Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0693675	08/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Drew County Laboratory	778 Scogin Drive, Monticello, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Through a review of Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016, Blood Transfusion/Utilization Committee Meeting Minutes, Drew Memorial Hospital transfusion statistics, review of the Plan of Correction for deficiency D3015 submitted for the CLIA survey conducted on 7/9/21 , lack of documentation, and interview it was determined the facility failed to meet this condition as evidenced by: D3015 - the facility failed to comply with Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016 requirements for blood utilization committee
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

	This STANDARD is not met as evidenced by: Through a review of Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016, the plan of correction dated 8/11/21 for deficiencies cited on a survey conducted on 7/9/21, Blood and Transfusion/Utilization Committee meeting minutes, and through interviews with staff, it was determined the facility failed to comply with Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016 requirements for blood utilization committee providing medical staff oversight of the transfusion of blood and blood components. This was previously cited as a deficiency in the survey conducted in July 2021. Findings follow: A) The Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016 stated in Chapter 19 (Laboratory) that "a committee of the Medical Staff shall fulfill the following responsibilities: establish criteria for the proper use of blood and its components; monitor the transfusion of blood and its components to ensure the established criteria for proper use are met; review the reports of suspected transfusion reactions; and establish criteria for therapeutic phlebotomies". B) A review of the plan of correction dated 8/11/21 revealed "a blood product utilization committee will be created " by February 2022 to: 1."Establish criteria for the proper use of blood and blood components," 2. "Monitor the transfusion of blood and its components to ensure the established criteria is (sic) met", 3. "An audit will be performed for patients as part of the blood utilization QA report", and, 4. " Review reports of suspected transfusion reactions" C) Review of the Blood Transfusion/Utilization Committee minutes revealed that the committee met on 2/10/22, 4/5/23, 5/4/23, 6/1/23 and 8/7/23. Review of the minutes of the most recent meeting (8/7/23) revealed that discussion was still underway for the establishment of criteria for blood and component use. Review of minutes revealed no audits for compliance with criteria had been conducted and no committee review of suspecteed transfusion reactions had been presented. D) On 8/24 /23 at 2:15 p.m. staff member (#4 as listed on the CMS 209 form) confirmed that criteria for the use of blood and components had not been created and accepted by the medical staff and the committee had not met for 14 months between 2/10/22 and 4/5 /23 due to staff activity to install a hospital-wide health information system The laboratory did not meet the elements accepted in the plan of correction submitted for the survey conducted on 7/9/21. Without written protocol for transfusion and regular meetings the committee cannot ensure that transfusions meet established criteria as required by the Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Through a review of personnel records for eight of eighteen Respiratory Therapy testing personnel performing moderately complex Arterial Blood Gas (ABG) determinations and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for eight of eight testing personnel to

	perform testing without direct supervision. Survey findings follow: A) A review of personnel records for eight randomly selected Respiratory Therapy employees, who have completed training for performing ABG deterninations, revealed that eight of eight (#17, #18, #21, #22, #23, #28, #31and #33 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform ABG testing without supervision. B) In an interview, at 12:35 p.m. on 8/23/23, laboratory employee #3 (as listed on the form CMS-209) confirmed the lack of written authorizations for the eight employees reviewed.