Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915056	08/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Oncology Group Lab I	3232 North North Hills Blvd, 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
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 on three of five testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that five testing personnel were employed by the laboratory. B) Review of competency assessment records revealed that the employee (# 4 on the CMS 209 form) had a date of hire of May 2019 and no record of competency evaluation was present; employee (# 5 on the CMS 209 form) had a hire date of June 2015 and the only competency assessment was dated 2 /24/21 and the employee (#7 on the CMS 209 form) had a hire date of May 1996 and the only competency was dated 2/24/21. C) Upon request, the laboratory was unable to provide competency assessments for the year 2020, and 2021 for employee (#4 on the CMS 209 form), competency assessments for the years 2020 and 2022 for employee (#5 on the CMS 209 form) or competency assessments for the years 2020 and 2022 for employee (#7 on the CMS 209 form). D) In an interview on 8/30/22 at 12:55 pm, the laboratory staff member (# 2 on the CMS 209 form) 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.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of March 2022 and July 2022 quality control results, a review of corrective action notes. a review of patient test results, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to evaluate patient test results back to the last successful QC when Total Protein (TP) quality control failed to meet the laboratory's criteria for acceptability. Survey findings include: A) Through a review of quality control documentation for March 2022 it was determined that on 3/9/22 QC for Lyphocheck Assayed Chemistry Control lot # 26490 with an acceptable range of 6.03 - 6.71 for TP level 1 and an acceptable range of 3.97 - 4.23 for PT level 2 was resulted as 5.9 for level 1 and 3.9 for level two which were outside the laboratory's acceptable range. Corrective action for the failure was "calibrated" which changed the testing system. B) Through a review of quality control documentation for March 2022 it was determined that on 3/10/22 QC for Lyphocheck Assayed Chemistry Control lot # 26490 with an acceptable range of 6.03 - 6.71 for TP level 1 and an acceptable range of 3.97 - 4.23 for PT level 2 was resulted as 4.9 for level 1 and 3.3 for level two which were outside the laboratory's acceptable range. Corrective action for the failure was "calibrated" which changed the testing system. C) In an interview, at 9:55 am on 8/31/22, the surveyor requested documentation that the 88 patient results were evaluated for the 2 days (3/8/22 and 3/9/22) when quality control did not meet the acceptable range and corrective action changed the operation of the testing system. None was provided. During the interview, laboratory employee #2 (as listed on the form CMS-209) stated that the laboratory did not have documentation of evaluating the results of the patients tested back to the last successful QC for TP testing when corrective action changed the testing system. D) Through a review of quality control documentation for July 2022 it was determined that on 7/20/22 QC for Lyphocheck Assayed Chemistry Control lot # 26490 with an acceptable range of 6.04 - 6.73 for TP level 1 and an acceptable range of 4.02 - 4.28 for TP level 2 was resulted as 5.9 for level 1 and 3.9 for level two which were outside the laboratory's acceptable range. Corrective action for the failure was "remove old TP reagents & RR Cal & QC for the new" which changed the testing system. E) In an interview, at 10:55 am on 8/31/22, the surveyor requested documentation that the 34 patient results were evaluated back to the last successful QC for TP on 7/19/22 when quality control did not meet the acceptable range and corrective action changed the operation of the testing system. None was provided. During the interview, laboratory employee #2 (as listed on the form CMS-209) stated that the laboratory did not have documentation of evaluating the results of the patients tested back to the last successful QC for PT testing when corrective action changed the testing system.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant 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 for five of five testing personnel listed on the form CMS-209, lack of documentation and through interviews with laboratory staff, it was determined the laboratory director failed to give written authorization to one of five testing personnel who perform moderately complex procedures. Survey findings include: A) The surveyor reviewed authorization to perform testing for five testing personnel (listed as #3 through #7 on the form CMS-209) who perform moderately complex laboratory procedures and no authorization to perform testing was present for employee (# 4 on the CMS 209 form). B) Upon request, the laboratory was unable to provide authorization to perform moderately complex testing for employee (#4 on the CMS 209 form) signed by the laboratory director. C) In an interview, at 12:55 pm on 8/30/22, laboratory employee (#2 on the CMS 209 form) confirmed that employee # 4 performs moderately complex testing and that there is no authorization to perform testing signed by the laboratory director. .