Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915057	02/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Oncology Group Lab Ii	808 South 52nd Street, Rogers, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on review of manufacturer's instruction, temperature and humidity logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for Sysmex XN-2000. Findings follow: A) Review of the Sysmex XN-2000 instrument manual (Automated Hematology Analyzer XN Series XN-2000 Instructions for Use (North American Edition), Code No. CJ410539en-am, rev. 06/2022), revealed the operating environment for relative humidity is "20 to 85% ". B) Review of the laboratory humidity log revealed humidity below 20% on 9 of 23 days of operation in February of 2026. D) During an interview on 2/25/26 at 10:09 am the technical consultant confirmed the operation of the Sysmex XN-2000 below 20% humidity.
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. This STANDARD is not met as evidenced by: Based on policy, lack of documentation and an interview, the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in analytic systems. Findings include: A. Policy titled "Quality Control Program" states "11. An on going review of QC (quality control) data should be performed. Long term assessment is not used to judge the immediate reporting of patient results, but to manage the testing process over the long run." B. For calcium chemistry testing, level II quality control results were above the mean for 45 of 46 days from 12/1/25 to 1/30/26. For calcium chemistry testing, level I quality control results were above the mean for 46 of 46 days from 12/1/25 to 1 /30/26. For calcium chemistry testing, level III quality control results were above the mean for 46 of 46 days from 12/1/25 to 1/30/26. C. Upon request, no documentation showing how the shift was addressed was available. D. On 2/24/26 at 2:38pm the Technical Consultant confirmed that documentation addressing the above shift was not available.