Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445864	01/28/2020
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of hematology proficiency testing (PT) records for 2018/2019 and interview with the laboratory director, the laboratory failed to ensure one of seven full-time testing personnel participated in the PT process who routinely perform patient testing. Findings: 1. No documentation was available to show testing personnel # 7 participated in hematology PT for 2018 and 2019. 2. Interview on January 28, 2020 at 11:45 AM, the laboratory director confirmed the laboratory failed to include all personnel who routinely perform patient testing, in the PT process.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the written hematology procedure manual and quality control (QC) records for April 2019 and interview with the laboratory director, the laboratory failed to follow the manual for corrective action procedures for unacceptable QC results. Findings: 1. The "Quality Control for Coulter Act Diff 2" procedure states, "If

	the results are not within the expected range, rerun the control starting at step # 7. If not within expected range, corrective action should be taken and documented." 2 Review of QC records for April 2019 revealed the laboratory tested the normal control eight times on April 22, 2019 before obtaining an acceptable hemoglobin result. The laboratory tested the high control three times on April 22, 2019 before obtaining an acceptable hemoglobin result. The laboratory did not have documentation to show corrective action steps taken for the unacceptable QC results on April 22, 2019. 3. Interview on January 28, 2020 at 11:45 AM, the laboratory director confirmed the laboratory failed to take corrective action for unacceptable QC results as stated in the QC procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory director, the procedure manual failed to include hematology reference intervals (normal values) for complete blood counts (CBC). Findings: 1. The procedure manual did not include normal values for the following: -WBC -RBC -HGB -MCV -MCH -MCHC -RDW -Platelet -MPV -Neut % (Auto) -Lymph % (Auto) -Mono % (Auto) -Neut # (Auto) -Lymph # (Auto) -Mono # (Auto) 2. Interview on January 28, 2020 at 11:45 AM, the laboratory director confirmed the procedure manual failed to include normal values for measured and calculated analytes for the CBC test reported on patients.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of hematology procedures and interview with the laboratory director, the laboratory failed to ensure procedures and changes in procedures were approved,

	signed and dated by the current laboratory director before use. Findings: 1. No documentation was available to show the current laboratory director approved signed and dated the hematology procedures before use. 2. Interview on January 28, 2020 at 11:45 AM, the laboratory director confirmed the procedures were not approved, signed and dated by the current director.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of an approved quality assessment (QA) program and interview with the technical consultant, the laboratory director failed to ensure QA programs were established.. Findings: 1. No documentation was available to show the laboratory director established/approved QA programs for general laboratory systems, preanalyic systems, analytic systems and postanalytic systems. 2. Interview on January 28, 2020 at 11:45 AM, the technical consultant confirmed QA programs specific to the laboratory were not established and approved by the laboratory director.