Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446983	09/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central Ozarks Medical Center	304 W Washington Ave, Richland, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of procedures and interview with testing personnel on September 26, 2018 at 10:30 AM the laboratory failed to establish policies and procedures for monitoring, assessing and when indicated correcting problems identified in the general laboratory systems.
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 chemistry quality control (QC) procedure and interview with testing personnel #1 the laboratory failed to follow procedure when controls are not with in acceptable limits. Findings: 1. Review of ABX Pentra 400 procedure shows "if any control results are outside acceptable ranges, perform the following: Re-run the control, clean the system and re-run the control, open a new vial of control, recalibrate the system. 2. On August 21, 2018 Glucose QC was ran 4 times and normal control

	was out with no documentation of corrective action. 3. On August 21, 2018 BUN QC was ran 4 times and normal control was out with no documentation of corrective action. 4. On August 23, 2018 Creatinine QC was ran 2 times and control was out with no documentation of corrective action. 5. Interview with testing personnel #1 on September 26, 2018 at 10:30 AM confirmed the laboratory failed to follow chemistry procedure when controls are not within acceptable limits.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the lack of documentation revealed and interview with testing personnel #1, the laboratory failed to define a function check protocol to verify the accuracy of the timer and speed mechanisms on two laboratory centrifuges and revealed a lack of documentation for microscope maintenance. Findings: 1. No documentation was found to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge for blood products. 2. No documentation was found to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the laboratory centrifuge for urine. 3. No documentation was found to show maintenance on the microscope. 3. Interview with the testing personnel #1 on September 26, 2018 at 10: 30 AM confirmed, the laboratory failed to to have a protocol to verify the accuracy of time and speed on the laboratory centrifuges and failed to have a protocol for microscope maintenance.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable

	limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Review of calibration records for the Horiba ABX Penta 400 chemistry analyzer and the Horiba ABX Pentra 60 hematology analyzer and interview with testing personnel #1 revealed, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the chemistry calibration records for 2017 to date for the analytes: albumin, alkaline phosphatase, ALT, AST, direct bilirubin, total bilirubin, BUN, calcium, carbon dioxide, chloride, total cholesterol, HDL cholesterol, creatinine, glucose, total protein, potassium, sodium and triglycerides showed the laboratory performed one three point calibration in the last 21 months. 2. Review of the hematology calibration records for 2017 showed only one calibration was completed. 2. Interview with testing personnel #1 on September 26, 2018 at 10:30 AM confirmed the laboratory failed to perform a three point chemistry calibration verification procedure and a hematology calibration at least once very six months.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) procedures and interview with the testing personnel #1, the laboratory failed to perform a positive and negative control each day of testing for moderately complex human chorionic gonadotrophin (HCG) kit testing. Findings: 1. Review of QC procedures for HCG kit testing showed the laboratory allowed usage of serum or urine for HCG. This changed the kits from waived complexity to moderate complexity. Review of the QC documentation revealed the laboratory failed to perform a positive and negative external control for these tests each day of testing. 2. Interview with testing personnel #1 on September 26, 2018 at 10:30 AM confirmed, the laboratory did not test a positive and negative control each day of HCG testing.