Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0856368	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Rheumotology Associates	822 Pine Street, Philadelphia, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, review of peer review records, interview with the Laboratory director (LD) and Phlebotomist, the LD failed to ensure that 2 of 4 Testing personnel (TP) performed in the verification of accuracy of the synovial fluid examination in 2018. Findings Include: 1. On the day of survey, 03/12 /2019, the LD could not provide a procedure manual for the peer review performed on the synovial fluid examinations from 2017 to March, 12, 2019. 2. TP#1 (the LD) and TP #2 did not perform in peer review in 2018. 3. The LD confirmed the findings above on 3/12/2019 around 10:00 am. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, interview of the laboratory director (LD) and phlebotomist, the LD failed to ensure that the quality control (QC) programs were established and maintained for synovial fluid examination performed from May 2017 to the date of survey. Findings Include: 1. On the date of survey, 03/12/2019, the LD could not provide documentation of QC procedures performed, each day of patient testing for

	the synovial fluid examination from May 2017 to 03/12/2019. 2. From May 2017 to December 2017, 18 synovial fluid examinations were performed. 3. In 2018 (January 2018 to December 2018), 31 synovial fluid examinations were performed. 4. From January 2019 to February 12, 2019, 9 synovial fluid examinations were performed. 5. The LD confirmed on 03/12/2019 around 11:00 am, that quality QC was not performed.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manual, interview with the Labortaory director (LD) and Phlebotomist, the LD failed to ensure a quality assessment (QA) programs was established and to assure the quality of laboratory services provided from 2017 to the day of survey. Findings Include: 1. On the date of survey, 03/12/2019, the LD could not provide a QA procedure or documentation of periodic evaluation of the laboratory, that assess its preanalytical, analytical, and postanalytical processes from May 22, 2017 to March 12th, 2019. 2. From May 2017 to December 2017, 18 synovial fluid examinations were performed. 3. In 2018 (January 2018 to December 2018), 31 synovial fluid examinations were performed. 4. From January 2019 to February 12, 2019, 9 synovial fluid examinations were performed. 5. The LD confirmed on 03/12/2019 around 10:45 that a QA policy does not exist.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, personnel competency assessment records, interview with the Laboratory director (LD) and Phlebotomist, the LD failed to ensure the competency of 3 of 3 testing personnel (TP) performing synovial fluid examination was assessed and document from 2017 to the date of survey. Findings Include: 1. On the day of survey, 03/12/2019, the LD could not provide documentation of competency assessment performed on 3 of 3 synovial fluid TP in 2017 and 2018. 2. The laboratory could not provide a competency assessment procedure for the synovial fluid examination TP. 3. From May 2017 to December 2017, 18 synovial fluid examinations were performed. 4. In 2018 (January 2018 to December 2018), 31 synovial fluid examinations were performed. 5. From January 2019 to February 12, 2019, 9 synovial fluid examinations were performed. 6. The LD confirmed the findings above on 3/12/2019 around 9:45 am **** THIS IS A REPEAT DEFICIENCY****