Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303225	06/22/2022
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the accuracy verification records and an interview with the General Supervisor, the surveyor determined the laboratory missed performing one of two accuracy verifications for TSPOT TB in 2021. The findings include: 1. A review of Immunology records revealed the laboratory performed split testing with a reference lab to verify the accuracy of TSPOT TB (a non-regulated manual assay for the detection of effector T-cells in patients with latent tuberculosis). 2. A review of the accuracy verification records revealed the laboratory only verified the accuracy of TSPOT TB the second half of 2021 on 9/17/2021. 3. During an interview on 6/21 /2022 at 3:55 PM, the General Supervisor confirmed the laboratory had not performed TSPOT TB accuracy verification the first half of 2021. .
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on a review of the test menu and test platforms during the entrance tour, a review of personnel records and an interview with the General Supervisor, the Laboratory Director failed to specify in writing the duties of six of six testing personnel after orientation and training. The findings include: 1. During the entrance tour on 6/21/2022 at 12:00 PM, the General Supervisor listed the moderate/high-complexity lab menu and testing platforms, as follows: A) Hematology testing using the Sysmex XN-550 B) Chemistries and Rheumatoid Factor (RF) on the Beckman Coulter AU480 C) Vitamin D and Thyroid Panel on the Beckman Coulter Access 2. D) ANA (Anti-Nuclear Antibodies) Panels on the Athena Luminex Multilyte E) TSPOT TB (a manual assay for the detection of effector T-cells in patients with latent tuberculosis). F) Synovial Fluid Crystal Identification 2. A review of personnel records revealed competencies for the testing personnel did not include all six testing platforms. Since some competencies were missing (Refer to D6151), the surveyor was unable to clearly determine which tests each of the testing personnel were allowed to perform. 3. During an interview on 6/22/2022 at 9:10 AM, the above noted findings were reviewed with the General Supervisor who confirmed the duties for each of the six testing personnel. The surveyor then explained the Laboratory Director was required to specify in writing the duties, examinations and procedures each individual was authorized to perform upon completion of their training. .
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the General Supervisor, the General Supervisor failed to perform and document competency assessments for three of six testing personnel (TP) in 2020 - 2021. The findings include: 1. A review of personnel records revealed the following: A) TP #1: No annual competency assessment for TSPOT TB in 2020 or 2021 B) TP #2: No semi-annual competency assessment for Immunology/ANA (Anti-Nuclear Antibodies) Panels on the Athena Luminex Multilyte and Hematology testing on the Sysmex XN-550 in early 2021 C) TP #6 : No annual competency assessment for Hematology testing on the Sysmex XN-550 in 2021 2. During an interview on 6/22/2022 at 9:10 AM, the above noted findings were reviewed and confirmed with the General Supervisor. SURVEYOR ID# 32558 Licensure and Certification Surveyor