Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1021094	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Allen Arthritis	997 Raintree Circle Suite 120, Allen, TX	

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	Based on the onsite survey conducted 05/15/2018, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1240 Preanalytic Systems 493.1441 Laboratory Director; High Complexity The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. The Laboratory Director and Testing Person were informed at the exit conference on 05/15/2018 that the survey results were being sent to CMS Regional Office for evaluation and review, and that the CMS 2567 survey report would be sent by the CMS Regional Office.
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 a review of College of American Pathologists (CAP) proficiency testing (PT) records, CAP codes instructions, and confirmed in interview, the laboratory failed to verify accuracy of special immunology and serology analytes not scored by the PT agency for 1 of 2 testing events in 2017 (2017 S2-B and 2017 RDS-B). Findings included: 1. Review of 2017 S2-B Special Immunology "Original Evaluation" PT document stated, "[27] = Lack of participant or referee consensus." Review of the laboratory's results for analyte Anti-RNP (Specimen S2-12) revealed "Your Result: Positive/Abnormal," "Your grade: [27];" and for Anti-SSA (Specimen S2-12) revealed "Your Result: Positive/Abnormal," "Your grade: [27]." 2. According to CAP "Actions Laboratories Should Take when a PT Result is Not Graded" document, the action required for code [27] stated, "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the Participant Summary. If comparison is not available, perform and

	document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." The laboratory did not verify accuracy of special immunology analytes Anti-RNP and Anti-SSA not scored by the PT agency. The laboratory only verified the accuracy once in 2017 of Anti-RNP and Anti-SSA (2017 S2-C). 3. Review of 2017 RDS-B Special Serology "Original Evaluation" PT document stated, "[20] = No appropriate target/response cannot be graded." Review of the laboratory's results for analyte Ant-ScI 70 (Specimen RD-04) revealed "Your Result: 127.0" "Your grade: [20];" and "No. of Labs: 6." 4. According to CAP "Actions Laboratories Should Take when a PT Result is Not Graded" document, the action required for code [20] stated, "Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, all method, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level ad extent that would have been tested." The laboratory did not document their evaluation and did ensure verification of accuracy for Anti-ScI 70 analyte, at least twice in 2017. 4. During an interview on 05/15/2018 at 10:30 am, the Testing Person reviewed and confirmed the above findings. Word Key: Anti-RNP = Anti- Ribonucleoprotein Anti-SSA = Anti-Sjgren's-syndrome-related antigen A
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 a review of the laboratory's test menu, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated immunology and serology analytes, at least twice annually for 1 of 2 testing events in 2017 (Anti-Centromere, Anti-CCP) and 2 of 2 testing in 2017 (Anti-Chromatin, Anti-ssDNA, Anti-ScI 70). Findings included: 1. Review of the laboratory's test menu included unregulated special immunology and serology analytes: Anti-ssDNA, Anti-ScI 70, Anti-Centromere, Anti-Chromatin and Anti-CCP. The analytes were tested on the TheraTest ELISA platform. 2. Review of CAP PT 2017 records revealed Anti-CCP (Cyclic Citrullinated peptide) analyte was verified for accuracy on 08/21/2017 (event 2017 RDS-B). Review of CAP PT 2017 records revealed Anti-Centromere analyte was verified for accuracy on 12/18/2017 (event 2017 S2-C). The laboratory did not ensure Anti-CCP and Anti-Centromere were verified for accuracy, at least twice in 2017. 3. Review of CAP PT 2017 records revealed Anti-ScI 70 analyte results included a [20] code for their grade (Specimen RD-04; result: 127.0) in event 2017 RDS-B. The "Original Evaluation" stated, "[20] = No appropriate target/response cannot be graded." According to CAP "Actions Laboratories Should Take when a PT Result is Not Graded" document, the action required for code [20] stated, "Document that the laboratory performed a self-evaluation using the data presented in the Participant Summary and compared its results to a similar method, all method, or all participant statistics if provided. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level ad extent that would have been tested." The laboratory did not document their evaluation and did ensure verification of accuracy for Anti-ScI 70 analyte, at least twice in 2017. 4. Review of CAP PT 2017 records revealed Anti-Chromatin and Anti-ssDNA (single-

	stranded deoxyribonucleic acid) analytes were not verified for accuracy, at least twice in 2017. 5. During an interview on 05/15/2018 at 11:00 am, the Testing Person reviewed and confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's procedure manual, manufacturer's instructions, patient data log, and patient test reports, the laboratory failed to meet the requirements of the preanalytic systems, as evidenced by: 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on TheraTest within the timeframe as defined by their policy (14 days refrigerated). Refer to D5305. 2. The laboratory failed to follow its own written policy for labeling patient blood collection tubes with the collection dates for 20 of 23 patient specimens in 05 /2018. Refer to D5311, I. 3. The laboratory failed to follow its own written policy in providing a correct collection date for 5 of 74 patients (random sampling) when tested on the TheraTest platform in 12/2017, 03/2018, 04/2018, and 05/2018. Refer to D5311, II. 4. The laboratory failed to follow its own written policy and manufacturer's instructions when testing specimens for TheraTest analytes within 14 days of collection (when refrigerated) for 38 of 74 patient specimens tested 12/2017, 02/2018, 04/2018, and 05/2018. Refer to D5311, III. 5. The laboratory failed to follow its own written policy when testing specimens for TheraTest Anti CCP analyte within 14 days of collection (when refrigerated) for 39 of 74 patient specimens tested 12/2017, 02 /2018, 04/2018, and 05/2018. Refer to D5311, IV.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by:

	Based on direct observation, review of laboratory's procedure manual, manufacturer's instructions, patient data log, patient test reports and confirmed in interview, the laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on TheraTest within the timeframe as defined by their policy (14 days refrigerated). Findings included: 1. Review of the laboratory's policy manual stated, "Samples received for testing should be labeled at least with the name of the patient and/or unique patient identifier and the draw date" and stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days" (this was consistent with manufacturer's instructions for stability/storage). The policy did not require a collection time to ensure specimens were tested with the defined timeframe. 2. During a tour of the laboratory on 05/15/18 at 2:00 pm, there were 20 patient specimens (random sampling) observed to be stored in the refrigerator without collection dates and without collection times documented on their blood collection tubes. According to test records, the patients were tested on the TheraTest platform on 05/06/2018 for RF/3, Anti-CCP, ANA Screen and ANA/9 tests. Refer to D5311, I. 3. Review of patient test reports and data logs revealed the laboratory tested 40 patient specimens after 14 days of collection (random sampling) in 12/2017, 02/2018, 04/2018, and 05/2018. Patient test reports included specimen collection dates but did not include specimens collection times to ensure testing occurred within 14 days of collection. Refer to D5311, III. 4. During an interview on 05/15/18 at 04:00 PM, the testing person confirmed the above findings. Word Key: ANA Screen - Antinuclear antibody screen RF/3 - Rheumatoid Factor Immunoglobulin M, Immunoglobulin G, Immunoglobulin A ANA/9 - Anti ssDNA; Anti ds DNA; Anti SM; Anti RNP; Anti SSA; Anti SSB; Anti Chromatin; Anti Scl 70; Anti Centromere Anti CCP - Anti cyclic citrullinated peptide
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's procedure manual, patient test reports and confirmed in interview, the laboratory failed to follow its own written policy for labeling patient blood collection tubes with the collection dates for 20 of 23 patient specimens in 05/2018. Findings included 1. Review of the laboratory's policy manual stated, "Samples received for testing should be labeled at least with the name of the patient and/or unique patient identifier and the draw date" and stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days" (this was consistent with manufacturer's instructions for stability/storage). 2. During a tour of the laboratory on 05/15/18 at 2:00 pm, the following 20 patient specimens (random sampling) were observed to be stored in the refrigerator without collection dates documented on their blood collection tubes: Patient I0166 Patient I0165 Patient I0164 Patient I0162 Patient I0161 Patient I0160 Patient I0159 Patient I0158 Patient I0157 Patient I0156 Patient I0155 Patient I0154 Patient I0153 Patient I0152 Patient I0151 Patient I0150 Patient

I0149 Patient I0148 Patient I0147 Patient I0144 According to test records, the patients were tested on the TheraTest platform on 05/06/2018 for RF/3, Anti-CCP, ANA Screen and ANA/9 tests. The laboratory did not ensure blood collection tubes were labeled with the draw dates as stated by their own written policy. 3. During an interview on 05/15/18 at 4:00 pm, the Testing Person confirmed the above findings. II. Based on direct observation, review of the laboratory's procedure manual, patient test reports and confirmed in interview, the laboratory failed to follow its own written policy in providing a correct collection date for 5 of 74 patients (random sampling) when tested on the TheraTest platform in 12/2017, 03/2018, 04/2018, and 05/2018. Findings included: 1. Review of the laboratory's policy manual stated, "Samples received for testing should be labeled at least with the name of the patient and/or unique patient identifier and the draw date" and stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days" (this was consistent with manufacturer's instructions for stability/storage). 2. During a tour of the laboratory on 05/15/18 at 2:00 pm, the following patient specimens (random sampling) were observed to be stored in the refrigerator without collection dates documented on their blood collection tubes: Patient I0165; test report drawn date was 00/00/0000 Patient I0166; test report drawn date was 00/00/0000 According to test records, the patients were tested on the TheraTest platform on 05/06/2018 for RF/3, Anti-CCP, ANA Screen and ANA/9 tests. The laboratory did not ensure collection dates were documented and provided for test reports. 3. Review of test reports from 12/2017, 03/2018, and 04/2018 revealed the following: Patient I0128; drawn 00/00/0000 Anti CCP tested on 04/09 /2018 RF3 tested on 03/20/2018 ANA/9 tested on 03/20/2018 ANA Scr tested on 04 /02/2018 Patient H0521; drawn 00/00/0000 Anti CCP tested on 12/07/2017 RF3 tested on 12/07/2017 ANA/9 tested on 12/07/2017 ANA Scr tested on 12/04/2017 Patient I0136; drawn (patient's date of birth) Anti CCP tested on 04/09/2018 RF3 tested on 04/09/2018 ANA Scr tested on 04/02/2018 The laboratory did not follow its own written policy in providing a correct collection date patients specimens when tested on the TheraTest platform. 4. During an interview on 05/15/18 at 4:00 pm, the Testing Person confirmed the above findings. III. Based on review of the laboratory's procedure manual, manufacturer's instructions, patient data log, patient test reports and confirmed in interview, the laboratory failed to follow its own written policy and manufacturer's instructions when testing specimens for TheraTest analytes within 14 days of collection (when refrigerated) for 38 of 74 patient specimens tested 12/2017, 02/2018, 04/2018, and 05/2018. Findings included: 1. Review of the laboratory's procedure manual for TheraTest ANA Scr, ANA/9, and RF3 stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days." TheraTest manufacturer's instrcutions for "SPECIMEN COLLECTION AND HANDLING" of ANA Scr and RF3, stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated. It should be tested within 14 days." TheraTest manufacturer's instrcutions for "SPECIMEN COLLECTION AND HANDLING" of ANA/9, stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days." 2. Review of patient test reports and data logs revealed the laboratory tested the following patient specimens after 14 days of collection (random sampling) in 12/2017, 02/2018, 04/2018, and 05 /2018: Patient H0499 collected 11/10/2017 - RF3, ANA/9 tested on 12/07/2017 (27 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (24 days of elapsed time between collection and analysis) Patient H0500 collected 11 /13/2017 - RF3, ANA/9 tested on 12/07/2017 (24 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (20 days of elapsed time between collection and analysis) Patient H0501 collected 11/13/2017 - RF3, ANA/9

tested on 12/07/2017 (24 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (20 days of elapsed time between collection and analysis) Patient H0502 collected 11/10/2017 - RF3, ANA/9 tested on 12/07/2017 (27 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (24 days of elapsed time between collection and analysis) Patient H0503 collected 11/16 /2017 - RF3, ANA/9 tested on 12/07/2017 (21 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (18 days of elapsed time between collection and analysis) Patient H0504 collected 11/17/2017 - RF3, ANA/9 tested on 12/07/2017 (20 days of elapsed time between collection and analysis; ANA Scr tested on 12/04/2017 (17 days of elapsed time between collection and analysis) Patient H0505 collected 11/17/2017 - RF3, ANA/9 tested on 12/07/2017 (20 days of elapsed time between collection and analysis); ANA Scr tested on 12/04/2017 (17 days of elapsed time between collection and analysis) Patient H0506 collected 11/20 /2017 - RF3, ANA/9 tested on 12/07/2017 (17 Days of elapsed time between collection and analysis) Patient H0507 collected 11/20/2017 -RF3, ANA/9 tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0508 collected 11/20/2017 - RF3, ANA/9 tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0509 collected 11/20/2017 - RF3, ANA/9 tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0510 collected 11/21/2017 - RF3, ANA/9 tested on 12/07/2017 (16 days of elapsed time between collection and analysis) Patient H0511 collected 11/21/2017 - RF3, ANA/9 tested on 12/07/2017 (16 days of elapsed time between collection and analysis) Patient H0512 collected 11/10/2017 - RF3, ANA/9 tested on 12/07/2017 (27 days of elapsed time between collection and analysis) Patient I0048 collected 01/24 /2018 - ANA Scr tested on 02/09/2018 (16 days of elapsed time between collection and analysis) Patient I0049 collected 01/24/2018 - ANA Scr tested on 02/09/2018 (16 days of elapsed time between collection and analysis) Patient I0050 collected 01/24 /2018 - ANA Scr tested on 02/09/2018 (16 days of elapsed time between collection and analysis) Patient I0051 collected 01/24/2018 - ANA Scr tested on 02/09/2018 (16 days of elapsed time between collection and analysis) Patient I0052 collected 01/24 /2018 - ANA Scr tested on 02/09/2018 (16 days of elapsed time between collection and analysis) Patient I0129 collected 03/19/2018 - RF3 tested on 04/09/2018 (21 days of elapsed time between collection and analysis) Patient I0130 collected 03/13/2018 - RF3 tested on 04/09/2018 (27 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (21 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (20 days of elapsed time between collection and analysis) Patient I0131 collected 03/13/2018 - RF3 tested on 04/09/2018 (27 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (21 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (20 days of elapsed time between collection and analysis) Patient I0135 collected 03 /14/2018 - RF3 tested on 04/09/2018 (26 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (20 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (19 days of elapsed time between collection and analysis) Patient I0142 collected 03/14/2018 - RF3 tested on 04/09 /2018 (26 days of elapsed time between collection and analysis); ANA/9 tested on 04 /03/2018 (20 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (19 days of elapsed time between collection and analysis) Patient I0132 collected 03/14/2018 - RF3 tested on 04/09/2018 (26 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (20 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (19 days of elapsed time between collection and analysis) Patient I0133 collected 03/14/2018 - RF3 tested on 04/09/2018 (26 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (20 days of elapsed time between collection and

analysis); ANA Scr tested on 04/02/2018 (19 days of elapsed time between collection and analysis) Patient I0134 collected 03/14/2018 - RF3 tested on 04/09/2018 (26 days of elapsed time between collection and analysis); ANA/9 tested on 04/03/2018 (20 days of elapsed time between collection and analysis); ANA Scr tested on 04/02/2018 (19 days of elapsed time between collection and analysis) Patient I0137 collected 03 /20/2018 - RF3 tested on 04/09/2018 (20 days of elapsed time between collection and analysis) Patient I0138 collected 03/20/2018 - RF3 tested on 04/09/2018 (20 days of elapsed time between collection and analysis) Patient I0139 collected 03/21/2018 - RF3 tested on 04/09/2018 (19 days of elapsed time between collection and analysis) Patient I0140 collected 03/22/2018 - RF3 tested on 04/09/2018 (18 days of elapsed time between collection and analysis) Patient I0141 collected 03/22/2018 -RF3 tested on 04/09/2018 (18 days of elapsed time between collection and analysis) Patient I0143 collected 03/23/2018 - RF3 tested on 04/09/2018 (17 days of elapsed time between collection and analysis) Patient I0144 collected 04/16/2018 - RF3 tested on 05/06/2018 (20 days of elapsed time between collection and analysis); ANA/9 tested on 05/04/2018 (18 days of elapsed time between collection and analysis); ANA Scr tested on 05/01/2018 (15 days of elapsed time between collection and analysis) Patient I0145 collected 04/16/2018 - RF3 tested on 05/06/2018 (20 days of elapsed time between collection and analysis); ANA/9 tested on 05/04/2018 (18 days of elapsed time between collection and analysis); ANA Scr tested on 05/01/2018 (15 days of elapsed time between collection and analysis) Patient I0146 collected 04/16 /2018 - RF3 tested on 05/06/2018 (20 days of elapsed time between collection and analysis); ANA/9 tested on 05/04/2018 (18 days of elapsed time between collection and analysis); ANA Scr tested on 05/01/2018 (15 days of elapsed time between collection and analysis Patient I0147 collected 04/17/2018 - RF3 tested on 05/06/2018 (19 days of elapsed time between collection and analysis); ANA/9 tested on 05/04 /2018 (17 days of elapsed time between collection and analysis) Patient I0148 collected 04/19/2018 - RF3 tested on 05/06/2018 (17 days of elapsed time between collection and analysis); ANA/9 tested on 05/04/2018 (15 days of elapsed time between collection and analysis) The laboratory did not ensure refrigerated specimens were tested for TheraTest analytes within 14 days of collection, as stated by their own written policy and manufacturer's instructions. 3. During an interview on 05/15/18 at 04:00 PM, the testing person confirmed the above findings. IV. Based on review of the laboratory's procedure manual, manufacturer's instructions, patient data log, patient test reports and confirmed in interview, the laboratory failed to follow its own written policy when testing specimens for TheraTest Anti CCP analyte within 14 days of collection (when refrigerated) for 39 of 74 patient specimens tested 12/2017, 02 /2018, 04/2018, and 05/2018. Findings included: 1. Review of the laboratory's procedure manual for Anti CCP stated, "Serum should be removed from the clot and placed in a labeled Specimen container and refrigerated (2-8C). It should be tested within 14 days." 2. Review of patient test reports and data logs revealed the laboratory tested the following patient specimens after 14 days of collection (random sampling) in 12/2017, 02/2018, 04/2018, and 05/2018: Patient H0499 collected 11/10/2017 - Anti CCP tested on 12/07/2017 (27 days of elapsed time between collection and analysis) Patient H0500 collected 11/13/2017 - Anti CCP tested on 12/07/2017 (24 days of elapsed time between collection and analysis) Patient H0501 collected 11/13 /2017 - Anti CCP tested on 12/07/2017 (24 days of elapsed time between collection and analysis) Patient H0502 collected 11/10/2017 - Anti CCP tested on 12/07/2017 (27 days of elapsed time between collection and analysis) Patient H0503 collected 11 /16/2017 - Anti CCP tested on 12/07/2017 (21 days of elapsed time between collection and analysis) Patient H0504 collected 11/17/2017 - Anti CCP tested on 12 /07/2017 (20 days of elapsed time between collection and analysis Patient H0505 collected 11/17/2017 - Anti CCP tested on 12/07/2017 (20 days of elapsed time

between collection and analysis) Patient H0506 collected 11/20/2017 - Anti CCP tested on 12/07/2017 (17 Days of elapsed time between collection and analysis) Patient H0507 collected 11/20/2017 - Anti CCP tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0508 collected 11/20/2017 - Anti CCP tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0509 collected 11/20/2017 -Anti CCP tested on 12/07/2017 (17 days of elapsed time between collection and analysis) Patient H0510 collected 11/21 /2017 - Anti CCP tested on 12/07/2017 (16 days of elapsed time between collection and analysis) Patient H0511 collected 11/21/2017 - Anti CCP tested on 12/07/2017 (16 days of elapsed time between collection and analysis) Patient H0512 collected 11 /10/2017 - Anti CCP tested on 12/07/2017 (27 days of elapsed time between collection and analysis) Patient I0049 collected 01/24/2018 - Anti CCP tested on 02/11 /2018 (18 days of elapsed time between collection and analysis) Patient I0050 collected 01/24/2018 - Anti CCP tested on 02/11/2018 (18 days of elapsed time between collection and analysis) Patient I0051 collected 01/24/2018 - Anti CCP tested on 02/11/2018 (18 days of elapsed time between collection and analysis) Patient I0052 collected 01/24/2018 - Anti CCP tested on 02/11/2018 (18 days of elapsed time between collection and analysis) Patient I0126 collected 03/12/2018 - Anti CCP tested on 04/09/2018 (28 days of elapsed time between collection and analysis) Patient I0127 collected 03/12/2018 - Anti CCP tested on 04/09/2018 (28 days of elapsed time between collection and analysis) Patient I0129 collected 03/19/2018 - Anti CCP tested on 04/09/2018 (21 days of elapsed time between collection and analysis) Patient I0130 collected 03/13/2018 - Anti CCP tested on 04/09/2018 (27 days of elapsed time between collection and analysis) Patient I0131 collected 03/13/2018 - Anti CCP tested on 04/09/2018 (27 days of elapsed time between collection and analysis) Patient I0135 collected 03/14/2018 - Anti CCP tested on 04/09/2018 (26 days of elapsed time between collection and analysis) Patient I0142 collected 03/14/2018 - Anti CCP tested on 04/09/2018 (26 days of elapsed time between collection and analysis) Patient I0132 collected 03/14/2018 - Anti CCP tested on 04/09/2018 (26 days of elapsed time between collection and analysis) Patient I0133 collected 03/14/2018 - Anti CCP tested on 04/09/2018 (26 days of elapsed time between collection and analysis) Patient I0134 collected 03/14/2018 - Anti CCP tested on 04/09/2018 (26 days of elapsed time between collection and analysis) Patient I0137 collected 03/20/2018 - Anti CCP tested on 04/09/2018 (20 days of elapsed time between collection and analysis) Patient I0138 collected 03/20/2018 - Anti CCP tested on 04/09/2018 (20 days of elapsed time between collection and analysis) Patient I0139 collected 03/21/2018 - Anti CCP tested on 04/09/2018 (19 days of elapsed time between collection and analysis) Patient I0140 collected 03/22/2018 - Anti CCP tested on 04/09/2018 (18 days of elapsed time between collection and analysis) Patient I0141 collected 03/22/2018 - Anti CCP tested on 04/09/2018 (18 days of elapsed time between collection and analysis) Patient I0143 collected 03/23/2018 - Anti CCP tested on 04/09/2018 (17 days of elapsed time between collection and analysis) Patient I0144 collected 04/16/2018 - Anti CCP tested on 05/06/2018 (20 days of elapsed time between collection and analysis) Patient I0145 collected 04/16/2018 - Anti CCP tested on 05/06/2018 (20 days of elapsed time between collection and analysis) Patient I0146 collected 04/16/2018 - Anti CCP tested on 05/06/2018 (20 days of elapsed time between collection and analysis) Patient I0147 collected 04/17/2018 - Anti CCP tested on 05/06/2018 (19 days of elapsed time between collection and analysis) Patient I0148 collected 04/19/2018 - Anti CCP tested on 05/06/2018 (17 days of elapsed time between collection and analysis) The laboratory did not ensure refrigerated specimens were tested for TheraTest analytes within 14 days of collection, as stated by their own written policy. 3. During an interview on 05/15/18 at 04:00 PM, the testing person confirmed the above findings. Word Key: ANA Screen - Antinuclear antibody screen RF/3 - Rheumatoid Factor

	Immunoglobulin M, Immunoglobulin G, Immunoglobulin A ANA/9 - Anti ssDNA; Anti ds DNA; Anti SM; Anti RNP; Anti SSA; Anti SSB; Anti Chromatin; Anti Scl 70; Anti Centromere Anti CCP - Anti cyclic citrullinated peptide
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 quality assessment (QA) records, laboratory's procedure manual, manufacturer's instructions, patient data log, and patient test reports, the laboratory failed to follow written QA procedures for the frequency of documented QA activities to correct problems identified in the preanalytic systems in 2017 and 2018. Findings included: 1. Review of QA documents reveal the last QA activities documented were 02/2016 for monthly QA and 10/2015 through 12/2015 for quarterly QA. The monthly document did not include monitoring preanalytic systems as a criteria for QA activities. The quarterly document included Proficiency Testing, Preanalytic, Analytic and Postanalytic systems criteria for QA. The preanalytic systems checklst included: "__Patient specimens were collected and handled according to our protocol and were acceptable for testing __Check Specimen Rejection Log: No specimen mix-ups occurred and all specimens received in the lab for testing __ All specimen were positively identified and optimum sample integrity maintained from the time of collection throughout the testing process." 2. The laboratory did not follow their own procedures for the frequency and documentation of QA activities in 2017 and 2018 to correct problems identified in preanalytic systems: a) The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on TheraTest within the timeframe as defined by their policy (14 days refrigerated). Refer to D5305. b) The laboratory failed to follow its own written policy for labeling patient blood collection tubes with the collection dates for 20 of 23 patient specimens in 05/2018. Refer to D5311, I. c) The laboratory failed to follow its own written policy in providing a correct collection date for 5 of 74 patients (random sampling) when tested on the TheraTest platform in 12/2017, 03/2018, 04/2018, and 05/2018. Refer to D5311, II. d) The laboratory failed to follow its own written policy and manufacturer's instructions when testing specimens for TheraTest analytes within 14 days of collection (when refrigerated) for 38 of 74 patient specimens tested 12/2017, 02/2018, 04/2018, and 05/2018. Refer to D5311, III. e) The laboratory failed to follow its own written policy when testing specimens for TheraTest Anti CCP analyte within 14 days of collection (when refrigerated) for 39 of 74 patient specimens tested 12 /2017, 02/2018, 04/2018, and 05/2018. Refer to D5311, IV. 3. During an interview on 05/15/2018 at 4:00 pm, the Laboratory Director and Testing Person reviewed and confirmed the above findings.
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: I. Based on direct observation, review of the manufacturer's instructions, laboratory's procedure manual, and confirmed in interview, the laboratory failed to store the prepared diluted wash buffer for TheraTest ELISA method in accordance with manufacturer's storage requirements. Findings included: 1. During a tour of the laboratory on 05/15/2018 at 1:30 pm, the following was observed to be stored in a cabinet (room temperature): Baxter Sterile Water for Irrigation (distilled water, lot #G131748, expiration date 12/20) USP (1000 mL) bottle with a label "10X Wash Buffer 10172484 (lot #), expiration 2020-09-16 (manufacturer expiration)" and the prepared date of "5/6/18." The bottle was not stored in refrigerated conditions as defined and required by the manufacturer (2-8C). (The prepared bottle was not labeled with the new expiration date [8 week stability refrigerated]. Refer to D5415) 2. Review of the manufacturer's instructions for Theratest ANA scr, ANA/9, RF3, and anti-CCP, stated, "When stored at 2-8C, the diluted Wash Buffer is stable for 8 weeks." Review of the laboratory's procedure manual for Theratest ANA scr, ANA/9, RF3, and anti-CCP, stated, "The diluted wash buffer is stable for 8 weeks when stored at 2-8C." The laboratory did not store the prepared diluted wash buffer in accordance with manufacturer's storage requirements at 2-8C. The manufacturer did not provide room temperature storage conditions and define stability when stored at room temperature. 3. During an interview on 05/15/18 at 1:30 pm, the Testing Person reviewed and confirmed the above findings. II. Based on direct observation, review of temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to define temperature ranges to ensure reagents maintained TheraTest manufacturer's storage requirements for 4 of 12 months in 2017 (04/2017 through 07/2017) and 2 of 5 months in 2018 (01/2018 and 04/2018). Findings include: 1. During a tour of the laboratory on 05/15/2018 at 2:00 pm, the following were TheraTest kits were observed to be stored in the refrigerator: EL-RF3 IgM, IgG, IgA Kit (Lot #12172603, expiration date 2018-10-10) EL-ANA Profiles ANA9 (Lot #09172419, expiration date 2018-09-12) 2. Review of TheraTest kit manufacturer's instructions stated, "All reagents must be brought to room temperature (18-25C) for 30 minutes prior to use" and stated,"Store all kit components at 2-8C when received." 3. Review of the laboratory temperature charts from 04/2017, 05/2017, 06/2017, 07 /2017, 01/2018, and 04/2018 included sections to record refrigerator temperature and room temperature. The temperature charts did not include defined ranges to ensure proper storage/use of reagents as stated by the manufacturer (2-8C and 18-25C). 4. During an interview on 05/15/18 at 4:00 pm, the Testing Person confirmed the above findings. Word Key: ANA - Antinuclear antibody RF/3 - Rheumatoid Factor Immunoglobulin M, Immunoglobulin G, Immunoglobulin A ANA/9 - Anti ssDNA; Anti ds DNA; Anti SM; Anti RNP; Anti SSA; Anti SSB; Anti Chromatin; Anti Scl 70; Anti Centromere
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 direct observation, review of the manufacturer's instructions, laboratory's procedure manual, and confirmed in interview, the laboratory failed to label the prepared diluted wash buffer for TheraTest ELISA method with the new expiration date. Findings included: 1. During a tour of the laboratory on 05/15/2018 at 1:30 pm, the following was observed to be stored in a cabinet: Baxter Sterile Water for Irrigation (distilled water, lot #G131748, expiration date 12/20) USP (1000 mL) bottle with a label "10X Wash Buffer 10172484 (lot #), expiration 2020-09-16 (manufacturer expiration)" and the prepared date of "5/6/18." The bottle was not labeled with the new expiration date (8 week stability refrigerated). (The prepared bottle was not stored in accordance with manufacturer's storage requirements. Refer to D5413) 2. Review of the manufacturer's instructions for Theratest ANA scr, ANA/9, RF3, and anti-CCP, stated, "When stored at 2-8C, the diluted Wash Buffer is stable for 8 weeks." Review of the laboratory's procedure manual for Theratest ANA scr, ANA/9, RF3, and anti-CCP, stated, "The diluted wash buffer is stable for 8 weeks when stored at 2-8C." The laboratory did not label the prepared diluted wash buffer with the new expiration date as defined by the manufacturer and their own written policy (8 week stability refrigerated). 3. During an interview on 05/15/18 at 1:30 pm, the Testing Person reviewed and confirmed the above findings.
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: Based on review of quality assessment (QA) records, laboratory's procedure manual, and manufacturer's instructions, the laboratory failed to follow written QA procedures for the frequency of documented QA activities to correct problems identified in the analytic systems in 2017 and 2018. Findings included: 1. Review of QA documents reveal the last QA activities documented were 02/2016 for monthly QA and 10/2015 through 12/2015 for quarterly QA. The monthly document included routine testing policies as a criteria for QA activities. The quarterly document included Proficiency Testing, Preanalytic, Analytic and Postanalytic systems criteria for QA. 2. The laboratory did not follow their own procedures for the frequency and documentation of QA activities in 2017 and 2018 to correct problems identified in analytic systems: a) The laboratory failed to store the prepared diluted wash buffer for TheraTest ELISA method in accordance with manufacturer's storage requirements. Refer to D5413, I. b) The laboratory failed to define temperature ranges to ensure reagents maintained TheraTest manufacturer's storage requirements for 4 of 12 months in 2017 (04/2017 through 07/2017) and 2 of 5 months in 2018 (01/2018 and 04/2018). Refer to D5413, II. c) The laboratory failed to label the prepared diluted wash buffer for TheraTest ELISA method with the new expiration date. Refer to D5415. 3. During an interview on 05/15/2018 at 4:00 pm, the Laboratory Director and Testing Person reviewed and confirmed the above findings.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of quality assessment (QA) records, laboratory's procedure manual, manufacturer's instructions, patient data log, and patient test reports, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure quality laboratory services for preanalytic phase of testing. Refer to D6082. 2. The laboratory director failed to ensure QA programs were established and maintained to assure quality of laboratory services provided. Refer to D6094.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory's procedure manual, manufacturer's instructions, patient data log, and patient test reports, the laboratory director failed to ensure quality laboratory services for preanalytic phase of testing, as evidenced by: 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on TheraTest within the timeframe as defined by their policy (14 days refrigerated). Refer to D5305. 2. The laboratory failed to follow its own written policy for labeling patient blood collection tubes with the collection dates for 20 of 23 patient specimens in 05/2018. Refer to D5311, I. 3. The laboratory failed to follow its own written policy in providing a correct collection date for 5 of 74 patients (random sampling) when tested on the TheraTest platform in 12/2017, 03/2018, 04/2018, and 05/2018. Refer to D5311, II. 4. The laboratory failed to follow its own written policy and manufacturer's instructions when testing specimens for TheraTest analytes within 14 days of collection (when refrigerated) for 38 of 74 patient specimens tested 12 /2017, 02/2018, 04/2018, and 05/2018. Refer to D5311, III. 5. The laboratory failed to follow its own written policy when testing specimens for TheraTest Anti CCP analyte within 14 days of collection (when refrigerated) for 39 of 74 patient specimens tested 12/2017, 02/2018, 04/2018, and 05/2018. Refer to D5311, IV.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by:

	Based on review of CMS 155 report, College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in interview, the laboratory director failed to ensure the laboratory was enrolled in a PT program for regulated analyte Rheumatoid Factor (RF) for 1 of 3 testing events in 2017 (RFA - 2017). Findings included: 1. Review of CMS 155 report revealed there were no PT scores for General Immunology (overall score) and RA/RF (analyte score) first event of 2017. 2. Review of General Immunology CAP PT records for 2017 revealed the laboratory did not participate in the first event of 2017 for regulated analyte RF (RFA-2017). The laboratory director did not ensure the laboratory was enrolled in the PT program for RF, to participate in all three events in 2017. 3. During an interview on 05/15/2018 at 11:08 am, the Testing Person confirmed the laboratory did not enroll in time to participate in all three PT events for RF in 2017. Word Key: CMS - Centers for Medicare and Medicaid Services RA - Rheumatoid Arthritis
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 quality assessment (QA) records, laboratory's procedure manual, manufacturer's instructions, patient data log, and patient test reports, the laboratory director failed to ensure QA programs were established and maintained to assure quality of laboratory services provided. The laboratory failed to follow written QA procedures for the frequency of documented QA activities to correct problems identified in the preanalytic systems in 2017 and 2018. Refer to D5391.