Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 13D0522197	**(X3) Date Survey Completed** 04/03/2019
Name of Provider or Supplier Coeur D'Alene Arthritis Clinic	**Street Address, City, State** 950 W Ironwood Dr, Coeur D'Alene, ID	
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**
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to have a written procedure for sulfosalicylic acid protein testing in urine specimens that include all elements of the pre-analytic, analytic, and post-analytic activities since the last survey on September 5, 2017. Findings: 1. A review of the laboratory's procedure manual revealed the laboratory failed to establish a written procedure for sulfosalicylic acid confirmatory protein testing in urine samples since the last survey. 2. The laboratory performed approximately 40 sulfosalicylic acid tests since the last survey. 3. An interview on April 3, 2019 at 11:15 AM, with the laboratory supervisor, confirmed the laboratory failed to write a procedure for sulfosalicylic acid tests.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory failed to perform quality control at least once each day of patient testing or establish an Individualized Quality Control Plan (IQCP) since the last survey on September 5, 2017. Findings: 1. A review of the laboratory records revealed the laboratory failed to perform quality control at least once each day of patient testing or establish an IQCP since the last survey. 2. The laboratory performed approximately 40 sulfosalicylic acid tests since the last survey. 3. An interview on April 3, 2019 at 11: 25 AM, with the laboratory supervisor, confirmed the laboratory failed to perform quality control for sulfosalicylic acid.