Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2183998	08/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Annapolis Rheumatology	510 Upper Chesapeake Dr Pavilion Ii #413, Bel Air, MD	

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
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 proficiency testing (PT) documentation and interview with the testing person (TP), the laboratory failed to verify the accuracy of all analytes tested at least twice annually. Findings: 1. The laboratory tested patient specimens using the TheraTest EL-anti-CCP/2 (cyclic citrullinated peptide) test kit and the TheraTest EL-ANA/9 test kit which is a multiplex immunoassay for the measurement of antinuclear antibodies in human serum. The EL-ANA/9 test kit detects antibodies against the following 9 nuclear antigens: single-stranded deoxyribonucleic acid (ssDNA), double-stranded DNA (dsDNA), Smith (Sm), ribonucleoprotein (RNP/Sm), Sjgren's syndrome (SSA and SSB), chromatin, schleroderma (Scl-70), and centromere. 2. The laboratory was enrolled in a PT program that included dsDNA, Sm, RNP/Sm, SSA, SSB, and centromere, but did not include ssDNA, Scl-70, nor chromatin. 3. The laboratory began testing patient specimens on 09/16/2020. 4. There were no records of the laboratory performing PT for anti-CCP. 5. The TP stated that the laboratory was enrolled in PT with TheraTest for ssDNA, Scl-70 and chromatin, but had not yet received a testing event. 6. During the exit interview at 3:30 PM, the TP confirmed that the laboratory had not verified the accuracy, via PT, of all tests performed on patient specimens.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) policy and laboratory records and interview with the testing person (TP), the laboratory failed to ensure that communications and rejected specimens were documented and reviewed as described in the QA policy. Findings: 1. The "General Quality Assessment Policy" was reviewed. 2. The section titled "Complaint Investigations" stated that "Once a quarter, the Laboratory Director/Supervisor will review the Complaints and Corrective Actions File to insure the resolution of all the reported complaints." 3. The section titled "Communications" stated "Any break down in communications with the physicians(s) is recorded as a note describing the nature of the problem and a written copy of the problem is stored in the Complaints and Corrective Actions, Binder #4." 4. The section titled "Preanalytic systems quality assessment" stated "When a sample is rejected, the submitting physician is notified immediately and arrangements for a new sample are made. The person receiving the sample will file a Complaint Form (Binder #4)." 5. The TP documented communications with the physicians in a spiral-bound notebook labelled "Communication Log." The "Communication Log" was not referred to in any of the laboratory's approved policies and procedures and there was no documentation that the "Communication Log" was reviewed once a quarter. 6. The laboratory kept another binder that included the test requisitions and reports for specimens tested. Rejected specimens were documented on indivudal patient requisitions/reports in this binder and referred to in the "Communication Log." There were no Complaint Forms filed for rejected specimens as described in the QA policy and no documentation that rejected specimens were reviewed once a quarter. 7. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that a "Communication Log" was used to record communications with physicians, Complaint Forms were not filed for rejected specimens, the procedures and policies did not reference the "Communication Log" and there was no documented quarterly review of communications and rejected specimens as described in the QA policy.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and records and interview with the testing person (TP), the laboratory failed to perform "within run variability" evaluations as described in the procedure manual. Findings: 1. Section "XI. Quality Control" of the procedures titled "Antinuclear Antibodies," "EL-anti-CCP/2," and "25-OH Vitamin D" stated that every 8 weeks the lab will perform "Within run variability" for each of these assays. 2. The procedures stated "Within run variability (duplicate Specimens) is assessed by randomly testing duplicate Specimens for the same patient" and provided instructions for creating a blind duplicate specimen. Each procedure included acceptability criteria for evaluating the results. 3. The procedures stated that the results were to be recorded in the "Controls and non-CAP Proficiency Testing

	binder." There was no record of "Within run variability" evaluations performed for any assay. 4. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that the laboratory was not performing the "Within run variability" evaluations as described in the "Antinuclear Antibodies," "EL-anti-CCP/2," and "25-OH Vitamin D" procedures.
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 the manufacturer's product insert (PI) and the laboratory's procedure and interview with the testing person (TP), the laboratory's procedure failed to include instructions for transferring patient specimens to QuantiFERON-TB Gold Plus (QFT-Plus) blood collection tubes. Findings: 1. The laboratory used Qiagen's QFT-Plus test kit to test for patient responses to antigens associated with Mycobacterium tuberculosis infection. The test kit included QFT-Plus blood collection tubes that are required for the test procedure. 2. The manufacturer's PI included instructions for 2 options to collect patient whole blood specimens into the QFT-Plus blood collection tubes. Option 1 was a direct draw from the patient into the blood collection tubes. Option 2 was for collecting patient whole blood specimens into a lithium-heparin tube and then transferring the whole blood from the lithium-heparin tube into the QFT-Plus blood collection tubes. 3. Section "VIII. Specimen Collection and Handling" of the laboratory procedure titled "QuantiFERON - TB Gold Plus" included instructions for the "Direct draw into QFT-Plus Blood Collection Tubes" only. 4. The TP stated that the phlebotomist draws patient whole blood into a lithium-heparin tube and the laboratory then transfers whole blood from the lithium-heparin tube into the QFT-Plus blood collection tubes. 5. During the exit interview on 08/04/2021 at 3:30 PM, the TP confirmed that the laboratory's procedure manual did not include instructions for transferring patient whole blood from a lithium-heparin tube into the QFT-Plus blood collection tubes.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory failed to ensure that all procedures were approved by the laboratory director (LD) before use. Findings: 1. The following procedures were not approved (signed and dated) by the LD: 1) "TheraTest Laboratories Dynex DSX Maintenance Procedure" (document 002232 POD version 061710), 2) "DSX General Cleaning Procedure" (document 002234 POD version 061710), and 3) "Temperature Documentation of Laboratory Equipment" (version 1, 9/10/20). 2. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that the listed procedures were not approved (signed and dated) by the LD.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the testing person (TP), the laboratory failed to ensure pouches containing microplates for enzyme-linked immunosorbent assay (ELISA) testing were labeled with the opened date and the new expiration dates. Findings: 1. Section "VI. Storage and Handling" of the procedures titled "Rheumatoid Factor" and "Antinuclear Antibodies" stated that the microwell strips for ELISA testing were stored in a metallized pouch. Once a pouch was opened, any unused microwell strips would be stored in the refrigerated resealed pouch and "should be used within 3 months." 2. Section "VI. Storage and Handling" of the procedure titled "25-OH Vitamin D" stated to return unused wells of a partly used microplate to the tightly sealed protective wrapping. The procedure stated to store the wells "in a dry place and at a temperature between 2-8C for 4 months, but not longer than the indicated expiry date." 3. The opened pouches in the refrigerator were not labeled with the opened date and the new expiration date. 4. During the exit interview on 08 /04/2021 at 3:30 PM, the TP confirmed that pouches containing the microwells for Rheumatoid Factor, Antinuclear Antibodies, and 25-OH Vitamin D ELISA testing were not labeled with the opened date and new expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the testing person (TP), the laboratory used

	blood collection tubes for the QuantiFERON-TB Gold Plus test beyond the expiration date. Findings: 1. A box of QuantiFERON-TB Gold Plus blood collection tubes was observed in the refrigerator. The expiration date on the box (lot number 56604768) was listed as 06/30/2021. 2. The TP stated that the blood collection tubes had been used for at least one batch of testing after 06/30/2021. 3. During the exit interview on 08/04/2021 at 3:30 PM, the TP confirmed that blood collection tubes for the QuantiFERON-TB Gold Plus test were used beyond the defined expiration date.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturers' product inserts (PI), the laboratory's procedures, and the laboratory's validation data and interview with the testing person (TP), the laboratory failed to establish test system performance for testing specimen matrices that were not validated by the manufacturer. Findings: 1. The "Intended Use" section of the TheraTest Rheumatoid Factor (RF) test kit PI, document 000507-091818, stated "The TheraTest EL-RF/3 (IgM-IgG-IgA) is an in vitro diagnostic test that measures rheumatoid factor (RF) of the IgM, IgG, and IgA classes in human serum and is intended as an aid to the diagnosis of Rheumatoid Arthritis (RA)." 2. The "Limitations of the Procedure" section of the TheraTest Antinuclear Antibodies test kit PI, document 000681-091117, stated "These assays have been tested with serum samples only. The performance using other types of Specimens has not been determined." 3. Section "II. Specimen Collection and Handling" of the laboratory's procedures titled "Rheumatoid Factor" and "Antinuclear Antibodies" stated "Fluids other than serum, such as fluids from serous cavities and joint fluids, may also be used in the assay." 4. The laboratory's validation data for the TheraTest EL-RF/3 and TheraTest Antinuclear Antibodies (EL-ANA/9) test kits did not include the establishment of performance specifications for non-serum specimen matrices. 5. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that the laboratory did not establish performance specifications for non-serum specimen matrices.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with the testing person (TP), the laboratory failed to ensure that pipettors were calibrated within the designated due date. Findings: 1. The documents titled "Pipette Accuracy Test Results" showed that the pipettors were last calibrated on 07/21/2020 and were due for another calibration on 01/21/2021. 2. The stickers affixed to each of the 3 pipettors located in the laboratory showed a calibration due date of 01/21/2021. 3. During the exit interview on 08/04/2021 at 3:30 PM, the TP confirmed that the pipettors were overdue for calibration.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on review of the quality assessment (QA) policy and laboratory records and interview with the testing person (TP), the laboratory failed to perform and document quarterly QA meetings. Findings: 1. The "General Quality Assessment Policy" stated that the laboratory will hold "quarterly meetings (or every time the CAP/TheraTest Laboratories, Inc. Survey results are received) to discuss all issues, including quality control." The procedure further stated that the "review of all the meetings held at Annapolis Rheumatology will be written and recorded in the Minutes of staff meetings." 2. The laboratory began testing patient specimens on 09/16/2020. 3. There was no documentation of "Minutes of staff meetings." 4. During the exit interview on 08/04/2021 at 3:30 PM, the TP confirmed that the laboratory had not held a quarterly meeting as described in the QA policy. II. Based on review of the QA policy, "Communication Log", and testing procedures and interview with the TP, the laboratory failed to incorporate records of testing issues into the laboratory's QA of their analytic system. Findings: 1. The "General Quality Assessment Policy" defined when a corrective action form should be completed and stated that "Once a quarter, the Laboratory Director/Supervisor will review the Complaints and Corrective Actions File. 2. The TP documented issues with testing in a spiral-bound notebook labeled "Communication Log." The "Communication Log" was not referred to in any of the laboratory's approved procedures or policies and was not reviewed as part of the laboratory's QA activities. 3. Examples of "Communication Log" entries were: 1) on 12/30/2020, calibrator and controls were out of range, the TP contacted the manufacturer, and the issue was resolved; 2) on 01/07/2021 the assay did not produce any calculated results, the TP contacted the manufacturer, after a physical adjustment to the instrument, the issue was resolved; and 3) on 02/26/2021 the assay failed, after repeating the assay, one calibrator was still out of range, the TP contacted the manufacturer and no resolution is documented. 4. None of the issues documented in the "Communication Log" were documented on the corrective action forms referred to in the QA policy and there was no documentation that the "Communication Log" was reviewed quarterly by the Laboratory Director/Supervisor. 5. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that the "Communication Log" was not referred to in the laboratory's approved policies and procedures and the incidents documented on the log were not reviewed as part of the laboratory's QA activities.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the final test reports and interview with the testing person (TP), the laboratory failed to include the address where the test was performed. Findings: 1. The laboratory stored patient test requisitions and final reports in a binder. Selected test reports located in the binder for testing performed in 2021 were reviewed. 2. The final test reports stated that the testing was performed at "Annapolis Rheumatology," but did not include the address where the laboratory was located. 3. During an interview on 08/04/2021 at 1:00 PM, the TP confirmed that the final test reports did not include the laboratory's address.