Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	21D0929322	11/18/2021

Name of Provider or Supplier	Street Address, City, State
Rheumatology Associates Of Balto Llc	1220b East Joppa Rd #310, Baltimore, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory failed to perform linearity/calibration verification every six months for the routine chemistry analyzer. Findings: 1. Laboratory records documented that the linearity/calibration verification for the chemistry analyzer was performed on 01/26 /2020. The laboratory suspended patient testing from 03/17/2020 through 11/12/2020. The next linearity/calibration verification was documented as performed on 09/11

	/2021. 2. During the exit interview on 11/18/2021 at 1:30 PM, the TC confirmed that linearity/calibration verification was not performed every six months for the chemistry analyzer as was required.
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: Based on record review and interview with the technical consultant (TC), the laboratory failed to consistently document corrective actions taken when quality control (QC) for routine chemistry testing failed and for patient test results potentially affected by failed QC. Findings: 1. The maintenance logs for the chemistry analyzer from 01/2020 through 10/2021 were reviewed. 2. The log for 07/2021 had hand written notes stating that on 07/19/2021, QC for potassium, chloride and sodium failed three times; on 07/22/2021, QC for chloride, glucose, calcium, total bilirubin, and direct bilirubin failed; and on 07/26/2021, QC for calcium, total protein, uric acid and creatinine failed. There was no documentation detailing what corrective actions were taken, if and when QC passed, and whether patient samples were run when QC failed. 3. The laboratory did not have another log for testing personnel (TP) to document QC failures and what corrective actions were taken for the failed QC and potentially affected patient test results. 4. During the exit interview on 11/18/2021 at 1:30 PM, the TC confirmed that corrective actions were not documented for the QC failures that occurred in 07/2021 and there was no other log for TP to document corrective actions for potential previous or future QC failures.