Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1081363	06/23/2023
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
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: Through obervation, review of policy and procedure manuals, lack of documentation and interview it was determined that policy and procedure for performing prothrombin time (PT) assays by the method currently in use by the laboratory was not available. Findings follow: A) In an initial tour of the laboratory on 6/21/23 at 08: 45 a.m. a Stago Satellite coagulation analyzer was observed in the hematology testing area of the laboratory and no other instrument capable of performing PT assays was observed. B) Review of the policy and procedure manual for coagulation testing revealed that a procedure for PT assays perfomed on the Siemans CA 500 analyzer was available but no procedure for PT testing perfomed on the Stago Satellite analyzer was present. C) In an interview 0n 6/21/23 at 11:45 a.m.the laboratory staff member (# 2 on the CMS 209 form) stated that the Stago Satellite analyzer replaced the CA 500 analyzer in 2018, all PT assays are currently performed on the Stago Satellite analyzer, and confirmed that no procedure for PT analysis performed on the Stago Satellite analyzer could be found.
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 review of policy and procedure for quality control for hematology assays, review of hematology quality control reports for November 2022, lack of documentation, patient result reports and interviews with laboratory staff it was determined that the laboratory failed to perform quality control testing for complete blood cell counts (CBC) prior to reporting patient results in one of thirty days of patient testing in November 2022. Findings follow: A) The policy and procedure for quality control in CBC assays, # 809.709.310, states "at the hospital all levels of controls must be run every eight hours of operation per the following schedule for hospital hematology: 0600, 1400, 2200". B) Review of CBC quality control reports for November 2022 revealed that on November 17, 2022 no quality control results for CBC analysis was documented before 1353 (1:53 p.m.). C) Review of patient results revealed that on November 17, 2022 CBC results were reported on patient Y1623360 at 6:18 a.m.and on patient Y1623592 at 9:27 a.m.. D) Upon request, the laboratory could not provide quality control results for CBC analysis on November 17, 2022 performed before the patient results identified above were reported. E) In an interview on 6/21/23 at 3:24 p.m. the laboratory staff member (#2 on the CMS 209 form) confirmed that quaity control was not performed before 1: 53 p.m. on November 17, 2022 and the patients identified above were reported prior to quality control being performed.
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: Through review of the sodium (NA) quality control (QC) summary reports for January 2023, the laboratory policy and procedure for quality control of chemistry assays (800.709.412) lack of documentation and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in three of three occasions when QC results failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of QC results for NA testing for January 2023 revealed that Biorad Level 3 lot # 5663 QC material had consecutive 2s flags on 1/14/23, 1/22/23 and 1/29/23 and the technical consultant made handwritten request to 'remed" (remediate patient results to the last successful QC performance) corresponding to the QC results reported on 1/14/23 and 1/29/23. B)

	Upon request, the laboratory could not provide documentation of the corrective action taken to correct the QC failures identified above. C) Review of the laboratory policy for quality control of chemistry assays (800.709.412) states"reject run if: c. one control is between 2 and 3 SD on two successive runs" and for "instrument procedures changes: rerun 5 patients from before your QC was due to begin with and compare with previous results they should be within 10% of each other to be okay". D) In an interview in 6/22/23 at 9:35 a.m. the laboratory staff member (# 2 on the CMS 209 form) confirmed that the consecutive 2s failures identified above did not have corrective action or previous results evaluation documented and should have had as per laboratory policy 800.709.412 and the technical consultant's request.