

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0926681	(X3) Date Survey Completed 10/06/2023
Name of Provider or Supplier Northshore University Healthsystems	Street Address, City, State 2150 Pfingsten Rd, Ste 3000, Glenview, IL	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to outline all components of the testing procedures for one of one hematology testing system (synovial fluid analysis) in 2021, 2022 and 2023. Findings include: 1. Review of the "NorthShore University HealthSystem Division of Rheumatology - Analysis of Synovial Fluid For Crystals" procedures manual revealed the lack of documentation to meet the procedure manual</p>

requirements (Standard 493.1251) for synovial fluid analysis for crystals in 2021, 2022, and 2023. a. Requirements for patient preparation and specimen collection. 2. On 10/06/2023 at 10:00 a.m., the LM confirmed the above findings.