Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0915057	04/04/2018
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Through a review of new instrument validation documentation for the Beckman Coulter Au680 Chemistry Analyzer, Sysmex XN-1000i Hematology Analyzer, TOSOH Endocrinology Analyzer, lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to have the director approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A. A review of the verification documentation for the Beckman Coulter Au680 Chemistry Analyzer, Sysmex Hematology Analyzer and the TOSOH Endocrinology Analyzer revealed the verification procedures were not approved and signed by the Laboratory Director. B. A review of the verification documentation for Beckman Coulter Au680 Chemistry Analyzer revealed the signature page of the procedure was signed on 12/27/2016 by Laboratory personnel #3 (as listed on CMS form 209). C. A review of the verification documentation for TOSOH Endocrinology Analyzer revealed the signature page of the procedure was signed by Laboratory personnel #2 (as listed on CMS form 209). D. A review of the verification documentation for Sysmex XN-1000i Hematology Analyzer revealed the signature page of the verification procedure was not signed. E.

	In an interview on 04/04/2018 at 1330, Laboratory personnel #3 (as listed on CMS form 209) confirm the verification procedure for the Chemistry, Hematology and Endocrinology Analyzers were not approved or signed by the Laboratory Director.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (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. This STANDARD is not met as evidenced by: . Through a review of proficiency testing events of 2017, 2016 and 2015, performance review and corrective action form, lack of documentation, as well as interview with staff, it was determined the corrective actions identified failed to prevent the recurrence of the deficient practice. The Laboratory failed four out of five proficiency testing events for the test Cancer Antigen (CA) 27.29. As evidenced by: A. A review of the American Proficiency Institute reports for 2015 revealed the Laboratory scored 0% in the third proficiency testing event for the test CA 27.29. B. The performance review and corrective action form for the API Chemistry third proficiency event of 2015 states " the Laboratory quality controls are within manufacturer's range. Linearity is good and calibrations in range." C. A review of the American Proficiency Institute (API) reports for 2016 revealed the laboratory scored 50% in the first proficiency testing event of 2016; 50% in the second proficiency testing event of 2016, and 0% in the third proficiency testing event of 2016 for the test CA 27.29. D. The performance review and corrective action form for the API Chemistry first and third proficiency event of 2016 states " Continued issues with CA 27.29. Values running just a little lower than peers. Controls within our range and well within manufacturers ranges. Linearity is good and calibrations in range." E. In an interview on 04/04/2018 at 1300, Laboratory personnel #3 (as listed on CMS form 209) confirmed the corrective action taken did not prevent the recurrence of the deficient practice.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: . Through a review of new instrument validation documentation for the Beckman Coulter Au680 Chemisty Analyzer, Sysmex XN-1000i Hematology Analyzer, TOSOH Endocrinology Analyzer, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to review and approve the

	verification procedures to ensure they are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method as cited at: 5421: the Laboratory failed to have the director approve the verification procedures of the Chemistry, Hematology and Endocrinology analyzers.