Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1010383	09/14/2020
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
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for the automated white blood cell (WBC) differential analyte in 2019 event two, 2020 event one, and 2020 event two, resulting in the second unsuccessful PT occurrence for the automated WBC differential analyte. (Refer to D2130)
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 desk review of the Centers for Medicare and Medicaid Services Casper Report 155 (CMS 155) and the laboratory's 2019 and 2020 proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory performance in three out of four PT events for the white blood cell (WBC) differential, resulting in the second unsuccessful occurrence for the WBC differential. The findings include: 1) Review of the CMS 155 revealed the following unsatisfactory WBC differential scores: 2019 event two = 73% 2020 event one = 0% 2020 event two = 73% 2) Review of the laboratory's 2019 event two PT evaluation report revealed unacceptable scores for WBC differential as follows: Granulocytes %-sample number HEM-06, Lymphocytes %-sample number HEM-07, Monocytes/Mids %-sample numbers HEM-06 and HEM-07, resulting in an overall score of 73% for the WBC differential. 3) Review of the laboratory's 2020 event one PT evaluation report revealed a score of 0% for the WBC differential for 'Failure to Participate.' 4) Review of the laboratory's 2020 event two PT evaluation report revealed unacceptable scores for WBC differential as follows: Granulocytes %-sample number HEM-06, Monocytes/Mids %-sample numbers HEM-06, HEM-08 and HEM-09, resulting in an overall score of 73% for the WBC differential, and the second unsuccessful PT occurrence.
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: The laboratory director failed to maintain compliance with successful white blood cell (WBC) differential analyte proficiency testing performance and failed to follow the approved allegation of compliance (AOC) for the WBC differential analyte, resulting in the second unsuccessful PT occurrence for the WBC differential analyte. (Refer to D6004)
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: Based on a desk review of the Centers for Medicare and Medicaid Services Casper

	report 155 (CMS 155), the laboratory's 2019 and 2020 proficiency testing (PT) evaluation reports and the laboratory's Allegation of compliance (AOC), the laboratory director failed to follow the approved May 12, 2020 AOC for the WBC differential analyte, resulting in the second unsuccessful PT occurrence for the WBC differential analyte. The findings include: 1) Review of the CMS 155 report and the laboratory's PT evaluation report for 2019 event two, 2020 event one and two revealed the WBC differential scores as follows: 2019 event two = 73%, 2020 event one = 0%, 2020 event two = 73%. 2) Review of the laboratory's AOC dated May 12, 2020, in reference to a previous failure to maintain compliance with successful PT, signed by the laboratory director on May 14, 2020 revealed the following statement: "To prevent this from reoccurring the TP were trained on sample handling, mixing and correct procedure for submitting results online." "The technical consultant will review this clinic quarterly to be sure this does not reoccur."