Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1010383	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Clinic Pllc	371 N Parkway, Ste 400, Jackson, TN	

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	During a recertification survey performed on 04/15/2024, the laboratory was found out compliance with the following conditions: 493.1208 Condition: General Immunology 493.1210 Condition: Routine Chemistry
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instructions for use, quality assessment documents, quality control records, manufacturer's quality control package inserts, calibration records, lack of records, environmental records, laboratory procedures, patient test records, and staff interviews, the laboratory failed to ensure the laboratory maintained patient specimen storage and stability according to the manufacturer's requirements (Refer to D5401), failed to ensure procedures for use were approved by the laboratory director (Refer to D5407), failed to define temperature ranges for quality control storage (Refer to D5413), failed to ensure quality controls were not used past the manufacturer expiration date (Refer to D5417), failed to perform required calibrations for reagent lot changes (Refer to D5437), failed to follow the procedure to establish ranges for unassayed controls (Refer to D5441 Citation two), and failed to follow the laboratory procedure to monitor quality controls (Refer to D5791).
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the

	laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instructions for use, quality assessment documents, quality control records, manufacturer's quality control package inserts, calibration records, lack of records, environmental records, laboratory procedures, patient test records, and staff interviews, the laboratory failed to ensure the laboratory director had approved procedures for use (Refer to D5407), failed to define temperature ranges for quality control storage (Refer to D5413), failed to perform required calibrations for reagent lot changes (Refer to D5437), failed to ensure testing personnel performed quality control before patient testing (Refer to D5441 Citation one), failed to follow the laboratory procedure to print and review quality controls for the (Refer to D5791), and failed to have an effective quality assessment process to identify quality control standard deviations that exceeded the manufacturer standard deviations (Refer to D5793) for the Ortho Vitros 5600 instrument.
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 observation of the laboratory, review of the manufacturer's instructions for use, quality assessment documents, and staff interviews, the laboratory failed to follow the procedure for specimen storage when testing was delayed for the antibody to hepatitis C virus (aHCV), hepatitis B surface antigen (HBsAg), and antibody to hepatitis B surface antigen (aHBS) analytes. The findings include: 1. Observation of the laboratory on 04/15/2024 at 8:45 am revealed an Ortho Vitros 5600 (Serial #J56004335) used for patient testing. During the observation, testing person one stated that patient samples for Hepatitis testing were processed and stored in the refrigerator and only tested on Thursdays. 2. A review of the manufacturer's instructions used as part of the laboratory's procedures revealed the following statement for the aHCV, HBsAg, and aHBs analytes: "If the test will not be completed within 48 hours or for shipment, freeze samples at or below -20 degrees Celsius (C)." 3. A review of the laboratory's quality assessment document dated 01/08/2024 revealed that the laboratory would only perform Hepatitis testing once a week on Thursdays. 4. An interview with the laboratory liaison on 04/15/2024 at 3:00 pm confirmed that the laboratory used the manufacturer's instructions as part of its procedure manual and failed to follow the established procedure for preserving and storing samples for Hepatitis testing in 2024.
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 observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory failed to ensure the procedure for the Sysmex XN 330 CBC instrument included step-by-step instructions and actions to take when results were flagged by the instrument. The findings include: 1. Observation of the laboratory on 04/15/2024 at 8:45 am revealed a Sysmex XN 330 (Serial 12846) used for patient CBC testing. 2. A review of the laboratory procedure for the Sysmex XN 330 revealed the procedure lacked step-by-step performance instructions and actions to take when results are flagged by the instrument. 3. Interview on 04/15/2024 at 3:00 pm with the laboratory liaison confirmed the survey findings.
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 observation of the laboratory, review of the laboratory procedures, and staff interviews, the laboratory failed to ensure the manufacturer instructions for use that were used as part of the laboratory's procedures for the Ortho Vitros 5600 instrument were signed and dated by the laboratory director. The findings include: 1. Observation of the laboratory on 04/15/2024 at 8:45 am revealed the Ortho Vitros 5600 (Serial #J560046635) used for patient testing. 2. A request for the laboratory's procedure manual for the Ortho Vitros 5600 revealed the laboratory used the manufacturer's instructions as part of its procedures. The manufacturer's method instructions for use were not signed or dated by the laboratory director. 3. Interview on 04/15/2024 at 3:00 pm with the laboratory liaison confirmed the survey 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: Based on observation of the laboratory, review of manufacturer package inserts, laboratory temperature logs, and staff interviews, the laboratory failed to define temperature ranges that were consistent with manufacturer requirements for frozen storage of BioRad quality control materials used on the Vitros 5600 instrument. This resulted in the storage of BioRad QC material that was not consistent with the manufacturer's requirements. The findings include: 1. Observation of the laboratory on 04/15/2024 at 9:15 am revealed a freezer in the research department used to store the BioRad quality controls (Liquichek Immunoassay Plus, Liquichek Immunology, Liquid Assayed Multiqual, Liquichek Specialty Immunoassay) for the Ortho Vitros 5600 instrument used for performing chemistry and immunoassay testing. 2. A review of the manufacturer's package inserts for all BioRad QC revealed the storage requirements were -20C to -70C when stored frozen. 3. A review of the laboratory's temperature logs revealed the following: The freezer temperature log did not include an acceptable temperature range. Six of the six months reviewed had recorded temperatures that were outside the manufacturer's acceptable range (eight of nine days in November 2023, seventeen of seventeen days in December 2023, nineteen of nineteen days in January 2024, twenty of twenty days in February 2024, twenty-one of twenty-one days in March 2024, and eleven of eleven days in April 2024). 4. Interview on 04/15/2024 at 3:00 pm with the laboratory liaison confirmed the laboratory failed to define acceptable temperature ranges for the freezer used for storage of BioRad QC material in 2023 and 2024.
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 of the laboratory, review of the quality control (QC) records, patient test records, and staff interviews, the laboratory failed to ensure the QC used for the c-reactive protein (CRP), complement (C3 and C4), and rheumatoid factor (RF) was not used past the expiration date in 2024. The findings include: 1. Observation of the laboratory on 04/15/2024 at 9:15 am revealed an Ortho Vitros 5600 (Serial #J56004335) used for patient testing. 2. A review of the laboratory's QC records for March 2024 revealed three levels of Liquichek Immunology Control used for CRP, C3, C4, and RF that were expired as follows: Immunology L1 (BRIML1) lot 58700 expiration 02/29/2024 Immunology L2 (BRIML2) lot 69002 expiration 02/29 /2024 Immunology L3 (BRIML3) lot 69003 expiration 02/29/2024 3. A review of patient test records revealed patient 38124 had a CRP reported on 03/26/2024. 4. The survey findings were confirmed in a phone interview on 04/24/2024 at 4:08 pm and an electronic interview on 04/26/2024 at 8:13 am.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

	CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instructions for use, lack of records, and staff interview, the laboratory failed to perform required calibration following reagent lot number changes on the Ortho Vitros 5600 instrument in 2023 and 2024. The findings include: 1. Observation of the laboratory on 04/15/2024 at 8:45 am revealed an Ortho Vitros 5600 (Serial # J56004335) used for patient testing. Reagents used included sodium (Na), potassium (K), chloride (Cl), c-reactive protein (CRP), electrolyte reference fluid (ERF), and immuno-wash fluid (IWF). During observation, testing person one described the calibration procedures for the Ortho Vitros 5600 and stated that testing personnel did not perform calibrations for ERF or IWF lot changes. 2. A review of the manufacturer's instructions for use for the ERF and IWF reagents revealed that the Na, K, and Cl analytes required calibration following a lot change of ERF, and the CRP analyte required calibration following a lot change of IWF. 3. Documentation for calibration of analytes following ERF and IWF lot changes was not available on the survey date (04/15/2024). 4. Interview on 04/15/2024 at 3:00 pm with the laboratory liaison confirmed the survey findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: CITATION ONE: Based on review of the laboratory's procedure, quality control (QC) records, final patient test report, and staff interviews, the laboratory failed to follow its procedure when the QC for the sodium (Na) analyte was not performed prior to patient testing in 2023 (one of four patients reviewed). 1. A review of the laboratory's procedure titled " QUALITY ASSESSMENT PROGRAM OUTLINE PHYSICAN'S OFFICE CONSULTING" section II. "ANALYTIC: Testing QUALITY CONTROL"

	revealed at least two levels of QC would be performed prior to patient testing. 2. A review of the laboratory's daily QC records for 02/15/2023 revealed Sample ID BRMQL1, BRMQL2, and BRMQL3 used for BioRad Liquid Assayed Multiqual controls (three levels) with an expiration date of 07/31/2024. The QC file did not contain the Na anlayte. 3. A review of patient 17695 revealed the laboratory reported the Na analyte on 02/15/2023 at 9:30 am. 4. Phone interviews with the laboratory liaison on 04/24/2024 at 4:08 pm and 04/29/2024 at 1:45 pm confirmed the survey findings. CITATION TWO: Based on a review of the laboratory procedure, laboratory's quality control (QC) records, manufacturer package inserts, and staff interview, the laboratory failed to follow the procedure for establishing the mean and standard deviation for unassayed QC used on the Vitros 5600 instrument for the antibody Hepatitis C virus (aHCV) and Hepatitis B surface antigen (HBsAg) analytes in 2023. The findings include: 1. A review of the laboratory procedure titled "Procedure for Quality Assessment of testing on the Vitos Analyzer" section "PROCEDUR FOR LOT CHANGE" revealed the laboratory would establish ranges for controls that did not have ranges provided by the manufacturer. 2. A review of the laboratory's August 2023 QC records revealed the mean and standard deviation were not defined for Viroclear (lot 107800) for the aHCV and HBsAg analytes, or for the Virotrol I (lot 118100) for the aHCV analyte. 3. A review of the manufacturer package inserts for the Viroclear and Virotrol QC revealed that the manufacturer did not provide ranges for use. 4. Interview on 04/24/2024 at 4:08 pm and electronic interview on 04/26/2024 at 8:00 am confirmed the laboratory failed to follow the procedure for establishing ranges for unassayed QC in 2023.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory and staff interviews, the laboratory failed to perform quality control (QC) after reagent change on the Sysmex XN 330 complete blood count (CBC) instrument. The findings include: 1. Observation of the laboratory on 04/15/2024 at 8:45 am revealed the Sysmex XN 330 (Serial # 12846) instrument used for patient CBC testing. During the observation, the testing person described when the laboratory personnel performed QC. She stated that testing personnel performed QC each morning before patient testing and did not perform QC following reagent changes. 2. An interview with the laboratory liaison on 04/15/2024 at 3:00 pm confirmed the survey 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 a review of laboratory procedures, a lack of records, and a staff interview, the laboratory failed to follow the procedures for printing and reviewing quality control (QC) for the Vitros 5600 instrument in 2022, 2023, or 2024 (five of five months reviewed). The findings include: 1. A review of the laboratory's procedure titled "Quality Control Policy and Troubleshooting" revealed the cumulative QC reports would be printed monthly and saved for technical consultant review. 2. A review of the laboratory's procedure titled "Quality Assessment Program Outline" revealed that the technical consultant would perform quarterly visits. 3. A review of the laboratory's QC records revealed cumulative QC reports for the Vitros 5600 for five of five months reviewed (November 2022, February 2023, August 2023, January 2024, and March 2024) had not been printed by the testing personnel for documented review by the technical consultant. 4. Interview on 04/15/2024 at 3:00 pm with the laboratory liaison confirmed the laboratory did not follow the procedures for printing and reviewing monthly cumulative QC for the Ortho Vitros 5600 instrument.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure, manufacturer package inserts, quality control (QC) records, quality assessment records, and staff interviews, the laboratory's quality assessment process did not identify the use of laboratory standard deviations (SD) that exceeded the manufacturer SD for analytes performed on the Vitros 5600 analyzer in 2024. The findings include: 1. A review of the laboratory's procedure for management of QC ranges revealed the laboratory would perform parallel testing with the current and new lots of QC and then establish a mean and two SD range from that data. The technical consultant would review prior to use and monthly thereafter. 2. A review of the manufacturer package inserts revealed the ranges provided by the manufacturer represented a three SD range. 2. A review of the laboratory's cumulative QC records received on 04/23/2024 and 04/24/2024 revealed the following analytes with a One SD that exceeded the manufacturer's One SD resulting in the use of QC limits that were outside the manufacturer package insert ranges as follows: Biorad Liquid Assayed Multiqual lot 45931, 45932, and 45933 Alkaline Phosphatase (Alk. Phos) March 2024 BioRad Range (45931) 29.6-45.1/ One SD-2.59 Laboratory Range 35.86-47.74/ One SD-2.97 Blood Urea Nitrogen (BUN) March 2024 BioRad Range (45933) 58.1-67.9/ One SD-1.63 Laboratory Range 56.7-75.9/ One SD-4.8 Sodium (Na) March 2024 BioRad Range (45933) 156-172/ One SD-2.67 Laboratory Range 149-181/ One SD-8 Potassium (K) March 2024 BioRad Range (45931) 2.39-2.65/ One SD- 0.04 Laboratory Range 2.46-2.66/ One SD- 0.05 BioRad Range (45933) 7.56-8.29/ One SD- 0.122 Laboratory Range 7.316-7.904/ One SD-0.147 BioRad Liquichek Immunoassay Plus Control lot 85321, 85322, 85333 Thyroid Stimulating Hormone (TSH) February 2024 BioRad Range (85321) .503-.732/ One SD- 0.038 Laboratory Range .463-.759/ One SD- 0.074 BioRad Range (85322) 3.99-5.41/ One

	SD- 0.237 Laboratory Range 3.824-5.756/ One SD- 0.483 BioRad Range (85323) 21.8-29.3/ One SD- 1.25 Laboratory Range 20.84-30.96/ One SD-2.53 Vitamin B-12 (B12) February 2024 BioRad Range (85321) 156-305/ One SD- 24.8 Laboratory Range 156-356/ One SD- 50.0 BioRad Range (85322) 388-638/ One SD- 41.7 Laboratory Range 441-893/ One SD- 113.0 BioRad Range (85323) 556-943/ One SD- 64.5 Laboratory Range 678.8-1125.2/ One SD- 111.6 3. A review of the laboratory's quality assessment records for 2024 (January 2024 and March 2024) revealed no documented corrective action for the laboratory's use of SDs that exceeded the manufacturer's SDs. 4. A telephone interview with the laboratory liaison on 04/24 /2024 at 4:08 pm, an electronic interview on 04/26/2024 at 8:00 am, and a phone interview on 04/29/2024 at 1:45 pm confirmed the survey findings.