

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0856368	(X3) Date Survey Completed 05/28/2021
Name of Provider or Supplier Pennsylvania Rheumatology Associates	Street Address, City, State 822 Pine Street, Philadelphia, PA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the laboratory director (LD), the laboratory failed to document quality control (QC) performed each day of patient testing for synovial fluid microscopic examinations from 2019 to the day of survey. Findings include: 1. On the day of survey, 05/28/2021, the laboratory could not provide documentation of daily QC performed for synovial fluid microscopic examinations from May 28, 2019 to May 28, 2021. 2. In 2019: 78 - synovial fluid microscopic examinations were analyzed. 3. In 2020: 56 - synovial fluid microscopic examinations were analyzed. 4. In 2021: 20 - synovial fluid microscopic examinations were analyzed. 5. The LD confirmed the findings above on 05/28/2021 around 09:45 am.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, review of personnel competency assessment records and interview with the laboratory director (LD), the technical supervisor (laboratory director) failed to ensure the competency assessment of 2 of 3 testing personnel (TP) performing synovial fluid microscopic examinations were assessed and completed in 2019, 2020 and 2021. Findings Include: 1. On the day of survey, 05/28/2021, review of 2 of 3 TP competency assessment records from 2019, 2020 and 2021 revealed: - TP competency assessment records were not signed by the LD in 2020. - TP were only assessed for 1 of the 6 points of competency (peer review). 2. The LD confirmed the findings above on 05/28/2021 around 10:00 am.