Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0693675	07/09/2021
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
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, "Monthly Blood Bank Totals" reports for the first five months of 2021, lack of documentation 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. Survey and document all transfusion activities. Findings follow: A) The Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016 state 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) Review of the "Monthly Blood Bank Totals" reports for the months of January though May of 2021 revealed in 2021 the laboratory reported 257 transfusions and that the reports contained statistical information regarding numbers of types of products and number of reported "adverse reactions" only. C) In an interview on 7/8/21 at 11:35 a.m. the laboratory staff member , identified as number one on the CMS 209 form, stated that the hospital does not have a blood utilization committee or any medical staff criteria governing the administration of blood products or any related committee, to her knowledge, and the only report submitted by the laboratory is the "Monthly Blood Bank Totals" report that is submitted to the hospital's Chief Nursing Officer. D) In an interview on 7/9/21 at 09:35 a.m. the hospital's Chief Nursing Officer/Quality Assurance Director, identified as number one on a separate staff identification list, stated that the hospital's

	Medical Staff Bylaws have no criteria for the admistration of blood products, that there is no blood utilization committee in the hospital, there is no current quality assurance activity analyzing the administration of blood products and the only blood bank information reported to the Medical Executive Committee is the statistical report identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Through a review of Respiratory policy and procedures, temperature logs for 2020, lack of documentation and interviews with staff, it was determined the Respiratory laboratory failed to monitor and document room and refrigerator temperatures that are essential for the storage of reagents and supplies. Survey findings follow: A. A review of Respiratory policy and procedure revealed: "Respiratory Temperature will be checked daily and recorded on the temperature logs. Refrigerator range 2-8 degrees Celsius: Room Temperature Range 15-28 degrees Celsius." B. A review of the refrigerator temperatures for January- December 2020 (twelve of twelve months) revealed the Respiratory laboratory failed to monitor and document refrigerator temperatures on one of thirty-one days in January; one of thirty-one days in March; one of thirty days in April; five of thirty-one days in May; one of thirty days in June; one of thirty-one days in July; three of thirty-one days in August; one of thirty-one days in October; one of thirty days in November and one of thirty-one days in December. C. A review of the room temperatures for January-December of 2020 (twelve of twelve months) revealed the Respiratory laboratory failed to monitor and document room temperatures on one of thirty-one days in March; one of thirty days in April; four of thirty-one days in May; one of thirty days in June; one of thirty-one days in July; two of thirty-one days in August; two of thirty days in September; one of thirty days in November and one of thirty-one days in December. D. In an interview with Respiratory testing personnel #1 (as listed on form CMS 209) confirmed the Respiratory laboratory failed to monitor or document room and refrigerator temperatures on the days mentioned.
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 review of policy and procedure manual, quality control(QC) data for 2020 and 2021, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to monitor the accuracy and precision of the quality control process and failed to monitor over time the accuracy and precision of test performance. As evidenced by: A. Through a review of the policy and procedure manual it was determined the laboratory failed to have a policy to monitor shifts and trends for the evaluation of accuracy and precision over time to meet the laboratory's established criteria for the Vitros 7600 Chemistry analyzer. B. A review of Levy Jennings charts for May 2021 (one of three months reviewed) revealed: Level 1 Cardiac Control Lot #87811, Myoglobin (MYO) results were below the assayed mean of 81.1 (22 points): Level III Cardiac Control Lot #87813, Myoglobin (MYO) results were below the assayed mean of 505.4 (18 points): Level I Control Lot #67634, Troponin results were below the assayed mean of 0.29 (15 points): Level I Control Lot #85211 Thyroid Stimulating Hormone (TSH) results were above the assayed mean of 0.62 (20 points). C. A review of Levy Jennings charts for June 2021 (two of three months reviewed) revealed Level I Control Lot #45891, Glucose results were below the assayed mean of 57.7 (25 points) and Level II Control Lot #45983, Glucose results were below the assayed mean of 370.0 (20 points). D. There was no documentation that the laboratory had identified the shifts or trends in test performance, or any actions performed to address the shifts or trends. E. In an interview on 7/8/2021 at 10:00 a.m., laboratory personnel #1 (as listed on form CMS-209) confirmed the laboratory did not evaluate the accuracy and precision over time to meet established criteria of acceptability.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of Chemistry policy and procedure manual, Chemistry Quality Control (QC) records for June 2021 laboratory patient log, lack of documentation as well as interview with staff it was determined the laboratory failed to document Chemistry QC when patients were tested. Survey Findings Follow: A. A review of the Chemistry policy manual revealed the Quality Control policy: "Two levels of Chemistry QC will be tested daily. " B. A review of Chemistry QC data for the analyte Blood Urea Nitrogen (BUN) in the month of June 2021(one of three months reviewed) revealed on June 8, 2021 (one of thirty days in June 2021) Level I QC (Lot #45891) was out of range (more than -3SD) with no repeated analysis. There was no documentation the laboratory had two levels of acceptable QC for the analyte BUN.

	C. A review of laboratory patient log revealed on 06/08/2021, the laboratory tested and resulted BUN on 105 patients. D. In an interview on 07/7/2021 at 10:30, laboratory personnel #1(as listed on form CMS 209) confirmed patients were tested and reported without acceptable Chemistry QC on June 8,2021.
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 review of the laboratory policy and procedure (Reference # 30-1027 "Emergency Release of Blood Products"), the Blood Bank log, lack of documentation and interview it was determined that the laboratory failed to complete compatibility testing for two of six instances of the emergency release of blood as required by CFR 606.160 (b) (3) (v). Findings follow: A) Review of laboratory policy and procedure (Reference # 30-1027 "Emergency Release of Blood Products") revealed in paragraph 6 "keep two segments of each unit of blood and label it with the unit number so that the crossmatch can be later completed" and , in paragraph 9, "set up cross-matches as soon as possible, the cross-matches must be carried through the coombs phase even if the blood has been transfused when time allows". B) Review of the Blood Bank Log of six most recent occasions of the emergency release of blood products revealed that on 12/28/20 unit # WO 265 20 956434 was released on an emergency basis to patient 1048745 with no follow-up cross-match result being recorded and on 1/26/21 unit # WO 265 20 001799 was released on an emergency release basis to patient 1052885 with no follow-up cross-match result being recorded. C) Upon request, the laboratory was unable to provide documentation of cross-matches being completed for the cases identified above or to provide documentation of the reasons that cross-matches were unable to be completed. D) In an interviw with laboratory staff member, identified as number one on the CMS 209 form, confirmed that the units identified above were released and administered to patients without follow-up cross-matches being performed or reasons for the lack of cross-matches documented.
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 a review of Quality Control (QC) documentation for May 2021 and interviews with laboratory staff, it was determined the laboratory failed to document

	all corrective actions taken when results of control material failed to meet established criteria for acceptability. Survey findings follow: A. A review of QC documentation for May 2021 (one of three months reviewed) revealed on 05/11/2021 Level I Myoglobin control was run four times before the result was acceptable. On 05/06 /2021 the Level II NT-proBNP control was run four times before the result was acceptable. There were no documented corrective actions taken to bring the controls into the acceptable range. B. In an interview at 14:00 on 06/07/2021 laboratory employee #1 (as listed on the form CMS-209) confirmed there were no documented corrective actions for the quality control failures.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Through a review of the temperature records for 2020 and 2021, lack of documentation, and interviews with staff, it was determined the Respiratory laboratory failed to document corrective actions taken when refrigerator temperatures were outside of the laboratory's acceptable criteria. Survey findings follow: A. A review of temperature logs for 2020 and 2021 revealed the laboratory refrigerator temperature acceptable range was listed as 2 to 8 degrees Celsius. B. A review of the temperature logs for twelve of twelve months in 2020 revealed the refrigerator temperature was documented outside the acceptable criteria and no corrective actions were performed. On January 20, 2020 refrigerator temperature was documented at 8.2 degrees Celsius. In September 2020 (three of thirty days) refrigerator temperatures were documented (8.1 degrees Celsius) outside acceptable range. In October, (one of thirty-one days), refrigerator temperature was documented (9.9 degrees Celsius) outside of acceptable range. C. A review of the temperature logs for three of three months in 2021 revealed the refrigerator temperatures were documented (11.4 degrees Celsius) outside the acceptable criteria and no corrective actions were performed on one of thirty-one days in January 2021; one of thirty-days in March 2021 (12.8 degrees Celsius). D. In an interview at 10:30 on 7/7/2021, the technical consultant confirmed the lack of documented corrective actions for refrigerator temperatures outside acceptable criteria.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Through a review of laboratory policy and procedure, lack of documentation and interviews with staff, it was determined the laboratory failed to have an ongoing mechanism to monitor and correct problems identified in the analytic systems. Refer to: Refer to: D5445, D5441, and D5553 D5441: Failure to identify shifts and trends in

	quality control process. D5445: Failure to have two levels of acceptable QC before testing patients. D5553: Failure to perform crossmatch on emergency release blood.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Through review of the CMS form 209, personnel records, lack of documentation, and interview with staff, it was determined that the technical consultant failed to document personnel competency on an annual basis for the general supervisor. Survey findings follow: A. A review of personnel records for one of seventeen Respiratory testing personnel revealed that the technical consultant failed to evaluate the competency for the general supervisor (as listed on form CMS 209) for 2020 and 2021. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 7/06/2021 at 10:30 a.m., the technical consultant confirmed that competency evaluations had not been performed on the general supervisor. .