Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0202529	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis Group Pc, Laboratory	7908 Bustleton Ave, 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
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 records, Competency Policy for assessment of Professional Medical Staff procedure, and interview with the Laboratory Manager (LM), the laboratory failed to follow their Competency Assessment (CA) procedure to assess 1 of 1 Clinical Consultants (CC) for their supervisory responsibilities and 1 of 2 Testing Personnel (TP) for Synovial fluid crystal microscopic examinations in 2020 and 2021. Findings Include: 1. The Competency Policy for Assessment of Professional Staff states: "1. Direct Observation of routine test Performance. 2. Monitoring The recording and Reporting of test reports 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. 6. Assessment of problem-solving skills. - Bruce I. Hoffman will be assessed annually for their supervisory competence in addition to laboratory testing competence." 2. On the day of survey, 12/16/2021 at 10:00 a.m. The laboratory could not provide competency assessment records for 1 of 1 CC (CMS 209 Personnel #2) for their supervisory responsibilities in 2020 and 2021. 3. Review of the competency assessment records in 2020 and 2021 for 1 of 2 TP revealed the laboratory did not follow their policy to evaluate points 2, 3, 5, and 6 for Synovial fluid crystal microscopic examinations. 4. The LM confirmed the findings above on 12/16/2021 at 12:45 p.m.

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 lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to verify twice annually the accuracy of Synovial Fluid Crystal microscopic examination performed from 12/16/2019 through the date of survey. Findings include: 1. On the day of survey, 12/16/2021 at 10:30 a.m., the laboratory could not provide documentation of verification of accuracy for Synovial Fluid Crystal microscopic examination performed from 12/16/2019 through the date of the survey. 2. The laboratory performed 300 Synovial Fluid Crystal microscopic examination in 2020 and 2021 3. The LM confirmed the findings above on 12/16 /2021 at 12:40 p.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to establish a quality assurance policy from 12/16/2019 to the date of survey. Findings Include: 1. On the day of survey, 12/16/2021 at 11:45 a.m, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs form 12/16/2019 to the date of survey. 2. The laboratory could not provide documentation for all quality assessment activities in 2020 and 2021 3. The LM confirmed the findings above on 12/16/2021 at 12:45 p.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to document quality control (QC) procedures for synovial fluid crystal microscopic examinations from 12/16/2021 to the day of survey. Findings Include: 1. On the day of survey, 12/16/2021 at 11:00 a.m., the laboratory could not provide QC performed for Synovial Fluid Crystal Examinations from 12/16/2019 to 12 /16/2021. 2. The laboratory performed 300 Synovial fluid crystal examinations in

	2020 and 2021. 3. The LM confirmed the findings above on 12/16/2021 at 12:45 p.m. *Repeated deficiency.