

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2184929	<b>(X3) Date Survey Completed</b> 09/14/2023
<b>Name of Provider or Supplier</b> Highlands Oncology Group Lab Iii	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> 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 quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Through lack of documentation and interviews with staff, it was determined that the laboratory failed to employ effective corrective action to prevent recurrence of quality control (QC) failures. Survey finding follow: A. A review of the quality control data for the DX700 Beckman Coulter Chemistry analyzer showed QC failures requiring a recalibration for correction on 20 of 22 days of operation in January of 2023. B. There were no notes or comments on the quality control documents reviewed. C. The surveyor requested the quality assurance documentation from January of 2023, and none were available. D. In an interview on 9/14/23 at 9:25 am the lab clinical director (noted with an asterisk on the entrance/exit interview sheet) confirmed the laboratory did not have any documentation addressing the recurring quality control failures.</p>
<b>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the 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 the postanalytic systems. Findings include:  
A. The "Quality Assurance Program Policy" included: "Corrective and Preventative Action (CAPA) the laboratory will implement corrective and preventative actions to improve performance and prevent errors. The CAPA program will include a documented process for identifying, reporting, and resolving quality related issues."  
B. Upon request, no documents or records showing corrective and preventative action were available for January of 2023. C. These findings were confirmed by the lab clinical director (noted with an asterix on the entrance/exit interview sheet) during an interview at 9:25am on 9/14/23.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the available documentation, laboratory policy, and interviews with laboratory staff, it was determined the Laboratory Director failed to ensure quality assessment programs were maintained to assure quality of laboratory services. Failure to assure quality of laboratory services had the potential to affect all patient test results reported Survey findings follow: The laboratory failed to follow written policies to monitor, assess, and correct problems in the analytic systems as cited at D5891 and D5793.