

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0915056	(X3) Date Survey Completed 07/11/2024
Name of Provider or Supplier Highlands Oncology Group Lab I	Street Address, City, State 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff determined that the laboratory failed to assess testing personnel competency twice during the first year of employment for one of three testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that three testing personnel were employed by the laboratory. B) Review of competency assessment records revealed that the employee (# 3 on the CMS 209 form) had a date of hire of February 2022 and had a single record of competency performed in July 2023 and no record of competency evaluation was present for calendar year 2022 and 2024. C) Upon request, the laboratory was unable to provide competency assessments for the year 2022 for employee (#3 on the CMS 209 form). D) In an interview on 7/10/24 at 9:50 a.m, the laboratory staff member (# 1 on the separate staff identification list) confirmed that two competency assessments during the first year of employment for the employee identified above were not performed and the employee had performed testing in the laboratory during the date range of February 2022 to July 2023.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems</p>

quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A review of American Proficiency Institute (API) proficiency test (PT) results for 2023 and 2024, laboratory notes of corrective action, and interview determined that the corrective action employed to correct PT deficiencies was unsuccessful. Findings follow: A) Review of API 2023 Chemistry Core 1st event revealed a score of 60% for Total Iron Binding Capacity (TIBC) with a corrective action note "calculation only, wrong method chosen". B) Review API 2023 Chemistry Core 2nd event revealed a score of 0% for Lactate Dehydrogenase (LDH) with a corrective action note "calculation only, 1st time using new instrument wrong method reported"; and 60% (unsuccessful) for TIBC with a note of corrective action "root cause indicates possible sample switch" C) Review API 2024 Chemistry Core 1st event revealed a score of 80% (missing 25 of 25 analytes in one of five challenges) with a note of corrective action "tech got IA-05 and CH-05 switched, reminded tech of importance of double checking specimens when pouring off into sample cup". D) Review API 2024 Chemistry Core 2nd event revealed a score of 80% (missing 25 of 25 analytes in one of five challenges) with a note of corrective action "wrong specimen looks like HH-06 was poured off into CH-08 cup by mistake". E) In an interview on 7/10/24 at 11:37 a. m., the laboratory staff member (#1 on the separate staff identification list) confirmed that corrective actions for the deficient PT performances were not effective.