Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1081363	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ozarks Community Hospital At Gravette	1101 Sw Jackson Street, Gravette, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through review of the laboratory's policy and procedure manual, manufacturer's instrument manuals, instrument calibration records, quality control reports, patient test results, lack of documentation, and interview it was determined that the laboratory failed to meet analytic system requirements or monitor and correct problems in the analytic systems as evidenced by: D5439 - the laboratory failed to perform calibrations on the Sysmex XN 1000i hematology analyzer within six month intervals at minimum, D5441 - the laboratory failed to implement quality control procedures to monitor change over time for Erythrocyte Sedimentation Rate (ESR) assays, D5469 - the laboraatory failed to establish criteria for acceptable ranges of quality control material for ESR analysis as required by the manufacturer's product insert, D5481- the laboratory failed to ensure quality control results were acceptable before reporting patient results, D5783- the laboratory failed to evaluate patient results back to the last acceptable quality control results when quality control results failed to meet criteria for acceptability, and, failed to document corrective action when quality control results failed to meet criteria for acceptability.
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: Through a review of the Operator's Manual for the Sysmex XN-1000i (serial number 28147), a review of Certificates of Calibration Verification, and through interviews with laboratory staff, it was determined the laboratory failed to perform calibration verification following manufacturer's instructions. Survey findings include: A. The Operator's Manual for the Sysmex XN-1000i states, "The laboratory must verify calibration every six months or on an as needed basis to ensure accuracy of the system." B. A review of Certificates of Calibration Verification for 2017, and 2018 revealed the following dates of calibration: January 24, 2017; November 28, 2017 (10 months after the previous documented calibration). There is no documentation that calibration verification has been performed every six months in 2017. C. In an interview at approximately10:00 AM on 11/14/2018, the laboratory staff, identified as number 1 on the Entrance and/or Exit Conference Attendance Record, confirmed the laboratory had not performed calibration every 6 months as required by the manufacturer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Through a lack of documentation, and interviews with staff, it was determined the laboratory failed to monitor the accuracy and precision of test performance over time for erythrocyte sedimentation rate (ESR) assays. Survey findings follow: A. Upon request, the laboratory could not provide levy-jennings charts or documentation of other methods for evaluating changes in test performance over time for ESR assays. B. In an interview on 11/14/18 at approximately 11:30 AM, the laboratory staff member identified as number 2 on the Entrance and/or Exit Conference Attendance Record, confirmed that the laboratory did not have a method of evaluating test accuracy and precision over time for the ESR assays.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--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: Through review of quality control records, control manufacturer ' s product inserts, and interview, it was determined that the laboratory did not establish the statistical parameters (mean and standard deviation) of Erythrocyte Sedimentation Rate (ESR) control materials. Findings follow: A. Package inserts for PolyMedCo Sed-Check 2 controls state that " each laboratory should establish its own acceptable ranges and use those provided only as guidelines " . B. QC records reviewed for November 2017, March 2018, and July 2018 included means and ranges that matched those provided in the Sed-Check 2 inserts and there was no documentation that the laboratory established it's own acceptable ranges. C. In an interview on 11/14/18 at 11:30 AM, laboratory staff member, identified as number 1 on the Entrance and/or Exit Conference Attendance Record, stated that values supplied on package inserts for Sed-Check 2 controls were used for performance specifications for ESR assays.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1) Through a review of the laboratory's "Quality Control Protocol", review of Erythrocyte Sedimentation Rate (ESR) quality control results for February, 2018, lack of documentation, review of patient logs and interview with laboratory staff, it was

	determined that twenty-six patient results were reported when results of control material failed to meet the criteria for acceptability in four of twenty-eight days reviewed. Survey findings follow: A. Review of the laboratory's quality control protocol revealed that both levels of control must be within acceptable limits when assays use only two controls. B. Review of the laboratory's ESR quality control reports revealed that Sed-Check 2 level 2 lot number 11502171A with an acceptable range of 42 to 77 was resulted as 37 on 2/5/18, 32 on 2/20/18, >140 on 2/16/17 and 78 on 2/28/18. C. Upon request, the laboratory could not show that quality control results had been within acceptable range on the days identified above. D. Review of patient logs revealed that ESR results had been reported on twenty-six patients identified as numbers one through five on patient identification list "C" on 2/5/18, patients identified as numbers six through nine on patient identification list "C" on 2/16/18, patients identified as numbers ten through twenty-three on patient identification list "C" on 2/20/18 and patients identified as numbers twenty-four through twenty-six on patient identification list "C" on 2/28/18. E. In an interview on 11/14/18 at approximately 11:30 AM, the laboratory staff member identified as number 2 on the Entrance and/or Exit Conference Attendance Record confirmed that patient ESR results had been reported when ESR quality control had not been within acceptable limits. 2). Through review of the laboratory's "Quality Control Protocol", review of Serum Glucose quality control results for May 13, 2018, lack of documentation, review of patient results and interview with laboratory staff, it was determined that nine patient results were reported when results of control material failed to meet the criteria for acceptability on May 13, 2018. Survey findings follow: A. Review of the laboratory's quality control protocol revealed that both levels of control must be within acceptable limits when assays use only two controls. B. Review of quality control results revealed that on 5/13/18 serum glucose quality control results were unacceptable in that at 12:51 AM results of QCPV1 was 94.3 flagged as +2 Standard Deviation Index (SDI) with an acceptable range of 85.44 to 93.76, and results of QCPV2 was 300.6 flagged as +2SDI with an acceptable range of 279.4 to 298.2. C. Review of quality control results revealed that on 5/13/18 serum glucose quality control was unacceptable in that at 02:27 AM results of QCPV1 was 99.3 flagged as +3 SDI with an acceptable range of 85.44 to 93.76, and results of QCPV2 was 318.4 flagged as +3SDI with an acceptable range of 279.4 to 298.2. D. Upon request, the laboratory could not provide documentation of successful quality control results for glucose on 5/13/18. E. Review of patient results revealed that glucose results were reported on 5/13/18 on nine patients identified on patient identification list A. F. In an interview on 11/14/18 at approximately 11:30 AM, the laboratory staff member identified as number 2 on the Entrance and/or Exit Conference Attendance Record confirmed that patient glucose results had been reported when glucose quality control results had not been within acceptable limits on 5/13/18.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Through observations made during a tour of the laboratory, lack of documentation,

	and interviews with staff, it was determined the laboratory failed to document semi-annual test comparison for testing performed on the Ortho-Diagnostics Vitros 5600 Chemistry Analyzer, and the Abbott I-stat Analyzer. As evidenced by: A. During a tour of the laboratory at 9:30 on 11/28/2018, the surveyor observed two Abbott I-stat analyzers labeled meter A (only run Troponin (TNI) and Chemistry 8+) and meter B (for Blood Gases only). B. During an interview (11/28/2018 at 0945), the general supervisor (as listed form CMS-209) stated that I-stat meter A serves as a secondary analyzer for the analytes Troponin (TNI) and Sodium (NA), Potassium (K+), Chloride (CL), Calcium(CA), Carbon Dioxide (CO2), Glucose (GLU), Blood Urea Nitrogen (BUN), and Creatinine (CREA). C. The surveyor requested documentation of semi-annual comparison of TNI, NA, K+, CL, CA, CO2, GLU, BUN, and CREA tests performed on both the Vitros 5600 and the I-stat analyzers. None was provided. D. In an interview at 0930 on 11/28/2018 the general supervisor (as listed form CMS-209) stated the semi-annual comparisons were not performed by the Laboratory.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: 1). Through review of the laboratory's policy for quality control, the quality control summary report for September 2018, patient results, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last acceptable quality control or document corrective action in two of two instances when quality control for Albumin failed to meet acceptable criteria. Findings follow: A. The laboratory's policy for corrective action (Policy: 800.709.609) states the control values must fall within the acceptable parameters (less than or equal to plus or minus 2 Standard Deviation Index (SDI) and "corrective action is reported and documented in the instrument log and paper action log for that instrument".. B. Review of the laboratory's quality control report by assay for September 2018 revealed that on 9/6/2018 quality control was unacceptable in that at 01:09 AM, Biorad Multiqual Level 1 lot # 45791 for serum Albumin was resulted as 2.26, flagged as -3 SDI with an acceptable range of (2.272 to 2.328). C. Review of the laboratory's quality control report by assay for September 2018 revealed that on 9/6 /2018 quality control was unacceptable in that at 02:34 AM, Biorad Multiqual Level 1 lot # 45791 for serum Albumin was resulted as 2.24, flagged as -3 SDI with an acceptable range of (2.272 to 2.328). D. Review of patient results revealed that seven patients, identified on "patient identification list B", had albumin assays reported on 9 /5/18 since the last acceptable quality control results. E. Upon request, the laboratory could not provide documentation of corrective action taken in response to the failures in quality control identified above or documentation of the evaluation of patient albumin results back to the last acceptable quality control results.. F. In an interview on 11/14/18 at approximately 04:00 PM the testing personnel identified as number 8 on the CMS 209 report confirmed that the quality control results for Albumin on 9/6 /18 identified above failed to meet the laboratory's criteria for acceptability and

	patient results for Albumin on 9/5/18 were not evaluated and corrective action was not documented.