Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0892797	12/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Triangle Arthritis & Rheumatology Associates	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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 API (American Proficiency Institute) and CAP (College of American Pathologists) proficiency testing records, review of 2020, 2021, and 2022 TheraTest verification records, and interview with the GS (general supervisor) 12/13/22, the laboratory failed to enroll in an HHS (Health and Human Services) approved proficiency testing program for the ANA (antinuclear antibodies) and RF (rheumatoid factor) testing performed. Findings: Review of the laboratory's "General Quality Assessment Policy" revealed on page 4 "... The CLIA reportable tests (Antinuclear Antibody Screen and Rheumatoid Factor IgM) are done through CAP or other accredited proficiency testing agencies. ...". On page 5, the policy states "The TheraTest Proficiency Testing Program, which is not HHS (Health and Human Services) approved, has two events per year. ...". Review of 2020, 2021, and 2022 API and CAP proficiency testing records revealed the laboratory was not enrolled for ANA and RF. Review of 2020, 2021, and 2022 TheraTest verification records revealed the laboratory participated for ANA and RF. During interview at approximately 2:50 p.m., the GS confirmed the laboratory had not participated in proficiency testing for their ANA and RF testing. She stated she was unaware the

	laboratory was required to enroll in an HHS-approved proficiency testing program for ANA and RF.
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 review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 API and CAP proficiency testing records, and interview with the GS 12/13 /22, the laboratory failed to verify the accuracy of the QuantiFERON-TB Gold test at least twice a year in 2020. Findings: Review of 2020, 2021, and 2022 API proficiency testing records revealed the laboratory enrolled in the mycobacteriology module from API for 2020. The module the laboratory enrolled in was for mycobacteriology cultures and was not the correct test system the laboratory uses for the QuantiFERON-TB Gold testing performed. Review of 2020, 2021, and 2022 CAP proficiency testing records revealed the laboratory enrolled in proficiency testing for the QuantiFERON-TB Gold in 2021, but there was no documentation of CAP enrollment for 2020. There was no documentation that the laboratory performed any other activity to verify the accuracy of the Quantiferon-TB Gold in 2020. During interview at approximately 2: 55 p.m., the GS confirmed that they did not perform any activity to verify the accuracy of the QuantiFERON-TB Gold in 2020.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with GS 12/13/22, the laboratory procedure manuals failed to include the laboratory's method for entering test results into the patients medical record, failed to include a procedure for the course of action to take if a test system becomes inoperable, failed to include the

	laboratory's panic or alert values and the protocol for notifying providers of panic or alert values. Findings: Review of laboratory procedure manuals revealed the procedure manuals failed to include the following procedures: 1. A procedure for the laboratory's method of entering test results into the patients medical record. 2. A procedure for the course of action to take if a test system becomes inoperable. 3. A procedure stating the panic or alert values for the testing performed and the protocol for notifying providers of panic or alert values. During exit interview at approximately 2:30 p.m. the GS confirmed the procedure manuals failed to include the procedures.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of hematology analyzer maintenance logs and interview with general supervisor (GS) 12/13/22, the laboratory failed to document daily maintenance of the Medonic M Series hematology analyzer for 2 of 12 months in 2020. Findings: Review of manufacturer's instructions (laboratory procedure) for the Medonic M Series analyzer revealed "All maintenance should be documented...". Review of 2020 Medonic M Series maintenance logs revealed no documentation of daily maintenance in November and December of 2020. Interview with GS at approximately 11:00 a.m. confirmed the daily maintenance of the Medonic M Series analyzer was not documented. She stated she must have performed the daily maintenance but did not document it.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2020, 2021, and 2022 calibration and/or calibration verification records, and interview with GS 12/13/22, the laboratory failed to perform calibration verifications every 6 months in 2021 on the Medonic M Series hematology analyzer and failed to perform calibration verifications every 6 months for the testing performed on the EasyRA chemistry analyzer for 2020, 2021 and 2022, a period of approximately 36 months in which calibration verifications were not performed. 1. The laboratory failed to perform calibration verifications every 6 months in 2021 on the Medonic M Series hematology analyzer. Findings: Review of laboratory procedure for the Medonic M Series hematology analyzer revealed on page 7 "CALIBRATION:...Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months.". Review of 2021 calibration verification records for the Medonic M Series hematology analyzer revealed a calibration verification was performed on 4/13/21, the next calibration verification was due by 10 /13/21 and was not completed until 2/16/22, a period of approximately 10 months in which a calibration verification was not performed. Interview with GS at approximately 10:30 a.m. confirmed the laboratory failed to perform calibration verifications every 6 months in 2021 on the Medonic M Series hematology analyzer. 2. The laboratory failed to perform calibration verifications for all testing performed on the EasyRA chemistry analyzer except the C-reactive protein in 2020, 2021 and 2022. Findings: Review of laboratory procedure "Chemistry Testing Routine Chemistries" revealed "CALIBRATION...Calibration Verification is required every 6 months for all tests performed on the EasyRA.". Review of 2020, 2021, and 2022 calibration records revealed the laboratory performs a one point calibration for the following analytes tested on the EasyRA chemistry analyzer: Urea Nitrogen, Uric Acid, Albumin, Alkaline phosphatase, Alanine aminotransferase, Aspartate aminotransferase, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Carbon Dioxide, Creatinine, Glucose, Phosphorus, Potassium, Sodium and Total Protein. The calibrations failed to demonstrate calibration verifications by including a minimal value, a mid-point value and a maximum value at least every 6 months for the 36 months reviewed. Interview with GS at approximately 12:45 p.m. confirmed the laboratory failed to perform calibration verifications every 6 months for the analytes in which only one point calibrations were performed. She stated she was unaware calibration verifications were required.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 API and CAP proficiency testing records and interview with the GS 12/13/22, the laboratory director failed to ensure all proficiency testing results were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Findings: Review of 2020, 2021, and 2022 API and CAP proficiency testing records revealed results for the following events were missing and had not been signed and dated by the laboratory director: 1. API 2020 1st event Immunology 2. API 2020 1st event Chemistry Core 3. API 2021

	1st event Hematology The GS was able to print the missing results during the survey. During interview at approximately 12:45 p.m., the GS stated that she was unaware the results were missing and had not been reviewed by the laboratory director.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's QA (quality assessment) procedures and interview with the GS 12/13/22, the laboratory director failed to ensure the quality assessment program was established and maintained to identify and correct problems and prevent their recurrence and assure the quality of laboratory services offered. Findings: The laboratory's "General Quality Assessment Policy" revealed the policy included information that did not reflect the laboratory's current practices. Examples: 1. On page 3, the QA policy states "... Every 4-8 weeks, the phlebotomist will provide two specimens from the same bleeding, one with the real name and record and the other with a fictitious patient name or number, with requisition forms for each sample. These specimens are then processed in the same manner as all other samples. After test completion, the Laboratory Supervisor/Director compares the results of the real sample with the duplicate sample, and completes the split sample form (see Appendix). ...". During interview at approximately 2:10 p.m. the GS stated they do not perform blind duplicate testing every eight weeks. 2. On page 4, the QA policy states "... For tests that are not offered by CAP or other accredited proficiency testing agencies, ... (the laboratory) participates twice annually in a proficiency testing programs available at: TheraTest Laboratories, Inc. ... and DEQAS Vitamin D External Quality Assessment Scheme ... The CLIA reportable tests (Antinuclear Antibody Screen and Rheumatoid Factor IgM) are done through CAP or other accredited proficiency testing agencies. During interview at approximately 11:00 a.m., the GS stated they do not participate in the DEQAS verification for Vitamin D. At approximately 2:50 p.m., the GS confirmed the laboratory had not participated in CAP proficiency testing for their ANA and RF testing. 3. On page 6, the QA policy states "... 8. Laboratory meetings are held to coincide with the receipt of the results from the proficiency testing surveys. ...". On page 15-16, the QA policy states "... A review of all the meetings ... will be written and recorded in the Minutes of staff meetings.". During interview at approximately 1:20 p.m., the GS stated she does meet with the laboratory director as needed, but the meetings are informal and not documented.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021,

	and 2022 TheraTest quality control records, and interview with the GS 12/13/22, testing personnel failed to follow the laboratory's procedures for performing quality control on the TheraTest procedures. Examples: 1. The laboratory's TheraTest procedure "25-OH Vitamin D and other hydroxylated metabolites in serum or plasma" states on page 16 "... E. Internal Controls. Every time a new lot number for a particular kit is purchased, the two Controls from the previous lot number kit are tested on the first run of the new kit. These Controls are referred to as Internal Controls. ...". 2. The laboratory's TheraTest procedure "Rheumatoid Factor IgM and RF/3 (IgM, IgG, IgA)" states on page 26 "... G. Internal Controls. Every time a new lot number for a particular kit is purchased, the Positive and Negative Controls from the previous lot number kit are tested on the first run of the new kit. These controls are referred to as Internal Controls. ...". Review of 2020, 2021, and 2022 TheraTest quality control records revealed the laboratory performed quality control for new kits using only the current lot number of quality control material. There was no documentation to indicate the laboratory tested the previous lot number of control material with each new kit. During interview at approximately 2:10 p.m., the GS stated they do not test controls from the previous lot number with each new kit.