Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931266	05/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Centers Of Texas	3600 Gaston Ave Suite 100, Dallas, 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
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: Revisit 05/13/2019 Based on review of manufacturer's instructions, laboratory policies, quality control and patient data, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for preanalytic phase of testing. Refer to D6007. 2. The laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. Refer to D6020. 3. The laboratory director failed to ensure the laboratory had documentation that evaluated patient test results in an unacceptable system run and after performing test system adjustments for chemistry QC (quality control). Refer to D6022.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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. (E) The laboratory director must-- (E)(1) 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: Revisit 05/13/2019 Based on review of manufacturer's instructions, laboratory's policy, and patient data, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for preanalytic phase of testing, as evidenced by: 1. The laboratory failed to follow manufacturer's for establishing a stability for patient complete blood count (CBC) specimens prior to testing on the Sysmex KX-21N analyzer. Refer to D5311-II 2. The laboratory failed to ensure synovial fluid specimens collected included all information according to the lab policy. Refer to D5311-III 3. The laboratory failed to have a system in place to ensure that specimens were collected, processed, and stored according to manufacturer's instructions for specimens submitted to the laboratory for testing from an outside clinic. Refer to D5317