

| | | |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0929322 | (X3) Date Survey Completed 06/12/2025 |
| Name of Provider or Supplier Rheumatology Associates Of Balto Llc | Street Address, City, State 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 |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D5219 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on observation in the laboratory, proficiency testing (PT) records, review of the procedures, and interview with the technical consultant (TC) and the laboratory director (LD), the laboratory failed to verify the accuracy of the review for uric acid crystals from synovial fluid collected at the laboratory for review and interpretation. Findings: 1. During the tour of the laboratory the surveyor observed a microscope. The LD was interviewed and he stated that the microscope was used to identify uric acid crystals in the synovial fluid and the results were recorded on the patient's chart. 2. The PT records showed that there were no comparisons performed twice a year to verify accuracy of the testing. The procedure manuals did not have a procedure for how to identify and record the findings of a synovial fluid. 3. During the survey on 06/12/2025 at 12:15 PM, the TC confirmed that the laboratory was not performing split samples for the verification of uric acid crystals from synovial fluid and there was no procedure for how to identify and record the findings of a synovial fluid.</p> |
| D6079 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical</p> |

consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the "Rheumatology Associates of Baltimore Director Responsibility- Delegation of Function" procedure, record review and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that all records were reviewed in tandem with the LD designee as part of their training. Findings: 1. The delegated responsibilities from the LD to the medical director (MD) in the "Rheumatology Associates of Baltimore Director Responsibility- Delegation of Function" procedure states, "Laboratory Director, I delegate the following to a Medical Director: 6. Review all Laboratory documents and activities at least once a month with the Laboratory Technical Consultant" 2. The Monthly "Lab Director Review of Documents" worksheets from January 2024 through May 2025 were reviewed and three of seventeen months were not reviewed by the LD listed on the CLIA certificate of compliance. Proficiency testing and competency from January 2024 through May 2025 showed that half were not reviewed by the LD listed on the CLIA certificate of compliance. 3. During the survey on 06/12/2025 at 12:15 PM, the TC and LD confirmed that while training the LD designee, all of the laboratory records were not reviewed in tandem to ensure that the LD designee received the continuous training to eventually qualify as a CLIA LD.