Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0892797	10/22/2019
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 laboratory records, review of 2017, 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records, and interview with general supervisor (GS) 10/22/19, the laboratory failed to enroll in a PT program for the analyte blood urea nitrogen (BUN). Findings: Review of laboratory records revealed the laboratory performs BUN testing on the Medica Easy RA chemistry analyzer. Review of 2017, 2018 and 2019 API PT records revealed the laboratory was enrolled and participating in API Chemistry Core events for all chemistry analytes tested except the analyte BUN. Review of laboratory records revealed the laboratory had not verified the accuracy of the BUN analyte since time of last survey 8/18/17 until time of current survey, a period of approximately 27 months. Interview with GS at approximately 1:00 p.m. confirmed the laboratory had not participated in a PT program for the analyte BUN. The GS stated she assumed BUN was included in the API Chemistry event and although they tested the PT samples for BUN she did not realize it was not included in the enrollment.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of 2017, 2018 and 2019 APT PT records, and interview with GS 10 /22/19, the laboratory director (LD) and/or the testing personnel (TP) failed to sign attestations for the PT events in which the laboratory participated. Findings: Review of 2017, 2018 and 2019 API PT records revealed attestations were not signed by the LD and the TP for the following API PT events: a. API 2017 Hem/Coag - 3rd event b. API 2017 Chem-Core - 3rd event c. API 2018 Chem-Core - 1st event d. API 2018 Hem/Coag - 2nd event e. API 2018 Chem-Core - 2nd event f. API 2018 Hem/Coag - 3rd event g. API 2018 Chem-Core - 3rd event h. API 2019 Hem/Coag - 1st event i. API 2019 Chem-Core - 1st event j. API 2019 Hem/Coag - 2nd event k. API 2019 Chem-Core - 2nd event l. API 2019 Hem/Coag - 3rd event Review of 2017, 2018 and 2019 API PT records revealed attestations were not signed by the LD for the following API PT event; a. API 2018 Hem/Coag - 1st event Exit interview with GS at approximately 3:00 p.m. confirmed attestations were not signed as required by the LD and/or TP.
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 laboratory records, review of laboratory PT records, and interview with GS 10/22/19, the laboratory failed to verify the accuracy of the C-reactive protein (CRP) analyte at least twice annually. Findings: Review of laboratory records revealed the laboratory performs CRP testing using TheraTest Labs Advanced Immunoassays. Review of 2017, 2018 and 2019 laboratory PT records revealed the laboratory was not enrolled in a PT program for the CRP analyte. The laboratory had performed the testing along with other immunoassays but had not reported it. Review of laboratory records revealed the laboratory had not verified the accuracy of the CRP analyte since time of last survey 8/18/17 until time of current survey, a period of approximately 27 months. Interview with GS at approximately 1:00 p.m. confirmed the laboratory had not participated in a PT program for CRP, she also confirmed the laboratory had not verified the accuracy of the CRP testing at least twice annually as required. The GS stated she did not realize the CRP was not included along with the other immunoassays that were reported.
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 manual and interview with GS 10/22/19, the laboratory procedure manual failed to include the laboratory's current system for entering results in the patient record, and a description of the course of action to take if a test system becomes inoperable. Findings: 1. Review of laboratory procedure manual revealed "Test Report...All laboratory reports must be sent promptly to the requesting physician...All test results are part of the medical record..." The procedure fails to include the laboratory's current system for entering results into the patient's medical record. 2. Review of laboratory procedure manual revealed the procedure manual failed to include a procedure for the course of action to take if a test system becomes inoperable. Interview with GS at approximately 10:30 a.m. confirmed the laboratory procedure manual did not include the laboratory's current system for entering results in the patient's medical record. She stated the laboratory has a computer data system in which tests are ordered and the copies of test results are printed from the analyzers and sent to the medical records department, where they scan them into the patients medical record. She also confirmed the manual did not include a procedure for the course of action to take if any analyzers should become inoperable.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of Medica Easy RA operator's manual, review of laboratory procedure manual, and interview with GS 10/22/19, the operator's manual for the Medica Easy RA chemistry analyzer failed to have complete quality control and calibration procedures. Findings: 1. Review of Medica Easy RA operator's manual revealed the quality control procedure failed to include the type of control used, the identity of the controls used, the criteria used to determine is quality control is acceptable, and the corrective action to take if control results fail to meet the acceptable criteria. For example: The operator's manual states "Daily Use of QC Material...Two levels of quality control should be run for each chemistry which is reported by the laboratory, each day." and "Quality Control Procedures...The

	laboratory is responsible for having control procedures, for each test system." 2. Review of Medica Easy RA operator's manual revealed the calibration procedures failed to include the type of calibrators used, the identity of the calibrators, the criteria used to determine is calibration is acceptable, and the corrective action to take if calibration fails to meet the acceptable criteria. For example: The operator's manual states " 4.2...Calibration - the submenu allows you to set up calibrators and calibrator preferences. You cannot run calibrators until you set up calibrators. EasyRA supports both single-level calibrations and multi-level calibrations. All calibrators purchased from Medica include a CD from which you can quickly load calibration setup information." Review of laboratory procedure manual revealed "Pg 9...493.1251 Standard: Procedure Manual...Written Procedure Manuals for all tests performed at... are available to, and followed by, laboratory personnel. The Procedure Manuals include the following:...Calibration and tolerance limits...Quality Control and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability;...". The procedure manual fails to state that the "written" procedures are via operator manuals for the analyzer and fails to have complete quality control and calibration procedures for the testing on the Medica Easy RA. Interview with GS at approximately 2:00 p.m. confirmed the operator's manual was not complete for what was required, she stated she was shown how to run and review the quality controls and calibrations when she was trained, but was unaware the operator's manual and the laboratory manual was not complete.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory records and interview with GS 10/22/19, the laboratory failed to document the temperature of the laboratory incubator used for the analysis of the Mycobacterium tuberculosis testing. Findings: The laboratory utilizes the QuantiFERON-TB Gold ELISA assay to test for Mycobacterium tuberculosis. Review of manufacturer's instructions for the QuantiFERON-TB Gold ELISA assay revealed once blood is drawn, "Transfer the tubes to a 37 degree Celcius (C) +/- 1 degree C incubator as soon as possible." Review of laboratory records revealed the laboratory failed to document the temperature of the incubator each day it was in use. Interview with GS at approximately 2:30 p.m. confirmed the laboratory had not documented the temperature of the incubator each day of use.
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 laboratory procedure manuals, lack of documentation and interview with GS 10/22/19, the laboratory director failed to ensure that quality assessment (QA) policies and procedures were established and monitored to assure the quality of the laboratory services provided. Findings: Review of laboratory procedure manual revealed no QA policies or procedures were established for the pre-analytical, analytical and post-analytical assessment of the laboratory services provided. For example; there were no QA policies for review of laboratory temperature logs, patient identification problems, review of instrument maintenance, QC or calibration reviews, PT review for completeness, or review of patient test reports for completeness and correlation to diagnosis. Interview with GS at approximately 10:30 a.m. confirmed the laboratory had not established quality assessment policies or procedures. She stated she was monitoring quality control and calibrations but was unaware that quality assessments policies were required.