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1069752	(X3) Date Survey Completed 09/17/2021
Name of Provider or Supplier Advanced Pain Management Center	Street Address, City, State 3 Woodland Road, #322, Stoneham, MA	
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
D0000	A CLIA recertification survey was conducted for the Advanced Pain Management Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Technical Consultant (TC) on 9/17/21, the laboratory failed to maintain a copy of all PT records as evidenced by the following: The surveyor reviewed College of American Pathologists (CAP) PT records for calendar years 2020 and 2021 on 9/17/21. The review revealed that attestation statements provided by CAP could not be located for the first event in 2021 and second event in 2020. The TC confirmed in an interview on 9/17/21 at 11:00 AM that signed attestation statements could not be located.</p>