Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0987642	04/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Pain Associates Of Pg County	7300 Hanover Drive Suite 201, Greenbelt, MD	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the testing person and technical consultant (TC), the laboratory did not handle PT specimens in the same manner as patient samples. Findings: 1. Hematology, Routine Chemistry, Endocrinology, and General Immunology PT records were reviewed for 6 events from 2016 to 2018. In 6 out of 6 events it was observed that each PT specimen had been run in duplicate. PT specimens for the 3rd event of 2016 were run 4 times each. 2. When interviewed, the testing person stated that they, "always run PT twice because it's normally abnormal." They also stated that routine patients are not automatically run in duplicate. 3. During an interview on 4/25/18 at 1:00 PM, the TC confirmed that the laboratory did not routinely run each patient sample more than once, and that PT specimens were not run in the same manner as patient specimens.
D2082	GENERAL IMMUNOLOGY CFR(s): 493.837(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory failed to ensure that corrective action was taken and documented for failed PT. Findings: 1. The laboratory failed ANA PT (60%) for 3rd event, 2017. 2. No corrective action was documented for the failed PT. 3. During an interview on 4/25/18 at 1:00 PM, the TC confirmed that there was no corrective action taken or documented for the failed PT.