Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465498	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ouachita County Medical Center	638 California Avenue Sw, Camden, 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	This is the CLIA survey of the laboratory conducted on 11/30/2021 through 12/1 /2021. At the time of the survey the laboratory was not in compliance with the following conditions: 493.1217 - Immunohematology 493.1421 - Laboratory Testing Personnel 493.1441 - Laboratory Director It was determined the lack of quality control in blood bank represented an immediate jeopardy to patients. The immediate jeopardy will be removed by performing quality control on each day of testing.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Through a review of immunohematology log book for 2021 as well as interviews with laboratory staff it was determined the laboratory failed to meet the requirements in 493.1271 as evidenced by: D5551 - the laboratory failed to perform and document quality control for immunohematology testing on three of thirty days of patient testing in September 2021 and one of thirty-one days of patient testing in October 2021
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 Laboratory Policy and Procedure Manual, immunohematology log book for 2021 and interviews with laboratory staff, it was determined the laboratory failed to perform and document quality control for immunohematology testing on three of thirty days of patient testing in September 2021 and one of thirty-one days of patient testing in October 2021. Survey findings follow: a. Through a review of the Laboratory Policy and Procedure Manual, it was revealed the Blood Bank "QC Confidence System" policy states, "The purpose of daily quality assurance in the Blood Bank is to confirm the reliability of the test system. The test system includes reagents, test procedures, and equipment. Testing known samples is an acceptable method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment, or contamination or deterioration of reagents. The source of the problem should be determined before patient test results are reported." b. A review of the Immunohematology log book for January through November 2021 (11 months), in which quality control and patient testing is documented, revealed the laboratory failed to document immunohematology (blood bank) quality control on the following days when tests were performed on patient samples: 9/6/2021; 9/23/2021; 9/29/2021 (three of thirty days in September); and 10/9 /2021 (one of thirty-one days in October). c. A review of the Immunohematology log book revealed the patients with blood bank testing on days without blood bank quality control are as follows: on 9/6/2021 Patient AB59955 blood type and Rh, antibody screen, and crossmatched for one unit of blood and transfused, Patient AB59947 blood type and Rh, antibody screen, and crossmatched for two units and transfused one unit, Patient AB76659 blood type and Rh, antibody screen, and crossmatched with two units but was not transfused, and patient #1092164 had a type and Rh performed on cord blood; on 9/23/2021 patient AB84570 blood type and Rh, antibody screen, and crossmatched with two units of blood and had one transfused; on 9/29 /2021 patient AH51921 had a type and antibody screen performed, patient AH67065 blood type and Rh, antibody screen, and crossmatched with one unit of cells and was transfused, patient 1092394 had a type, Rh, and Direct Antiglobulin Test (DAT) performed on cord blood, patient 49924 had a type and antibody screen performed, patient AH67049 had a type and antibody screen performed, patient AH54553 blood type and Rh, antibody screen, and crossmatched with two units of packed cells and transfused both units, patient 1092397 had a type and Rh and DAT performed on cord blood, and patient AH67057 had a type and antibody screen performed; on 10/9/2021 patient AH67849 blood type and Rh, antibody screen, and crossmatched with two units of packed cells and one unit was transfused and patient AH54001 blood type and Rh, antibody screen, and crossmatched with two units of cells and both units were transfused. d. At 11:48 on 12/1/2021 laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of documented quality control on days of blood bank testing. e. The laboratory had not identified the failure to perform and document quality control for immunohematology testing and had not remediated patients who were tested on days without quality control documentation.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS

	CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by:
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Through a review of personnel files for fifteen of fifteen laboratory testing personnel listed on the Personnel Identification Worksheet, through a lack of documentation, and through interviews with staff, it was determined that two of fifteen laboratory testing personnel failed to meet qualification requirements as testing personnel as evidenced by: D6065 - two of fifteen laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Through a review of laboratory personnel records for fifteen testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed document that laboratory employees two of fifteen testing personnel (#16 and #17 as listed on the Personnel Identification Worksheet) met educational requirements to perform moderate complexity testing. Survey findings follow: a. In an interview, at 2:00 p.m. on 12/1/2021, employee #2 (as listed on the Personnel Identification Worksheet) confirmed employees #16 and #17 perform Activated Clotting Times (ACT) in the Cardiac Catheterization Lab using the moderate complexity I-Stat test system. b. The laboratory failed to have documentation of education that would qualify laboratory employees #16 and #17 to perform moderate complexity testing. c. In the interview, at 2:00 p.m. on 12/1/2021, laboratory employee #2 confirmed the lack of documentation of highest level of education, which would qualify employees #16 and #17 as a moderate complexity testing personnel.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Through a review of immunohematology log book for 2021 as well as interviews with laboratory staff, and through a review of personnel records for fifteen testing personnel, it was determined the laboratory director failed to ensure quality control programs were maintained and failed to ensure testing personnel had appropriate education, as evidenced by: D6093 - the laboratory director failed ensure that the quality control programs are maintained
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Through a review of immunohematology log book for 2021 as well as interviews with laboratory staff, it was determined the laboratory director failed ensure that the quality control programs are maintained. Survey findings include: D5551 - the laboratory failed to perform and document quality control for immunohematology testing on three of thirty days of patient testing in September 2021 and one of thirty-one days of patient testing in October 2021