

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0900881	(X3) Date Survey Completed 11/12/2025
Name of Provider or Supplier Rheumatology Consultants,Pa	Street Address, City, State 1902 North Scott Street, Wilmington, DE	
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
D0000	A Recertification Survey was conducted on November 12, 2025 at approximately 9:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
D5789	<p>TEST RECORDS CFR(s): 493.1283(b)</p> <p>(b) Records of patient testing including, if applicable, instrument printouts, must be retained.</p> <p>This STANDARD is not met as evidenced by: Based on record review, document review, interview, and facility policy review, the laboratory failed to retain original records of patient testing for the microscopic analysis of synovial fluid for crystals for 4 (Patients #1, #2, #5, and #7) of 10 sampled patients. Findings included: A facility policy titled, "Procedure Manual for Analysis of Synovial Fluid," updated 10/24/2025, indicated "5. The results of the specimen are recorded on the log sheet." The "Crystal analysis 2024-2025" log sheet indicated staff documented "Gout" in the column labeled "crystals present" for Patient #1 on 10/03/2024; however, Patient #1's medical record indicated on 10/03/2024, "No crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "Pseudogout" in the column labeled "crystals present" for Patient #2 on 02/05/2025; however, Patient #2's medical record indicated on 02/05/2025, "No crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "None" in the column labeled "crystals present" for Patient #5 on 10/03/2024; however, Patient #5's medical record indicated on 10/03/2024, "Gout crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "None" in the column labeled "crystals present" for Patient #7 on 02/04/2025; however, Patient #7's medical record indicated on 02/04</p>

/2025, "Pseudogout crystals were seen under compensated, polarizing microscopy." During an interview on 11/12/2025 at 10:50 AM, the Laboratory Director (LD) stated the results of the microscopic examinations of synovial fluid were handwritten in the log, then the log was used to transcribe the results in the patients' medical records. The LD stated the handwritten logs were then typed and discarded.

D5801

TEST REPORT
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on record review, document review, interview, and facility policy review, the laboratory failed to ensure results of microscopic examinations of synovial fluid for crystals were accurately documented on the patient log sheet for 4 (Patients #1, #2, #5, and #7) of 10 sampled patients. Findings included: A facility policy titled, "Procedure Manual for Analysis of Synovial Fluid," updated 10/24/2025, indicated "5. The results of the specimen are recorded on the log sheet." The "Crystal analysis 2024-2025" log sheet indicated staff documented "Gout" in the column labeled "crystals present" for Patient #1 on 10/03/2024; however, Patient #1's medical record indicated on 10/03/2024, "No crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "Pseudogout" in the column labeled "crystals present" for Patient #2 on 02/05/2025; however, Patient #2's medical record indicated on 02/05/2025, "No crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "None" in the column labeled "crystals present" for Patient #5 on 10/03/2024; however, Patient #5's medical record indicated on 10/03/2024, "Gout crystals were seen under compensated, polarizing microscopy." The "Crystal analysis 2024-2025" log sheet indicated staff documented "None" in the column labeled "crystals present" for Patient #7 on 02/04/2025; however, Patient #7's medical record indicated on 02/04/2025, "Pseudogout crystals were seen under compensated, polarizing microscopy." During an interview on 11/12/2025 at 10:50 AM, the Laboratory Director (LD) stated the results of the microscopic examinations of synovial fluid were handwritten on the log, then the log was used to transcribe the results in the patients' medical records. The LD stated the handwritten logs were then typed and discarded. The LD stated he believed the discrepancies between the results on the "Crystal analysis 2024-2025" log sheet verses the results in the patients' medical records were due to a transcription error.