Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0926918	**(X3) Date Survey Completed** 09/21/2021
Name of Provider or Supplier Rheumatology Assoc Of N A	**Street Address, City, State** 1120 South Jackson Highway, Suite 205, Sheffield, 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**
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Sysmex XN-430 Hematology analyzer, and an interview with the Laboratory Supervisor, the surveyor determined the Laboratory Director failed to document the review and approval of the procedures as verification of the manufacturer's performance specifications before patient testing began. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. A review of the 10/10/2019 validation records for the Sysmex XN-430 Hematology analyzer revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. 2. During a review of the records, and an interview on 9/21/2021 at 2:40 PM, the General Supervisor confirmed the above noted findings. The surveyor then asked when patient CBC (Complete Blood Count) testing began on the instrument; the Supervisor answered, "11/25/2019". .
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)

	Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a lack of training documentation in employee files, a review of the installation records for the Sysmex XN-430 Hematology analyzer, and an interview with the Laboratory Supervisor, the surveyor determined the laboratory failed to ensure training for two of two testing personnel was performed and documented. The findings include: 1. A review of personnel files for two of two testing personnel revealed no training on the new Sysmex XN-430 Hematology analyzer installed on 10 /10/2019. 2. During an interview on 9/21/2021 at 2:40 PM, the surveyor requested the training records for the testing personnel using the Sysmex XN-430. The General Supervisor stated the employees were trained by the Sysmex technician when the instrument was installed, however she was unable to provide the documentation. The surveyor then asked when patient CBC (Complete Blood Count) testing began on the instrument; the Supervisor answered, "11/25/2019". SURVEYOR ID #32558 Licensure and Certification Surveyor