Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0868396	03/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
North Suburban Pediatrics Sc	2530 Ridge Avenue, Evanston, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory testing records, lack of documentation and interview with testing personnel (TP) #2; the laboratory failed to retain complete blood count quality control (QC) testing records for one of five days of patient testing reviewed. Findings include: 1. A review of quality control testing records revealed the laboratory failed to have complete blood count QC testing records for the Sysmex XP-300 analyzer used for patient testing on 11/15/2024. 2. Interview with TP #2 on 03/24/2026, at 08:15 am, confirmed the laboratory did not have the QC records for 11/15/2024. The paper records had been destroyed after having liquid spilled on them. TP #2 was unable to access the QC data from that time frame on the analyzer. 3. Review of patient testing records revealed that one patient had complete blood count testing completed on 11/15/2024. Patient Record Number: 46281
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to outline all required components for one of one procedure for complete blood count hematology testing on the Sysmex XP- 300 analyzer. Findings include: 1. Review of laboratory policies and procedures revealed the procedure for complete blood count hematology testing on the Sysmex XP -300 analyzer, failed to outline the following required components of a test procedure: A. 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. B. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. C. Calibration and calibration verification procedures. D. The reportable range for test results for the test system as established or verified in 493.1253. E. Control procedures. F. Limitations in the test methodology, including interfering substances. G. Imminently life-threatening test results, or panic or alert values. 2. Interview with TP #2 on 03/23/2026, at 03:15 pm, confirmed the laboratory failed to outline all required components of the test procedure for complete blood count testing on the Sysmex XP-300 analyzer.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory's policy and procedure manual, testing personnel competency records, and interview with testing personnel (TP) #2; the laboratory failed to have competency assessments performed by a qualified technical consultant (TC) for one of one new TP performing moderate-complexity complete blood count hematology testing semiannually during the first year the TP tested patient specimens. Findings include: 1. Review of laboratory records revealed a document titled "Laboratory director, Technical consultant and Clinical consultant responsibilities" which stated, "The lab director is also responsible for clinical and technical supervision, and renders opinions concerning the diagnosis, treatment, and management of patient care, and is responsible for technical and scientific oversight, and will be available when needed to provide consultation either on-site, by telephone,

	or electronically". 2. Review of the laboratory policy titled, "Employee Responsibilities at North Suburban Pediatrics", stated the following, "TP #2: Lab managing. CBC controls when opening the lab in the morning or when scheduled to work on the weekend and to make sure they are in range before doing patient samples, temperature reporting, and at the end of the day shutting down CBC machine. Review control logs for TC, Mono, Rapid Flue, Cholesterol, Glucose, and illumigene Strep A. Review at the end of each month the following logs: in-house, out-going, TC /illumigene and lead. Also at the end of the month chart audits that would be done on either the in-house or out-going. Review on PT testing and to follow-up on any failed or unacceptable results. Have lab review on staff and new staff. This MA is qualified and responsible to do all lab procedures." 3. Review of testing personnel competency records revealed one of one new TP performing complete blood count hematology testing failed to have competency assessments performed by a qualified technical consultant in their first year of testing. New testing personnel: TP #9 Individual performing competency: TP #2 Dates of evaluation: 9/30/2025 & 12/10/2025 4. Interview with TP #2 on 03/23/2026, at 01:00 pm, confirmed the laboratory failed to have competency assessments performed by a qualified technical consultant in their first year of testing for one of one new TP performing moderate complexity complete blood count testing in the specialty of hematology.