Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2123677	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Rheumatism Associates	2231 Hill Park Cove, Jonesboro, AR	

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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for quality control, review of the quality control summary reports for August 2020, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results back to the last successful quality control run on one of one instances when quality control results for total sodium failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure for quality control revealed that quality control results are unacceptable when one of two levels of quality controls are greater than three standard deviation index (SDI) from the target value. B) Review of the laboratory's policy and procedure for quality control revealed that there was no requirement mentioned in the policy to evaluate patient results back to the last successful quality control run when quality control failed to meet acceptable criteria. C) Review of the quality control sumary report for August 2020 revealed that Vitros Performance Verifier Level 1 lot H6976 with a target of 120 for serum sodium and an acceptable range of 117.2 to 122.8 was reported as 125 at 07: 55 AM on 8/6/20 greater than 3SDI from the target value , as 125 at 08:02 am greater than 3 SDI from the target value, as 123 at 8.08 AM greater than 2 SDI fro the target value before an acceptable result of 122 at 8.08 AM. Vitros Performance Verifier Level 2 lot J6978 with a target of 143 for serum sodium and an acceptable range of

	140.2 to 145.8 was reported as 147 at 07:59 AM on 8/6/20 greater than 3SDI from the target value , as 148 at 08:12 AM greater than 3 SDI from the target value, before an acceptable result of 144 at 8.08 AM D) Review of documented corrective action revealed that corrective action included "New ERF, new tip, cleaned" was performed before an acceptable quality control result was obtained which indicated a change in the test system. E) Review of the quality control summary report for August 2020 revealed that the last successful quality control result prior to the failures identified above ocurred on 8/5/21 at 07:54 AM. F) Upon request, the laboratory was unable to provide documentation that the sodium tests performed and reported on patients between 8/5/20 at 07:54 AM and 8/6/20 at 07:59 AM had been evaluated. G) In an interview on 8/18/21 at 02:00 PM., the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the sodium results identified above had not been evaluated.