Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0990236	01/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Rheumatism Center, Pa	1107 East Sara Swamy Drive, Sherman, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.803 Successful Participation PT 493.1403 Laboratory Director, (moderate complexity). Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy

	to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records from 2021, and confirmed in staff interview, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analyte Hematocrit, for two of three consecutive testing events in 2021 , resulting in an unsuccessful PT performance for Hematocrit. Refer to 2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records from 2021, and confirmed in staff interview, it was determined the laboratory failed to achieve satisfactory performance (at least 80%) in the specialty of hematology for the analyte Hematocrit, for two of three consecutive testing events in 2021 , resulting in an unsuccessful PT performance for Hematocrit. Findings included: 1. Review of American Proficiency Institute (API) proficiency testing records from 2021, revealed the following: "2021 API 2nd event Hematocrit - 0% 2021 API 3rd Event Hematocrit- 40 % Unsuccessful" 2. A proficiency desk review of the API proficiency testing records from 2021 confirmed that the laboratory received the following scores for the analyte RBC for two of three testing events in 2021. "2021 API 2nd event Hematocrit - 0% 2021 API 3rd Event Hematocrit- 40 % Unsuccessful" Two out of three unsatisfactory scores of the same analyte result in unsuccessful PT performance. 3. During an interview with the laboratory director in the facility office, on 01/19/2022 at 11:00 a.m., the laboratory director stated the analyzer was not operational during the 2nd API Event of 2021, but could not supply documentation that API was notified. This confirmed the above findings,
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of competency assessment, based on the position responsibilities, for 1 of 2 testing personnel (TP-1) in 2020 and 2021. Findings Included: 1. Review of laboratory policy titled, "Personnel Competency Assessment Policies"(Reviewed by Laboratory Director (Dr.Tummala)

	2021) revealed the following: "Dr.Tummala will complete a competency evaluation in six months the first year and once a year thereafter for all employees involved with testing and reporting results." 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed two Testing Persons (TP-1 and TC-2) for moderate complexity testing. 3. Review of laboratory personnel records from 2020 and 2021 revealed there was no documented competency assessment for the duties performed as a testing person for TP-1. 4. During an interview on 01/19/2022 at 11:27 am in the facility office, the Laboratory Director was asked to provide documentation of TP-1 competency assessment for 2020 and 2021. No documentation was provided. This confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) 2020 and 2021 records, and staff interview, it was revealed the laboratory failed to have documentation of laboratory director review for 2 of 5 Hematology proficiency testing events. Findings included: 1. Review of the laboratory's API proficiency testing 2020 records (Hematology 1st, 2nd, and 3 Events) and 2021 records (Hematology 1st and 2nd Events) revealed the laboratory director failed to document review of the following proficiency testing events: 2020 API Hematology 1st Event 2020 API Hematology 3rd Event 2. During an interview on 01/19/2022 at 11:30 am in the facility office, the Laboratory Director, after review of the proficiency testing records, confirmed the above findings.
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 laboratory policy, laboratory records and staff interview, the laboratory failed to follow their own written policy for hematology quality control (QC) lot rollovers for 1 of 1 rollover in 2021. Findings Included: 1. Review of laboratory policy titled, "Maintenance, Calibration etc."(Reviewed by Laboratory Director (Dr.Tummala) 2021) revealed the following: "When there is a change in lot numbers for controls the previous and new controls will be run together for 5 days before the cross over is complete." 2. Review of laboratory records revealed the previous hematology QC information and current: Previous: Lot Number: 22107-0K Lot Expiration: November 23, 2021 Current: Lot Number: 22109-3K Lot Expiration: February 8, 2022 Further review of laboratory records revealed the laboratory did not perform a lot cross over for the new hematology QC lot. 3. During an interview on 01

	/19/2022 at 11:27 am in the facility office, the Laboratory Director was asked to provide documentation of hematology QC lot cross over. No documentation was provided. This confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory's policy, manufacturer's instructions, patient test records, and quality control records, the laboratory director failed provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure laboratory overall operations and test systems were in compliance with regulations. Refer to D2016.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: