Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0719487	02/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Hills Surgery Center	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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, and I-STAT Quality Control Reports for 2022, and through interviews with laboratory staff, it was determined the laboratory failed to monitor, over time, the accuracy of the hematology test results. Survey findings include: A. A review of the general policy and procedure manual revealed a quality control policy stating that acceptable quality control ranges for each control will be written on each I-STAT Quality Control Record sheet. B. A review of I-STAT Quality Control Reports for 2022 and Eurotrol Package inserts revealed incorrect Quality control ranges were used from 3/4/22 until 5/10/22, without corrective actions. During the specified time period the reference range of Eutrotol Level 1 was listed as 116-124 for Sodium (Na), 2.3-3.1 for Potassium (K), 74-84 for Chloride (Cl), 51-65 for Blood Urea Nitrogen (BUN), 262-346 for Glucose (Glu), and 14-20 for Hematocrit (HCT). The correct ranges for Eutorol Level 1 were 115-123 for Na, 2.3-3.1 for K, 75-85 for Cl, 53-67 for BUN, 271-355 for Glu, and 13-19 for HCT. During the specified time period the reference range of Eutrotol Level 2 was listed as 133-141 for Na, 3.2-4.0 for K, 94-104 for Cl, 9-15 for BUN, 130-158 for Glu, and 32-

	38 for HCT. The correct ranges for Eutorol Level 2 were 131-139 for Na, 3.2-4.0 for K, 94-104 for Cl, 9-15 for BUN, 135-163 for Glu, and 32-38 for HCT. During the specified time period the reference range of Eutrotol Level 3 was listed as 159-169 for Na, 5.6-6.6 for K, 115-127 for Cl, 9-13 for BUN, 39-57 for Glu, and 50-58 for HCT. The correct ranges for Eutorol Level 2 were 156-166 for Na, 5.6-6.6 for K, 117-129 for Cl, 9-13 for BUN, 42-60 for Glu, and 49-57 for HCT. C. In an interview, at 10:50 a.m. on 2/10//2032, laboratory employee #9 (as listed on the CMS-209 form) confirmed the QC ranges utilized from 3/4/22 until 5/10/22 were incorrect, without documented corrective actions.