Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468125	04/28/2021
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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Through a review of proficiency test records for 2019, 2020, and 2021, and through interviews with laboratory staff, it was determined the corrective actions taken for failed Erythrocyte Sedimentation Rate proficiency testing did not prevent recurrence of failures. Survey findings follow: A. A review of proficiency test records for 2019, 2020, and 2021 revealed the laboratory scored 50% on the Erythrocyte Sedimentation Rate (ESR) on the 3rd proficiency testing event of 2019 then scored 0% on the second event of 2020. The corrective actions documented on the second event of 2020 after the laboratory had failed on two of three events stated, "clerical". The laboratory failed again on the third testing event of 2020 with a score of 0%. Corrective actions for the third event 2019 and second event of 2020 failed to prevent recurrences of failure of ESR proficiency testing. B. In an interview at 3:01 on 4/27/2021, employee #1 (as documented on the form CMS-209) stated that the laboratory has plans to purchase a new ESR test system but confirmed the laboratory had not yet taken actions to prevent subsequent failures.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, a review of quality control documentation for July and November 2020 as well as March 2021, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control for complete blood counts (CBC) each day of patient testing. Survey findings include: A. The laboratory performs Complete Blood Counts (CBC) on the Coulter DxH 600. The laboratory policy for CBC quality control states that 3 levels of quality control will be run each day of testing patients. B. During a review of quality control results for November 2020 it was determined that quality control was not documented on 11/13/2020 (68 patients tested), 11/17 /2020 (54 patients tested), 11/20/2020 (47 patients tested), and 11/26/2020 (27 patients tested). Quality control was not documented on four of thirty days in November 2020. C. In an interview at 10:24 p.m. on 4/28/2021, employee #1 (as listed on the form CMS-209) confirmed the lack of quality control on the four days in November, and further confirmed patient CBCs were tested on those days without quality control. D. Through a review of quality control results for March 2021, it was revealed that only one level of quality control was documented as acceptable results on 3/16/2021. Level 2 was documented but had many system error messages and no test results. Level 1 was not documented. Although only one level of quality control had acceptable results documented, 30 patients were reported on 3/16/2021. Patients were reported on one of thirty-one days in March 2021 without two levels of quality control being documented. E. In an interview at 2:25 on 4/28/2021, laboratory employee #1 (as listed on the form CMS-209) confirmed that patients were tested on 3 /16/2021 without acceptable quality control documentation.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of the blood bank logs for 2020 and 2021, as well as interviews with laboratory staff it was determined the laboratory failed to perform and document quality control for immunohematology testing on two days of patient testing. Survey findings follow: A. Through a review of the blood bank logs for 2020 and 2021 it was determined the laboratory failed to document immunohematology (blood bank) quality control on 11/11/2020 (one of thirty days in November) and 3/13/2021 (one of thirty-one days in March). B. Through a review of the blood bank logs for 2020 and

	2021 it was revealed that on patient (#53094) had a crossmatch documented on 11/11 /2020 and one patient (#40177) had a crossmatch documented on 3/13/2021. C. At 3: 07 on 4/28/2021 laboratory employee #1, from the Form CMS-209, confirmed the lack of documented quality control on the two days of blood bank patient testing in 2020 and 2021.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of the blood bank log book for 2020 and 2021, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document visual inspection of red blood cells immediately before distribution as required at 21 CFR 606.160(b)(3)(ii). Survey findings include: A. During a review of the blood bank log books for January 2020 through March 2021 it was observed that three units of blood were documented as given to patients without documentation of visual inspection at the time the laboratory signed the units out for transfusion. On 6 /26/2020 patient #58607 was issued unit W2009 20 36572500 without documentation of visual inspection, on 11/5/2020 patient #33441 was issued unit W2011 20 39345300 without documenting visual inspection, and on 2/27/2021 patient #41041 was issued unit W2040 21 22627900 without documentation of visual inspection. B. In an interview at 2:46 on 4/28/2021 laboratory employee #1 (as listed on the form CMS-209) confirmed visual inspection of the units of blood were not documented at the time the above units were issued from the laboratory. She further confirmed there was no other document on which the visual inspections would be documented.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Through a review of laboratory personnel records for all personnel listed on the Form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to ensure that all personnel receive training and demonstrate that they can perform all testing prior to testing patients' specimens. Survey findings include: A. During a review of personnel records for eight laboratory employees listed as testing personnel on the form CMS-209, it was determined that three of eight employees failed to have documented training or competency. Employee #5 (as listed on the form CMS-209) started testing in November 2020 but has no documentation of training, competency, or authorization from the laboratory

	director, to perform testing without supervision. Employee #6 started testing in September 2020 but has no documentation of training, competency, or authorization from the laboratory director, to perform testing without supervision. Employee #5 started testing in 2019 but has no documentation of training, competency, or authorization from the laboratory director, to perform testing without supervision. B. In an interview, at 1:51 p.m. on 4/27/2021, lab employee #1 (as listed on the form CMS-209) confirmed the lack of training, authorization, and competency assessments on three of eight testing personnel.