Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2184929	06/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Oncology Group Lab Iii	3901 Parkway Circle, Springdale, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the form CMS 209, laboratory policy and procedure, personnel records, lack of documentation, delegation of authority documents, attestation documentation for proficiency testing events in 2024 and 2025, and interview, the laboratory did not verify the competency of the technical consultants on an annual basis. Findings follow: A) Review of the form CMS 209 provided by the laboratory on 6/17/25 revealed that staff member (number 2 as listed on form CMS 209) was identified as technical consultant. B) Review of a "Delegation of Duties" form revealed that the laboratory staff member (number 2 on the form CMS 209) was delegated the duties of technical consultant for "all moderate complexity testing performed in the General Laboratory". C) Review of personnel records revealed that no competency was provided for staff member (number 2 on the form CMS 209). D) Review of the attestation statements for proficiency testing was signed as laboratory director designee by the laboratory staff member (number #2 on the form CMS 209) for all events in 2024 and 2025. E) Upon request, the laboratory was unable to provide any competency assessments for the position of technical conultant for the laboratory staff member (number 2 on form CMS 209).
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based upon review of the package insert for Dade Innovin Protrombin Time (PT) reagents, observation of Sysmex 2500 coagulation analyzer instrument settings, lack of documentation, laboratory policy and procedure, Beckman Coulter AU 680 quality control (QC) reports, package insert for Biorad Multiqual chemistry control material, observations made during a tour of the laboratory, and interviews with laboratory staff, laboratory testing failed to meet the applicable analytic systems requirements as evidenced by: D5411: The laboratory failed to determine the normal patient prothrombin time used in the calculation of the international normalized ratio (INR) and failed to set the correct International Sensitivity Index (ISI) used to calculate the INR in the Sysmex 2500 coagulation analyzer. D5417: The laboratory had BD Na Citrate blood collections tubes used for coagulation testing blood samples available for use past their date of expiration. D5469: The laboratory failed to establish acceptable ranges for QC results for chemistry assays in a manner consistent with laboratory policy and procedure and manufacturer instructions.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based upon review of the package insert for Dade Innovin reagent for Prothrombin Time (PT) assays , lack of documentation, observation of instrument settings, and interview, the laboratory failed to determine the normal patient mean (MNPT) value for the laboratory's patient population used in the calculation of International Normalized Ratio (INR) values in accordance with manufacturer's instruction and failed to use the correct international sensitivity index (ISI) value in the calculation of the INR . Findings follow: 1. The laboratory failed to determine the MNPT in accordance with manufacturer's instruction. A) Review of the package insert fof Dade Innovin revealed that the MNPT used in the calculation of the INR "must be determined specifically for each thromboplastin lot using the method to analyze the patient samples using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing MNPT for US customers the appropriate CLSI guideline is recommended". B) When asked to present the data used to establish the MNPT with the change to Dade Innovin lot # 564649, the data was unavailable. C) In an interview on 6/17/25 at 01:20 p.m. , the laboratory staff member, (number 3 on the CMS 209 form), stated the data could not be located. 2. The laboratory failed to use the correct ISI value in the calculation of INR determinations. A) On 6/18/25 at 08:40 a.m., the instrument settings for the ISI values of Dade Innovin used on Sysmex 2500 coagulation analyzer was observed to be set at 1.06 with an MNPT set at 10.9. B) Review of the manufactuer's package insert for Dade Innovin lot # 564649 (current lot in use) revealed that the ISI value for the Sysmex

	2500 analyzer was 1.09. C) In an interview on 6/18/25 at 08:40 a.m. the laboratory staff member (#3 on the form CMS 209) confirmed the correct ISI for the lot # 564649 for the Sysmex 2500 was 1.09, that lot 564649 was the lot currently in use on the Sysmex 2500 coagulation analyzer, and the ISI setting of 1.06 set on the instrument was the incorrect value.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon observations made during a tour of the laboratory, and interviews with laboratory staff, the laboratory had blood collection tubes available for use after their expiration date in one of eight phlebotomy stations. Findings follow: A) During a tour of the laboratory on 6/18/25 at 10:40 a.m. two BD Blue Top Na Citrate blood collection tubes (lot# 4222854 expiration date 2025-05-31) were observed in a group of six tubes in one of eight phlebotomy stations in the laboratory. B) In an interview on 6/18/25 at 10:40 a.m. laboratory personnel (numbers 2 and 3 on the form CMS 209) confirmed that the tubes were expired and available for use.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based upon written policies and procedures for quality control, a review of the BioRad Control manufacturer's requirements, and a review of the Beckman Coulter AU 680 quality control (QC) documentation, as well as interviews with laboratory staff, the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for two of two tests reviewed for the AU 680 in which BioRad Controls were the quality control material. Survey findings include: A) During a review of the laboratory policies and procedures for "Quality Control Program" section "QC Ranges for New Lot" revealed "determine the mean and SD's for each analyte instrument software programs, laboratory information systems (LIS) or EXCEL spreadsheets to perform calculations" . B) BioRad quality control instructions for use (as stated on their quality control website QCnet My e-Inserts) state, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." C) Through a review of Beckman Coulter AU 680 quality control documentation for November 2024 the surveyor observed quality control

	ranges used as 2 standard deviation (SD) acceptable ranges that were much wider than the calculated 2 SD ranges listed in the Highland Oncology Group Levery-Jennings Report. Examples of ranges that were much wider than the calculated ranges are as follows for quality control lot # 245963 which expires 10/31/25: ALT Level III 2 SD in use by the laboratory was 20 and the calculated 2 SD based on 19 points was 2.39; AST Level III 2 SD in use by the laboratory was 30 and the calculated 2 SD based on 19 points was 6.81; D) In an interview, at 11:35 a.m. on 6/18/25, laboratory employee #2 (as listed on the form CMS-209) confirmed that written policies for establishing quality control ranges required calculating standard deviations and confirmed the quality control ranges in use were too wide for identifying failures of the test system and that ranges used from 11/1/24 through 11/13 24 were the manufacturer's published ranges and they were "tightened" after 11/13/24 without the use of mathematical calculations..
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of personnel records of six testing personnel performing moderately complex laboratory assays and interviews with laboratory staff, the laboratory director failed to give written authorization for two of six testing personnel to perform moderately complex procedures without direct supervision. Survey findings follow: A) A review of personnel records of testing personnel, who have completed training for performing moderately complex procedures, revealed that two (#4 and #6 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform moderately complex testing without supervision. B) In an interview, at 09:30 a.m. on 6/17/25, laboratory employee (#2 as listed on the form CMS-209) confirmed the lack of written authorizations for the two personnel identified above and that they performed moderately complex testing .