

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1061170	(X3) Date Survey Completed 10/03/2018
Name of Provider or Supplier Iron County Medical Center	Street Address, City, State 301 N Hwy 21, Pilot Knob, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology procedure manual and interview with the general supervisor on October 3, 2018 at 2:30 PM confirmed the manual failed to include written quality control procedures (instructions) for quantitative tests.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) program, laboratory procedure manuals and interview with the laboratory director, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the approved QC program and procedure manuals revealed, the laboratory did not establish and define statistical parameter criteria (standard deviations) for acceptability of quantitative QC results reported on the hematology, coagulation and chemistry analyzers. 2. Interview with the laboratory director on October 3, 2018 at 2:30 PM confirmed the laboratory failed to have written criteria for acceptability of quantitative QC results.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on review of patient test reports, review of the procedure manual and reference literature and interview with the laboratory director, the laboratory director failed to include accurate reference intervals(normal values) on the patient report. Findings: 1. Review of the normal values on the patient test report for urine microscopic showed a value of "none seen" for white blood cell(WBC) and red blood cell(RBC). 2. Review of the pertinent reference literature for urine microscopic exam revealed normal values of 0-3 for WBC and 0-3 for RBC results. Review of the procedure manual revealed no urine microscopic normal values. 3. Review of the normal values on the patient test report and the procedure manual for CBC and LDH revealed: patient test report procedure manual MCV 7.00-11.50 4.6-10.2 % basophils 0.00-2.00 0.00-2.50 LDH 313-618 125-220 4. Interview with the laboratory director on October 3, 2018 at 2:30 PM confirmed the laboratory director failed to include accurate normal values on the patient report.