Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049580	10/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mena Regional Health System	311 North Morrow Street, Mena, 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	A CLIA conplaint investigation was performed on 10/17/2022 through 10/27/2022. The laboratory was not in compliance with the following conditions: 493.1250 Analytic Systems 493.1441 Laboratory Director (High Complexity) 493.1487 Testing personnel (High Complexity)
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, Medical Staff Bylaws, and Blood and Tissue 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 that includes documenting all transfusion activities in 2022. This was previously cited as a deficiency in the validation survey conducted in January 2020. 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) The Medical Staff Bylaws last amended on July 11 2017 stated the following: "The blood and tissue committee shall consist of a chairman, who is an associate or active member of the medical/dental /podiatric staff , director of medical records, director of laboratory, and the operating room supervisor." and "In addition, the committee shall provide a mechanism that ensures the review of blood transfusions for proper utilization and evaluation of all

	confirmed transfusion reactions." C) A review of Blood and Tissue Committee Meeting Minutes dated 2/5/20 stated under the heading of "policy" "The blood and tissue committee will meet quarterly under the blood utilization section to review transfusion services including pre-analytical, analytical, and post analytical processes these processes include but are not exclusive to the following transfusion services: 1. Rates of transfusions. 2. Adherence to Policy of Criteria to Tranfuse and use of blood products. 3. Documentation of variances thereof. 4. Use of emergent released units. 5. Possible transfusion reaction work ups. 6. Review of transfusion services policies. 7. Quality monitors which should be congruent and periodical". D) In an interview on 10 /17/22 at 11:10 a.m. when asked for the Blood and Tissue Committee meeting minutes the personnel (#1 and #2 as listed on the entrance conference attendance record) stated the committee minutes "whereabouts" are unknown since the last laboratory manager left. E) At 03:17 p.m. staff member (#1 as listed on the entrance conference attendance record) presented copies of Transfusion Committee reports for 2/5/20, 3/9/15/20, 12/14/20, 3/24/21, 6/24/21 and 9/23/21. When asked for Blood and Transfusion Committee minutes since 9/23/21 the staff member stated that the committee had stopped meeting at the instruction of the laboratory manager "due to covid". F) Review of the Blood and Tissue Committee minutes presented contained no reports concerning the adherence to policy, criteria to transfuse, and use of blood products or documentation of variances thereof. In an interview at 3:17 p.m. on 10/17 /22 staff member (#1 as listed on the entrance conference attendance record), when asked if quality assurance monitors for the adherence criteria to transfuse and use of blood products were documented ,stated that she had never seen those criteria in writing. 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.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of the policy titled, "Receiving and Storage of Blood Products", a review of the Blood Bank Log book, "Request for Investigation of Transfusion Reaction" from September 2020 through September 2022, the Root Cause Analysis Incident Investigation Tool, patient blood type results, personnel records, and interviews with laboratory staff, it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5553 - The laboratory failed to document the release and visual inspection of two units of packed red blood cells immediately before the blood was distributed for infusion to the patient. D5559 - The laboratory failed to document pathologist's final judgement and signature on five of fifteen transfusion reaction workups D5787 - The laboratory failed to maintain a record system with dates of all specimen testing D5791 - The laboratory used incorrect data and failed to identify the problem when ABO incompatible blood was transfused to a patient.

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 policy titled, "Receiving and Storage of Blood Products", a review of the Blood Bank Log book, and interviews with laboratory staff, it was determined the laboratory failed to document the release and visual inspection of two units of packed red blood cells immediately before the blood was distributed for infusion to the patient on 9/19/2022. Survey findings include: A. The laboratory policy titled, "Receiving and Storage of Blood Products", "To release a unit: Only those employees authorized to perform blood bank testing may release blood or blood products. To verify the correct patient/unit is being released, the Blood Bank Log book and the Unit Tag must match. The Tech may read the Log and the Nurse may read the unit (or vise versa). Tech and Nurse must identify the patient using name, D. O.B., and Blood Bank Identification Band, as well as the Unit number, Blood Type and Rh, and expiration date. The Blood Bank Log book, product hang tag, and labels all must match before issuing and releasing. The Tech must also review the test results, including the antibody and crossmatch interpretations to insure they are negative and compatible, and the blood band number on the worksheet for errors and omissions prior to release of the unit. If there is a discrepancy, the unit cannot be released until the problem is fixed. The tech must document the visual inspection of the unit in provided space in the Blood Bank log book. Fill in the release section, including the date and time, on both the worksheet and the Blood Bank log book." B. A review of the Transfusion Service Testing Logs for 2021 and 2022 revealed that on 9/19/2022 two units of blood were signed out for patient #1500289 by a registered nurse without documentation that the authorized testing person from the laboratory performed any of the required procedures listed in the policy. C. In an interview, at 2: 32 p.m. on 10/17/2022, laboratory employee #3 (as listed on the personnel worksheet) confirmed the lack of laboratory documentation at the time the blood was taken from the laboratory on 9/19/2022.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 all "Request for Investigation of Transfusion Reaction" from September 2020 through September 2022 and through interviews with laboratory staff, it was determined the laboratory failed to document pathologist's final judgement and signature on five of fifteen transfusion reaction workups. Survey findings include: A. Through a review of "Request for Investigation of Transfusion Reaction" it was determined that the forms included a section for the Pathologists Final Judgement and the Clinical Laboratory Director's signature. On five of the fifteen forms completed for possible transfusion reactions in the last 24 months (Patient #1 as listed on the Patient Identification Worksheet dated 9/28/2020, Patient #2 as listed on the Patient Identification Worksheet dated 1/21/2021, Patient #3 as listed on the Patient Identification Worksheet dated 9/2/2021, Patient #4 as listed on the Patient Identification Worksheet dated 9/19/2022, and Patient #5 as listed on the Patient Identification Worksheet dated 9/29/2022), the Pathologists Final Judgement and the Clinical Laboratory Director's signature were not completed. B. In an interview, at 2:38 p.m. on 10/17/2022, laboratory personnel #3 (as listed on the personnel worksheet) confirmed the pathologist failed to complete his section of the transfusion reaction workups on five of fifteen possible transfusion reactions. C. Without the pathologist's final judgement documented, the laboratory was unable to make recommendations to the medical staff regarding improvements in transfusion procedures, to take necessary remedial actions to prevent recurrences of transfusion reactions, or to ensure that all policies and procedures are reviewed and updated to ensure the safety of individuals being transfused.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Through a review of the Transfusion Reaction Request for Investigations, the Blood Bank Log book, and interviews with laboratory staff, it was determined the laboratory failed to maintain a record system with dates of all specimen testing for one of fifteen. Survey findings include: A. A review of fifteen Transfusion Reaction Request for Investigation forms included one 9/29/2022 for patient #129564. The form was completed with results from laboratory testing of pre and post transfusion samples. B. The laboratory used a manually documented Blood Bank Log to document all blood bank test results. A review of the Blood Bank Log book revealed that the pre and post transfusion testing performed as a response to the Transfusion Reaction Request for Investigation were not documented in the Blood Bank Log. There was no documentation in the Log to support the results documented on the transfusion reaction form for one (Patient #5 from the Patient Identification Worksheet) of fifteen patients reviewed . C. In an interview, at 2:29 p.m. on 10/17/2022, employee #3 (as listed on Entrance Conference Sign In Sheet) confirmed the lack of documented test results in the Blood Bank Log to support the findings on the Transfusion Reaction forms.

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 the Root Cause Analysis Incident Investigation Tool, patient blood type results, and the "Request for Investigation of Transfusion Reaction", personnel records, and through interviews with staff, it was determined the laboratory used incorrect data and misidentified the problem when ABO incompatible blood was transfused to a patient. Survey findings follow: A. A review of the Root Cause Analysis Incident Investigation Tool and supporting data revealed the laboratory test results that the team used in the investigation were incorrect and caused the team to make incorrect assumptions. The data used by the root cause analysis team included a pre-transfusion and post-transfusion blood type. The data used included an A positive result for pre-transfusion and an O positive result for post-transfusion and the team concluded the pre-transfusion sample was mislabeled. B. A review of the "Request for Investigation of Transfusion Reaction" for Patient #5 (as listed on the Patient Identification Worksheet) revealed the patient's pre-transfusion sample tested as O positive and the post-reaction sample tested as O positive. Personnel #5 documented these results on a Laboratory Problem / Error form that stated, "patient was Typed and Screened as A positive on 9/28 and was assigned a unit of A positive blood. During transfusion 9-29, she began to have a transfusion reaction. Protocol was immediately implemented and following a Type and Screen of both her Pre-transfusion and Post-Transfusion blood draws, it was determine the patient is O positive." C. A review of the printouts of test results that the root cause analysis team had used in their investigation revealed the pretransfusion result used was tested by employee #3 (as listed on the personnel worksheet) who originally mistyped and miscrossmatched the patient. This result was the original result of A positive that was an error and caused the O positive patient to get A positive blood. D. The root cause analysis stated, "Labeling of blood product - wrong label that reflected the wrong blood type being tagged for patient" and "The incident was R/T human error of mislabeling the blood" but the transfusion reaction investigation performed on 9/29/2022 documents retyping of the patient samples and the unit of blood. Patient samples typed as O positive and the unit (which was labeled as A positive) typed as A positive. The samples and the blood were all labeled correctly in order for employee #5 to obtain these results. E. In a review of the Request For Investigation of Transfusion it was observed that the Pathologist's Final Judgement stated, "Dr Wang remented [sic] for more tranning [sic] of Med teck [sic] in the lab" F. A review of the personnel records for laboratory employee #3 (as listed on a separate personnel identification list) revealed that the employee began employment on 7/1/19, training records were not presented, and the only competency evaluation was dated 10/22/21. On the Blood Bank section of that competency the employee was scored as "needs work" on "Fetal Cell Screens" and "Verifies Expiration Dates of Reagents and Controls" and the employee was not scored for "Performs as Needed for All Tests" and "Accurately Reports and Records Patient Results". G. The root cause analysis failed to document the recommendation on the transfusion reaction investigation for more training or that the employee involved lacked training documentation and competency assessment for blood bank.

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: Based on a review of facility records and staff interviews, it was revealed the laboratory director failed to provide overall management for the laboratory (refer to citations at D6102, D6103, and D6107).
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 personnel records, proficiency testing results for 2021 and 2022, cease testing letter from accreditation agency, transfusion reaction investigation documents and interviews with laboratory staff, it was determined the director failed to ensure that personnel have received appropriate training prior to testing patient specimens. Survey findings follow: A) Review of American Proficiency Institute (API) Immunohematology proficiency testing results for 2021 and 2022 revealed: - that the laboratory scored 80% (unacceptable) for compatability testing on the 2nd testing event of 2021 the root cause/corrective action documented was for not testing a sample with a known atypical antibody to the AHG phase compatability test and it further cited a need of "additional training". - that the laboratory scored 80% (unsuccessful performance) for compatability testing on the 3rd testing event of 2021 with a cause/corrective action cited as "clerical error". - that the laboratory scored 80% (unsuccessful three of five events) for compatability testing on the 2nd testing event of 2022 for not testing a sample with a known atypical antibody to the AHG phase of compatability testing with a cause/corrective action cited of "additional training". B) In a letter from the accreditation agency dated 9/29/22 the laboratory was instructed to cease compatability testing based upon three of five unsuccessful proficiency testing events. C) Review of a 'Request for Investigation of Transfusion Reaction" revealed that a patient, identified as number 1 on a separate patient identification list, was tranfused with blood incompatible with the patient's ABO type on 9/28/22 resulting in a "transfusion reaction due to human error" as cited by the laboratory director. D) Review of the Blood Bank Log entry for 9/28/22 revealed that employee #3 (as listed on the personnel identification list) performed the compatability testing for the transfusion reaction identified above and was responsible for the human error. E) A review of the personnel records for laboratory employee #3 (as listed on a separate personnel identification list) revealed that the employee began employment on 7/1/19, training records were not presented, and the only competency evaluation was dated 10/22/21. On the Blood Bank section of that competency the employee was scored as "needs work" on "Fetal Cell Screens" and "Verifies

	Expiration Dates of Reagents and Controls" and the employee was not scored for "Performs as Needed for All Tests" and "Accurately Reports and Records Patient Results". F) In an interview on 10/17/22 at 02:40 p.m. , laboratory staff member #3 (as listed on the personnel identification list) when asked if other personnel records were available for review stated "I have a lot of work to do, I asked HR for personnel records and these are all they gave me." .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Through a review of personnel files for testing personnel as well as interviews with staff, it was determined the laboratory director failed to ensure that testing personnel are competent and maintain their competency to perform test procedures for one of five testing personnel for which records were presented. The director failed to ensure that personnel competency was evaluated at least twice during the first year of employment and annually thereafter. Survey findings follow: A) Review of the personnel files for the testing personnel, (#3 as listed on a separate personnel identification list), revealed that the hire date was listed as 7/1/19 and only one competency evaluation dated as performed on 10/22/21 was presented. B) In an interview on 10/17/22 at 02:40 p.m. , laboratory staff member #3 (as listed on the personnel identification list) was asked if other personnel records were available for review. She stated "I have a lot of work to do, I asked HR for personnel records and these are all they gave me."
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: Based upon review of personnel records, lack of documentation, and interview it was determined that the laboratory director failed to specify in writing the examinations and procedures that personnel are authorized to perform for five of five testing personnel for which records were presented. Findings follow: A) Upon review, personnel files for testing personnel (numbers 1 through 5 inclusive on a separate personnel identification list) did not contain written authorization by the laboratory director to perform procedures and examinations. B) Upon request, the laboratory was

	unable to provide written authorization by the laboratory director to perform procedures and examinations for testing personnel identified as numbers 1 through 5 inclusive on the separate personnel identification list. C) In an interview on 10/17/22 at 02:40 p.m. , laboratory staff member #3 (as listed on the personnel identification list) when asked if other personnel records were available for review stated "I have a lot of work to do, I asked HR for personnel records and these are all they gave me."
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Through a review of the testing personnel list provided by the laboratory, a review of transcripts for employee #5 (as listed on separate personnel list), and interviews with laboratory staff, it was determined one of five testing personnel failed to meet the qualifications for high complexity testing personnel as evidenced by: D6171 - testing personnel failed to meet the educational qualifications for high complexity testing personnel
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory

	Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Through a review of the list of testing personnel, a review of personnel records presented for employee #5 (as listed on the separate personnel identification list), and interviews with laboratory staff, it was determined one of five testing personnel failed to meet the educational qualifications for high complexity testing personnel. Survey findings include: A) During a review of the testing personnel list presented it was revealed that the laboratory had five individuals listed as testing personnel (listed as #1, #2, #3, #4, and #5). B) Through a review of the records for employee #5, it was determined that no educational qualifications were presented. C) During an interview, at 02:40 p.m. on 10/17/22 laboratory staff member (#3 as listed on the separate personnel identification list) confirmed that employee #5 performs high complexity testing and stated "I have a lot of work to do, I asked HR for personnel records and these are all they gave me."