Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2161279	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Regional Arthritis & Rheumatology Associates	2500 Highland Road, Suite 101, Hermitage, PA	

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
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 review of the laboratory procedure manual and interview with the Technical Supervisor on 06/12/2019, the Laboratory Director failed to approve the laboratory procedures in use, from 05/31/2019 through 06/11/2019. Findings include: 1. Review of the laboratory procedures in use at the time of the survey (13:30 June 12, 2019), revealed the Laboratory Director failed to document signature and date of approval prior to use. 2. 35 patients were tested for Antibody Profile on the BioTek EL 800 plate reader, from 05/31/2019 through 06/11/2019 . 3. During the survey (14:00 June 12, 2019), the Technical Supervisor confirmed the above findings.