

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0892797	(X3) Date Survey Completed 10/17/2024
Name of Provider or Supplier Triangle Arthritis & Rheumatology Associates	Street Address, City, State 3101 John Humphries Wynd, Raleigh, NC	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records, review of "Proficiency Testing Results Review Sheets" and interview with technical supervisor (TS) 10/17/24, the laboratory failed to evaluate unacceptable PT results to determine if corrective action was necessary for 4 of 14 PT events reviewed. Findings: Review of 2023 and 2024 API PT results revealed the following 4 PT events with unacceptable results in which an evaluation was not performed: 1. 2023 API Chemistry - Core - 1st event - Sample CH-01 and CH-02 - unacceptable results for Total Protein (TP). 2. 2023 API Chemistry - Core - 2nd event - Sample CH-07 - unacceptable result for Urea Nitrogen (BUN). 3. 2024 API Hematology/Coagulation - 2nd event - Sample HSY-07 - unacceptable results for Mean Cell Hemoglobin (MCH) and Mean Corpuscular Hemoglobin Concentration (MCHC). 4. 2024 API Chemistry - Core - 3rd event - Sample CH-14 - Unacceptable result for Carbon Dioxide (CO2). Review of "Proficiency Testing Results Review Sheets" for the PT events revealed a checklist and the statement "Analytes Passed" for 3 of the 4 reviewed. The review sheet for 2023 API Chemistry - Core - 1st event did note an evaluation and corrective action for samples IAS-01 and IAS-02 for 25-OH Vitamin D unacceptable results, but there was no documentation of an evaluation or corrective action for the unacceptable results listed previously. During exit interview with TS at approximately 2:30 p.m., the TS stated she was unaware that all unacceptable results required documented evaluations and corrective action if necessary. She also stated she assumed if the laboratory received at least an 80% score for the analyte than no evaluation was required.</p>

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records, review of "Proficiency Testing Results Review Sheet" forms, review of "Proficiency Testing Performance Evaluation" forms and interview with technical supervisor (TS) 10/17/24, the laboratory failed to evaluate PT results that were "Not Graded" by the PT program due to variance or no consensus to determine if corrective action was necessary for 3 of 14 PT events reviewed. Findings: Review of 2023 and 2024 API PT results revealed the following PT events with "Not Graded" results, due to variance or no consensus, in which an evaluation was not performed: 1. 2024 API Chemistry - Core - 1st event - Samples CH-02, CH-03, and CH-05 - "Not Graded" due to result variance for Total Bilirubin (TBIL). 2. 2024 API Immunology /Immunohematology - 1st event - Sample ANA-01 - "Not Graded" due to no consensus for Anti-dsDNA and Anti-RNP/Sm. 3. 2024 API Immunology /Immunohematology - 2nd event - Sample ANA-07 - "Not Graded" due to no consensus for Anti-dsDNA and Anti-Sm. Review of the "Proficiency Testing Results Review Sheet" for the 2024 API Chemistry - Core - 1st event revealed the statement "Analytes Passed". There was no documentation of an evaluation of the "Not Graded" results. Review of the "Proficiency Testing Performance Evaluation" forms for the 2024 API Immunology/Immunohematology 1st and 2nd events revealed no documentation of an evaluation of the "Not Graded" results and no documentation of correction action. During exit interview with TS at approximately 2:30 p.m., the TS stated she was unaware that PT results that were "Not Graded" required documented evaluations and corrective action if needed.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review 2024 American Proficiency Institute (API) proficiency testing (PT) records for Immunology/Immunohematology, review of "Proficiency Testing Performance Evaluation" forms, and interview with technical supervisor (TS) 10/17/24, the laboratory failed to evaluate PT results that were "Not Graded" and given a passing score by the PT program, due to the laboratory reporting a test problem, to determine if any correction action was necessary for 2 of 2 PT events reviewed. Findings: Review 2024 API PT Immunology/Immunohematology results revealed the following PT events with "Not Graded" results that were given a passing score due to the laboratory reporting a test problem in which an evaluation was not performed: 1. 2024 API Immunology/Immunohematology - 1st event - Samples ANA-01 and ANA-

04 for Antinuclear Antibody (ANA), and Samples RF-01, RF-03 and RF-05 for Rheumatoid Factor (RF). 2. 2024 API Immunology/Immunochemistry - 2nd event - Samples ANA-06, ANA-07 and ANA-10 for ANA and Samples RF-07, RF-09 and RF-10 for RF. Review of the "Proficiency Testing Performance Evaluation" forms for the 2024 API Immunology/Immunochemistry 1st and 2nd events revealed no documentation of an evaluation of the "Not Graded" results and no documentation of correction action. During exit interview with TS at approximately 2:30 p.m., the TS stated she was unaware that PT results that were "Not Graded" required documented evaluations and corrective action if needed. She also stated she had spoken to the API PT program in regards to reporting the results because the PT program does not report the same as the laboratory, and they told her to report the results as "Lab Reported Test Problems".