Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0893127	07/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Rheumatism Associates Pl	612 Druid Rd E, Clearwater, FL	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #B the laboratory failed to perform the 6 month competency evaluations on 2 out of 2 (#B and #C) new Testing Personnel. Findings Included: Review of competency evaluations found no competency evaluations for Testing Person #B and #C. During an interview on 07/30 /18 at 10:34 AM, Testing Person #B confirmed that no 6 month competency evaluations had been performed for Testing Person #B and #C.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing and interview with Testing Person #C the laboratory failed to evaluate ungraded results in proficiency testing for 2 (3rd testing event in 2016 and 2nd testing event in 2017) out of 5 (1st testing event in 2018, 1st, 2nd, 3rd testing event in 2017, and 3rd testing event 2016) testing events for Monocytes. Findings Included: Review of API proficiency testing results in the 2nd testing event for 2017 found 2 out of 5 scores for

	Monocytes were ungraded with no corrective action. Review of API proficiency testing results for the 3rd testing event in 2016 found 1 out of 5 scores for Monocytes were ungraded with no corrective action. During an interview on 07/30/18 at 10:00 AM Testing Person #C revealed that the ungraded scores were not evaluated for accuracy.
D5459	CONTROL PROCEDURES CFR(s): 493.1256(d)(5)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #C the laboratory failed to perform lot to lot comparisons when changing lot numbers of controls for Complete Blood Count (CBC) testing in Hematology for 2 out of 2 (2016-2018) years reviewed. Findings Included: Review of quality control records revealed that there was no lot to lot verification performed when changing the lot numbers of controls for CBC testing. During an interview on 07/30/18 at 10:11 AM, Testing Person #C confirmed that they do not perform a lot to lot comparison when changing lot numbers of controls.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person #B the laboratory failed to have a QA (Quality Assessment) program that encompassed all facets of the laboratory's technical and non-technical functions performed for 2 out of 2 (2016-2018) years reviewed. Findings Included: Review of laboratory policies and procedures revealed no policy for QA. No QA documentation was provided at the time of survey. During an interview on 07/30/18 at 10:44 AM, Testing Person #B confirmed that there was no QA performed.