Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2117969	01/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Rheumatology Center Pc	11731 Pointe Place, Roswell, GA	

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	An Initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on January 5, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to implement an established safety procedure to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. During the laboratory tour it was observed there was not a maintenance log for the eyewash equipment for 2016 and 2017. 2. An interview with Staff #2 (CMS 209) during the laboratory tour on 1/5/18 at approximately 1:30 p.m. confirmed the eyewash equipment was not maintained during 2016 and 2017.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to provide a policy and procedure for monitoring laboratory temperature and humdity. Findings include: 1. SOP document review revealed the laboratory had not written a policy and procedure for monitoring the temperature and humidity as required by the Horiba Micros 60 hematology analyzer. 2. An interview with the office manager on 1/5/18 at approximately 2:15 PM in an offuce area confirmed there was not a policy and procedure in the SOP for monitoring laboratory temperature and humidity.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on general laboratory systems document review and staff interview, the laboratory failed to document laboratory temperature and humidity as required by the manufacturer. Findings include: 1. General laboratory systems document review revealed the laboratory failed to document laboratory temperature and humidity for 2016 and 2017 as required for the Horiba Micros 60 hematology analyzer. 2. An interview with Staff #2 (CMS 209) in the laboratory on 1/5/18 at approximately 1:30 p.m. confirmed laboratory temperature and humidity were observed but not recorded for 2016 and 2017. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical supervisor/laboratory director (TS/LD) failed to evaluate and document the TP responsible for high complexity testing semi-annually during the first year. Findings include: 1. TP document review revealed the TS/LD did not perform a six-month competency on Staff #2 (CMS 209) in 2017. 2. An interview with Staff #2 (CMS 209) on 1/5/18 in an office area at approximately 2:15 p.m. confirmed a six-month competency was not performed for Staff #2 (CMS 209).
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) 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. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview the TS/LD (Technical Supervisor/Laboratory Director) failed to perform an annual competency on high-complexity TP. Findings include: 1. TP document review revealed the TS/LD did not perform an annual competency on Staff#2 (CMS 209) in 2017. 2. An interview with Staff #2 (CMS 209) in an office area on 1/5/18 confirmed the TS/LD did not perform an annual competency on Staff #2 (CMS 209) in 2017.