Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303225	02/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatology Associates Of N A	4606 Bellewood Drive, Huntsville, AL	

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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of quality control records and an interview with the General Supervisor, the laboratory failed to document Chemistry/Endocrinology quality control (QC) shifts and trends over time for a two and a half year period from the previous survey on 9/21/2017 till the date of the current survey on 2/18/2020. The findings include: 1. A review of the QC records for the Beckman Coulter (B/C) AU480 and Access 2 analyzers revealed only the daily QC printouts were available for review. The laboratory had no records documenting the monitoring of QC shifts and trends over time. (Examples include printing Levi-Jennings charts periodically or submitting data to a QC company's Interlaboratory Quality Assurance Program [IQAP]). 2. During an interview on 2/19/2020 at approximately 4:00 PM, the General Supervisor explained she had not had time to print the Levi-Jennings charts for the Chemistry / Endocrinology tests; because she had missed a lot of work over the last two years, she had reviewed the QC "on the computer", then she documented her review with "QC reviewed" on the maintenance charts for each analyzer. 3. As the interview continued at approximately 4:15 PM, the surveyor explained electronic

	review of QC was acceptable as long as the records for the survey period (9/21/2017-2/18/2020) were available for the surveyor's review. In the Chemistry area, the surveyor and General Supervisor reviewed the Levi-Jennings QC records on the B/C Access 2 computer from 1/19/2020 thru 2/19/2020. However, when the surveyor requested QC from before 1/19/2020, the General Supervisor was unable to "pull up" any of the older records. The Supervisor also confirmed this was a new Access 2 analyzer installed in May 2018, so any records on the previous Access 2 were definitely lost. The General Supervisor was unable retrieve any Levi-Jennings QC records from the B/C AU480 Chemistry analyzer. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor