Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445864	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lake Regional Health System - Eldon Clinic	416 S Maple Ste C, Eldon, MO	

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
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of complete blood counts (CBC) normal values on patient test reports and CBC normal values included in the approved procedure manual, the laboratory failed to ensure pertinent normal values, as determined by the laboratory, were available for interpretation of the test results. Findings: 1. Review of CBC normal values included on patient test reports generated by the laboratory information system (LIS) showed the laboratory reports a single set of normal values for all patient age groups and genders for CBC analytes. 2. Review of CBC normal values included in the approved procedure manual showed multiple age groups and gender specific patient normal values for CBC analytes. 3. Interview with the technical consultant on January 30, 2017 at 11:00 AM confirmed age and gender specific CBC normal values included in the approved procedure manual differ from normal values on patient CBC test reports.
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: Based on review of hematology verification procedures and interview with the technical consultant, the laboratory did not have documentation to show the director reviewed and approved verification procedures for the hematology analyzer (complete blood counts/ CBC) before patient testing started September 5, 2017. Findings: 1. The laboratory did not have documentation to show the director reviewed and approved verification procedures to determine the accuracy, precision, reportable range and reference range performance characteristics for the AcTdiff hematology analyzer # 14608 before patient testing started September 5, 2017. 2. Interview with technical consultant on January 30, 2018 at 11:00 AM confirmed no documentation to show the director approved the verification procedures for the hematology analyzer. Interview with testing personnel #1 on January 30, 2018 at 11:00 AM revealed the laboratory performed 12 to 15 patient CBCs per month on hematology analyzer # 14608.