Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915057	05/24/2024
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
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: Through review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to assess testing personnel competency on an annual basis for two of four testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that four testing personnel were employed by the laboratory. B) Review of competency assessment records revealed that the employee (# 2 on the CMS 209 form) had a date of hire of February 2013 and no record of competency evaluation was present for calendar year 2021 and 2022; employee (# 3 on the CMS 209 form) had a hire date of August 2020 and the only competency asseessments were dated February 2021 and July 2023. C) Upon request, the laboratory was unable to provide competency assessments for the year 2021, and 2022 for employee (#2 on the CMS 209 form), and competency assessments for the year 2022 for employee (#3 on the CMS 209 form). D) In an interview on 5/22/24 at 2:30 pm, the laboratory staff member (# 1 on the separate employee identification list) confirmed that competency assessments for the dates and employees identified above were not performed and the employees had performed testing in the laboratory since their dates of hire.
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: Lack of documentation, review of laboratory policies and procedures, quality control policy and procedure, review of the BioRad Control manufacturer's requirements, user's intructions for the Excyte MiniSed Erythrocyte Sedimentation Rate (ESR) instrument, chemistry assay Levey-Jennings reports, result listing by patient reports, review of the Beckman Coulter AU 680 and TOSOH AIA - 2000 quality control (QC) documentation, and interviews with laboratory staff determined the laboratory failed to meet analytic systems requirements as evidenced by: D5445 - the laboratory failed to perform quality control on each day of ESR testing D5469 - the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for nine of nine tests reviewed for the AU 680 and two of two tests reviewed for the TOSOH AIA in which BioRad Controls were the quality control material D5481 - the laboratory did not follow its policy of taking corrective action before releasing patient test results when quality control results were outside of acceptable range
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of the laboratory's procedure for Quality Control (QC) program, Levey-Jennings Chemistry Quality Control (QC) reports for March 2024, review of the package insert for Biorad Multi-Qual quality control material, and interview with laboratory staff determined that the laboratory did not establish acceptable ranges by the use of appropriate statistical methods. This is a repeated deficiency cited at the last CLIA survey conducted on 8/10/22. Survey findings follow: A) Review of the laboratory's procedure for quantitative procedure QC revealed that acceptable QC is based upon Standard Deviations (SD) from the established mean with unacceptable QC results being any value greater than 3SD from the mean/target value. B) Review of the March 2024 "Levey-Jennings Reports" for clinical chemistry assays using Biorad Multi-Qual QC material Lot # 4596 and Biorad Immunoassay Control Lot # 85343 revealed that all values showed an atypical distribution from the target value (nothing varying over one SD), and SD's utilized for QC being magitudes greater than

	the actual SD's experienced. For example: Sodium Level 1, the 2SD Utilized for acceptable range is 8.5, Actual 2SD Calculated is 2.11 Sodium Level 3, the 2SD Utilized for acceptable range is 8., Actual 2SD Calculated is 4.06 ALP Level 1, the 2SD Utilized for acceptable range is 10.5, Actual 2SD Calculated is 3.01 ALP Level 3, the 2SD Utilized for acceptable range is 84, Actual 2SD Calculated is 12.38 CL Level 1, the 2SD Utilized for acceptable range is 6, Actual 2SD Calculated is 2.23 CL Level 3, the 2SD Utilized for acceptable range is 6, Actual 2SD Calculated is 3.76 TSH Level 1, the 2SD Utilized for acceptable range is 0.9, Actual 2SD Calculated is 0.04 TSH Level 3, the 2SD Utilized for acceptable range is 4.25, Actual 2SD Calculated is 2.36 C) In an interview on 5/23/24 at 2:25 p.m. the laboratory staff member (#1 on the separate personnel identification list) when asked how the +/- 2SD was obtained for the control materials identified above stated that she did not know and would ask the chemistry technologist who established the range to come for interview. D) In an interview on 5/23/24 at 3:05 p.m., the laboratory staff member (#5 on the CMS 209 form) confirmed that she established the 2SD range used in the chemistry QC program by defining a target/mean value through 20 runs and subtracting the established target/mean from the high range published on the package insert instead of calculating 2 standard deviations.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of the laboratory's Policy for Quality Assurance, quality control results for September 2022, January 2023, and May 2023, "Result Listing by Patient Report" for May 2024, and interview with laboratory staff determined that the laboratory reported patient results for Prostatic Specific Antigen (PSA) tests on one of twenty-one days of testing when QC results failed to meet the laboratory's criteria for acceptability. This is a repeat citation from the survey completed 8/10/2022. Survey findings follow: A) Review of the Laboratory's Policy for "Quality Assurance Quality Control Program" revealed "QC rules followed for rejection of the QC and holding patient results 13SD - result outside of 3SD". B) Review of the QC report for PSA assays for May 2024 revealed that Biorad QC level 3 lot# 85323 with an acceptable range of 17.5 to 19.5 was reported as 16.86 with a flag of :>3SD on 5/24/24 st 10:05 a.m. C) Review of the "Result Listing by Patient Report" for May 24, 2023 revealed that PSA assays were performed and reported on eight patients (identified as A through H on a separate patient identification list). D) In an interview on 5/23/24 at 1:20 p.m., the laboratory staff member (identified as #1 on the separate staff identification list) confimed that patient results were released for PSA assays on 5/24/23 against laboratory policy when QC result of any level of control was > 3SD of the target value.