Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468125	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Piggott Community Hospital Laboratory	1206 Gordon Duckworth Drive, Piggott, 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
D0000	Piggott Community Hospital Laboratory was not in compliance with the following condition: CFR 493.1215 Hematology as cited at D5547
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Through review of patient result reports, quality control reports, lack of documentation and interview it was determined that the laboratory failed to document quality control results for prothrombin times as cited at: D5547
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of patient result reports, quality control reports, lack of documentation and interview it was determined that the laboratory failed to document quality control results for prothrombin time testing on seven of thirty-one days of testing in November 2017, two of thirty-one days of testing in March 2018 and two of

	thirty-one days of testing in July 2018. Findings follow: A. Review of quality control reports for prothrombin time testing revealed that no quality control results were provided for 11/3/17, 11/4/17, 11/5/17, 11/6/17, 11/12/17, 11/18/17, 11/26/17, 3/23 /18, 3/24/18, 7/7/18 and 7/20/18. B. Review of patient results for November 2017 revealed that prothrombin times were performed on seven patients, identified as numbers one through seven on a patient identification list "A", on 11/3/17; five patients, identified as numbers eight through twelve on a patient identification list "A", on 11/4/17; five patients, identified as numbers thirteen through seventeen on a patient identification list "A", on 11/5/17; seven patients, identified as numbers eighteen through twenty-four on a patient identification list "A", on 11/6/17; nine patients, identified as numbers twenty-five through thirty-three on a patient identification list "A", on 11/12/17; twelve patients, identified as numbers thirty-four through forty-five on a patient identification list "A", on 11/18/17; thirteen patients, identified as numbers forty-six through fifty-eight on a patient identification list "A", on 11/26/17. C. . Review of patient results for March 2018 revealed that prothrombin times were performed on ten patients, identified as numbers one through ten on a patient identification list "B", on 3/23/18 and twenty patients, identified as numbers eleven through thirty on a patient identification list "B", on 3/24/18. D .Review of patient results for July 2018 revealed that prothrombin times were performed on twelve patients, identified as numbers one through twelve on a patient identification list "C", on 7/7/18 and fourteen patients, identified as numbers thirteen through twenty-six on a patient identification list "C", on 7/20/18. E. Upon request, the laboratory was unable to provide documentation of quality control results for prothrombin time testing for the dates identified above. F. In an interview on 8/29/18 at approximately 09:45AM the technical consultants identified as numbers 2, 3, and 4 on the CMS 209 form confirmed that the laboratory was unable to provide documentation of quality control results for prothrombin time testing for the dates identified above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Through review of the manufacturer's system operator's guide, the laboratory's humidity records, lack of documentation and interview it was determined that the laboratory failed to take corrective action when humidity levels were below the instrument operating requirement on eighteen of thirty days of operation in November 2017 and on twenty of thirty-one days of operation in March 2018. Findings follow: A. The Manufacturer's System Operator's Guide for the Dimension EXL chemistry analyzer states the "relative humidity must be maintained at greater than or equal to 20% and less than or equal to 80%". B. Review of the laboratory's humidity records revealed that humidity was recorded as less than 20% on eighteen of thirty days in

	November 2017 and twenty of thirty-one days in March of 2018. C. Upon request, the laboratory was unable to produce documentation of corrective action taken on days when humidity was recorded as less than 20% in November 2017 and March 2018. D. In an interview on 8/29/18 at approximately 3:45 PM, the technical consultant identified as number 2 on the CMS 209 form confirmed that no corrective action was taken on days when the humidity levels were recorded as less than 20%.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Through review of quality control reports for complete blood cell analysis (CBC), review of patient CBC final reports, and interview it was determined that the laboratory failed to include the name and address of the performing laboratory on six of six CBC's referred to an outside laboratory on 11/19/17 and 11/20/17. Findings follow: A. Review of the quality control report for CBC testing performed in November 2017 revealed a notation that the CBC instrument was out of service and CBC tests were referred on those days. B. Review of patient result reports revealed that three of three CBC tests performed on 11/19/17 on patients, identified as numbers one through three on patient identification list "D", lacked the name of the performing laboratory and three of three CBC tests performed on 11/20/17 on patients, identified as numbers four through six on patient identification list "D", lacked the name and address of the performing laboratory. C. In an interview on 8/30/18 at approximately 12:45 PM, the technical consultant, identified as number 2 on the CMS 209 report, stated that on 11/19/17 and 11/20/17 the CBC instrument was out of service and CBC tests were referred to an outside laboratory and confirmed that the test results for the CBC tests that were referred lacked the name and address of the performing laboratory.