Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0719487	(X3) Date Survey Completed 09/27/2024
Name of Provider or Supplier North Hills Surgery Center	**Street Address, City, State** 3271 North Wimberly Drive, Ste 1, Fayetteville, AR	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Review of the proficiency test attestation records for five events in 2023 and 2024, lack of documentation, and interviews with laboratory staff, determined that required signatures to attest to the routine integration of proficiency test samples in the patient workload were not present on one of the five events reviewed. Survey findings follow: A) Review of the attestation forms for American Proficiency Testing Institue (API) Chemistry Core 2023 and 2024 revealed that no attestation form for the API Chemistry Core 2024 2nd event was presented. B) In an interview, at 11:40 a.m. on 9/27/24, the laboratory staff member (# 3 as listed on the form CMS-209) confirmed the attestation form identified above was not present and could not be located.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Observation, review of temperature records, lack of documentation and interview demonstrated that the laboratory failed to monitor the temperature on each day of operation in one of one room in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 9/27/24 at 10:34 a.m., the surveyor observed one rooms (Pre-Op) containing laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were recorded for the Pre-Op room for the period of April 2023 to the date of the survey. C) During a tour of the laboratory on 9/27/24 at 10:40 a.m. the surveyor observed 2 boxes of Medline HCg Combo Pregnancy Tests, lot # 0000841323, expiration date 2026-08-03 with a storage temperature requirement of 36 degrees to 86 degrees Fahrenheit (F) and one box of I-Stat CHEM 8+ test cartridges , lot # 24211A, expiration date 10/10/24, with a temperature storage requirement of 18 degrees Centigrade (C) to 30 degrees C. in the Pre-Op area. D) Upon request, the laboratory could not present the temperature records for the Pre-Op room in which the supplies identified above were stored. E) In an interview on 9/27 /24 at 10:37 a.m., the laboratory staff member (# 3 on form CMS 209) confirmed that temperature records for the Pre-Op were not recorded since April 2023.
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: Review of the quality control (QC) records for the moderately complex serum HCg testing, the manuafacturer's package insert for moderately complex Medline HCg Combo+ testing system, the laboratory's Individualized Quality Control Plan (IQCP) for serum HCg testing, testing personnel competency determination records, and interview with laboratory staff, determined that the laboratory failed to follow manufacturer's test instructions and the laboratory's IQCP for quality control of serum HCg determinations. Findings follow: A) Review of the manufacturer's package insert for the Medline Combo HCg+ serum HCg test revealed that external QC is to be performed with each new lot or shipment of the tests, at least monthly, and with each new operator. B) Review of the laboratory's IQCP for serum HCg testing revealed that external QC is to be performed with each new lot and shipment, at least monthly and with each new operator. C) Review of the personnel records for the testing personnel (# 11 on the form CMS 209) revealed that the employee was hired in January 2024. D) Review of external QC records for serum HCg testing using the Medline HCg Combo+ system revealed that no external QC was recorded for testing personnel (# 11 on from CMS 209). E) In an interview on 9/27/24 at 10:05, the laboratory staff member (# 3 on form CMS 209) , confirmed that there is no documentation of performing external QC testing for the testing personnel identified above and the testing personnel has performed serum HCg testing.