

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202529	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Arthritis Group Pc, Laboratory	Street Address, City, State 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory manager, the laboratory failed to establish a written policy to assess 1 of 1 testing personnel's competency for synovial fluid crystal examination from 2019 to the date of survey. Findings Include: 1. On the day of survey, 02/05/2020, the laboratory could not provide a written policy to assess 1 of 1 testing personnel's competency for synovial fluid crystal examination. 2. The laboratory manager confirmed the finding on 02/05/2020 around 9:15 am.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory manager, the laboratory failed to establish a written or electronic requests for patient testing for synovial fluid crystal examinations from 10/21/2019 to the day of survey. Findings Include: 1. On the day of survey, 02/05/2020, the laboratory could not provide a</p>

	<p>written or electronic test request mechanism for synovial fluid crystal examinations from 10/21/2019 to 02/05/2020. 2. The laboratory manager confirmed the finding on 02/05/2020 around 9:30 am.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory manager, the laboratory failed to establish a written procedure manual for synovial fluid crystal examination performed from 10/21/2019 to 02/05/2020. Findings Include: 1. On the day of survey, 02/05/2020, the laboratory could not provide a written procedure manual for synovial fluid crystal examination performed from 10/21/2019 to 02/05/2020. 2. The laboratory manager confirmed the finding on 02/05/2020 around 9:45 am.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of records, and interview with the laboratory manager, the laboratory failed to document quality control (QC) procedures for synovial fluid crystal examinations performed from 10/21/2019 to the day of survey. Findings Include: 1. On the day of survey, 02/05/2020, the laboratory could not provide QC performed for synovial fluid crystal examinations performed from 10/21/2019 to 02/05/2020. 2. The laboratory manager confirmed the finding above on 02/05/2020 around 10:00 am.</p>