Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2083982	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Care Specialist Of Md	6350 Stevens Forest Rd Suite 101, Columbia, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records and interview with the technical consultant (TC), the laboratory did not have all proficiency testing (PT) attestations signed by the laboratory director and the testing person. Findings: 1. The testing person nor the laboratory director signed the PT attestations for hematology and chemistry testing during the year 2017. 2. The laboratory submitted all three events for each speciality of patient testing during the year 2017 without signed attestations. 3. The TC stated that she begin overseeing the laboratory testing during the month of November 2017 and was not aware that 2017 PT attestations did not have the required signatures prior to submitting results.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In

	addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of the chemistry quality control (QC) and interview with the technical consultant (TC), the laboratory did not maintain all printed chemistry QC reports during the year 2017. Findings: 1. The laboratory did not keep the analyzer printed copies of the chemistry QC when the QC was out of range. 2. The laboratory kept only the repeated QC that was in range and without errors. 3. On dates November 13th, May 25th, and May 24th during the year 2017 chemistry QC was out of range and repeated by the testing person. 4. The TC stated that she was not aware that all printed analyzer copies of QC needed to be kept when QC was out of range or when errors were reported.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) and interview with the technical consultant (TC), the laboratory did not document corrective action procedures when QC did not meet the laboratory's criteria of acceptability. Findings: 1. The laboratory did not document the reason for repeating chemistry QC. 2. On dates November 13th, May 25th, and May 24th during the year 2017 chemistry QC was repeated. 3. On 11/13/17 the chemistry level 1 QC print out stated in the corrective action section "rerun CA, AST, ALP, TP, CK, UA , recal and rerun UA with new reagent, and rerun AST and ALP" 4. On 5/25/17 the chemistry level 2 QC print out stated in the corrective action section "rerun GLU, NA and UA" 5. On 5/24/17 the chemistry level 1 QC print out stated in the corrective action section "rerun K" 6. On 5/24/17 the chemistry level 2 QC print out stated in the corrective action section "rerun ALT and cal/rerun CL and NA". 7. The TC confirmed that the reason for repeating the chemistry QC was not documented.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) procedures and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that QA procedures were performed in all areas of the laboratory when the quality of laboratory services did not meet the laboratory's criteria of acceptability. Findings: 1. The laboratory moved to a new location in July 2018 and the address of the previous location was still printing on the patient final reports. 2. The TC stated that she was not aware of the error until a week prior to the day of the survey. The TC stated that she was able to have the information technology department fix the issue and the current location of the laboratory is now printing on the patient reports. 3. The LD was not made aware of the issue and the problem was not documented on the QA report, reviewed and signed by the LD. 4. The laboratory incubator door was broken during the laboratory move in July 2018. 5. The TC became aware of the issue during the validation performed and repeated during the months of July and August 2018. The TC noticed that the temperature was out of range. 6. The TC called the manufacturer and was told that using Duct tape will keep the door of the incubator closed during testing. 7. The TC revalidated the incubator and the validation passed. 8. The LD was not made aware of the issue and the problem was not documented on the QA report, reviewed and signed by the LD 9. The TC confirmed that the LD was not made aware of all laboratory problems.