Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049580	01/23/2020
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	This is the validation survey of the laboratory conducted on 1/21/2020 through 1/23 /2020. At the time of the validation survey the laboratory was not in compliance with the following conditions with immediate jeopardy: 493.1100 Facility Administration (Immediate Jeopardy) 493.1217 Immunohematology (Immediate Jeopardy) 493.1250 Analytic Systems 493.1441 Laboratory Director High Complexity (Immediate Jeopardy)
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, Medical Staff Bylaws, Blood and Tissue Committee Meeting Minutes, Mena Regional Health System transfusion statistics, Mena Regional Health System / Laboratory Blood Bank Department "Transfusion Reaction Policy", Mena Regional Health System "Blood Components Administration" policy, Perry & Potter current edition "Clinical Nursing Skills & Techniques", MRHS Employee In Service "Skills for Administering Parenteral Fluids and Blood Products" Power-Point slide summary, the Mena Regional Health System "Transfusion Reaction:Request for Investigation" form, patient blood administration records for October and November

	2019, lack of documentation, and interview it was determined the facility failed to meet CLIA requirements 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 D3025 - the facility failed to ensure transfusion reaction policies promptly identified, investigated and documented transfusion reactions for all blood products Failure to meet CLIA facility requirements is an immediate jeopardy to patient care.
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. 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. The Medical Staff Bylaws last amended on July 11 2017 state 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 the ensures the review of blood transfusions for proper utilization and evaluation of all confirmed transfusion reactions." This does not meet the hospital licensure requirements that suspected transfusion reactions are to be reviewed. C. A review of Blood and Tissue Committee Meeting Minutes for the three quarterly meetings in 2019 revealed three meetings were documented on March 1, 2019 (to review transfusions from fourth quarter of 2018), May 17, 2019 (to review transfusions from first quarter 2019), and August 20, 2019 (to review transfusions for the second quarter 2019). The minutes for the three meetings document only the committee chairman and the laboratory supervisor were in attendance (two of four members). There is no documentation that transfusions from the third or fourth quarter of 2019 were reviewed. In an interview at 10:46 on 1 /23/2020 the current Director of Laboratory Services (a member of the committee) who has been employed since September 2019, stated that he had never met the Blood and Tissue Committee chairman and that he was unaware of any meetings after the one dated August 20, 2019. D. The Blood and Tissue Committee Meeting Minutes for the May and August quarterly meetings stated that all transfusions "met protocols". Upon request, protocols could not be produced. The surveyor requested a copy of the transfusion protocols in use by the Blood and Tissue committee and was told that there are no written protocols. Laboratory employee #2 (as listed on the form CMS-209), who is also in the role of Director of Laboratory Services and therefore a member of the committee, stated (1/23/2020 at 10:46) that he had no knowledge of written protocols. Employee #2 directed me to hospital administration in order to

	obtain a copy of written protocols for transfusions but administrative personnel were unable to provide written protocol for transfusion. Without written protocol for transfusion the committee cannot ensure that transfusions meet established criteria as required by the Rules and Regulations for Hospitals and Related Institutions in Arkansas 2016.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: 35451 . 35659 Based upon a review of Mena Regional Health System provided statistics, lack of documentation, Mena Regional Health System / Laboratory Blood Bank Department "Transfusion Reaction Policy", Mena Regional Health System "Blood Components Administration" policy, Perry & Potter current edition "Clinical Nursing Skills & Techniques", MRHS Employee In Service "Skills for Administering Parenteral Fluids and Blood Products" Power-Point slide summary, the Mena Regional Health System "Transfusion Reaction:Request for Investigation" form, patient blood administration records for October and November 2019, and interview the facility failed to ensure transfusion reaction policies promptly identified, investigated and documented transfusion reactions for all blood products. Findings follow: A) Review of the Mena Regional Health Systems transfusion statistics revealed that 438 units of blood products were transfused in 2018 and 397 units of blood products were transfused in 2019. B) Upon request, the laboratory could not provide records of transfusion reaction investigations and , in an interview on 1/22/20 at approximately 02:00 PM, the laboratory staff member, identified as number 2 on the CMS 209 form, stated there were no possible transfusion reactions reported in 2018 or 2019. C) Review of the Mena Regional Health System/Laboratory Blood Bank Department "Transfusion Reaction Policy" revealed "in event that the reaction involves a rise in the patient's temperature of 2 degrees C or higher the following protocol must be followed: a. The RN shall immediately notify patient's physician and the blood bank, b. The registered nurse will complete the patient information portion of the transfusion reaction form and return it to the Blood Bank along with blood component bag, the attached transfusion set and IV solutions when possible, c. The registered nurse will order and collect the urine specimen for a post transfusion urinalysis and send it to the Clinical Laboratory. d. The Clinical Laboratory will collect a new, properly labeled, blood sample from the patient. D) Review of the Mena Regional Health System nursing policy and procedure for "Blood Components Administration" reveals that it refers for procedure to Potter & Perry current edition " Clinical Nursing Skills and Techniques" and "if a patient experiences a reaction at any time, STOP the transfusion immediately, stay with the patient, and notify the physician". That vital signs should be recorded prior to the transfusion, at 15 minutes, 30 minutes, and hourly until the transfusion is completed. E) Review of the MRHS In-Service "Skills for Administering Parenteral Fluids and Blood Products" Power Point presentation reveals that nursing staff is informed to "stay with pt for at least the first 15 minute (50 ml) of infusion, reaction can occur at any time, even afterwards, but usually occur in the first 15 minutes (if reaction = STOP stat), Monitor VS after first 15 minutes, then every 30 minutes after increasing rate, then every hour, Any

reaction: STOP the blood, run in NS to slow KVO and notify the physician and the lab" F) In an interview on 1/22/20 at approximately 1:40 PM, the hospital staff member, identified as number 1 on the separate hospital staff list who holds the position of QA Director, stated that she would recognize a possible transfusion reaction if there was a temperature increase 1 degree C above baseline, that the official nursing policy and procedure is Perry & Potter "Clinical Nursing Skills and Techniques" 9th edition, that she "doesn't know what the lab side looks like" and she "knows we have had some (possible transfusion reactions), we cut pig tails off and sent them to the lab" but she couldn't tell the number. She then called the hospital staff member, identified as number 2 on the separate staff identification list who holds the position of Nursing IT supervisor, who stated they knew of no definitions of changes in blood pressure that would trigger a possible transfusion reaction investigation. Asked if the laboratory would have access, in any form, to the vital signs registered during a transfusion the hospital staff member, identified as number 1 on the separate staff identification list, said that they didn't know. They then called the hospital staff member, identified as number 3 on the separate staff identification list who holds the position of CNO, who stated that they knew they had a possible transfusion reaction in October or November of 2019 because they were called at home and informed and they instructed staff to stop the transfusion and collect blood and urine specimens and send to lab for investigation but they couldn't remember the date or name of the patient. Surveyors requested the hospital staff member to try to identify the patient and date of the incident. G) In an interview on 1/23/2020 at 12:48 p.m. facility staff member, identified as number 6 on the staff identification list, who is a registered nurse in ICU, was asked to explain her processes when administering blood and blood products to a patient and to explain what she consider signs and syptoms of a transfusion reaction. She stated that if the patient's temperature went over 100 degrees Fahrenheit or if a significant increase or decrease in the blood pressure occurred she would suspect a transfusion reaction. When asked what a "significant" change would be she stated that there is not anything definite. She further stated that she would stop the transfusionand call the hospitalist but not the laboratory and that she would let the hospitalist decide whether to call the lab. On 1/23/2020 at 1:05 p.m. the surveyor interviewed a facility staff member identified as number 7 on the staff identification list, who is a registered nurse (charge nurse) in the med/surg unit. In the interview she stated that she would suspect a transfusion reaction if the patient's temperature changed by a degree or if the blood pressure increased or decreased by 20. She stated that she would notify the laboratory and the physician and that the laboratory would come draw blood from the patient and get a "tag" from the blood. Due to lack of specific written policies for monitoring patients during transfusion the nursing staff did not make consistent statements regarding transfusion reaction signs and symptoms. H) In an interview on 1/22/20 at approximately 02:30 PM, laboratory testing personnel, identified as number 5 on the CMS 209 form, stated that they had not received a request for transfusion reaction investigation, that they remember an instance when a unit was brought back to the laboratory but there was no transfusion reaction investigation initiated. I) In an interview on 1/23/20 at approximately 08:45 AM, the hospital staff member, identified as number 3 on the separate staff identification list, stated that they were not able to identify the possible transfusion reaction that they had mentioned on the previous day but they thought is was a outpatient who declined the transfusion and no blood was given. When shown the "Transfusion Reaction: Request for Investigation" form, they indicated that it was not an official form and made a copy. J) A review of the Mean Regional Health System (MRHS) policy Skills for Administering Parenteral Fluids and Blood Products revealed the nursing personnel training in-service on Blood Administration and Blood Transfusion Reactions:" 1. Sign and Symptoms of Reaction: Statement of "not feeling

	right" Chills Fever Low back pain Pruritis Hypotension N/V (Nausea/Vomiting) Decreased urine output Chest pain "Dyspnea" 2. If you suspect a reaction: STOP infusion immediately KVO (Keep vein open) with NS (Normal Saline) and notify doctor and blood bank immediately Monitor VS (Vital Signs) and urine output q15m (every 15 minutes) Provide reassurance to the patient Watch for S&S (Signs and Symptoms) of shock K) Transfusion History of Patient #80925: Source Nursing Notes from Nursing Personnel #5 On 11/14/19 patient #80925 was admitted to the hospital. On 11/15/19 at 0707 patient #80925 had a Hemoglobin of 9.4 g/dl and Hematocrit of 30%. At 0847 on 11/15/19 patient's Hemoglobin was 6.1 g/dl and Hematocrit 20%. The physician was notified by nursing personnel #4 (as identified on personnel worksheet #1) and a- Crossmatch for three units of Packed Red Blood Cells was ordered. On 11/15/19 at 1408 unit W091019361687 (A positive) was started with pre-transfusion vitals: Temperature 98.3, Pulse: 100, Blood pressure 104/61 and Respirations: 18. At 1414 on 11/15/16 patient #80925 stated "I'm burning up". Nursing personnel #5(as listed on staff identificatin list) stated" patient emphatically c /o being hot and burning up. Temperature is increased from start of transfusion. Physician notified. Blood Stopped. At 15:10 on 11/15/19 blood was restarted by nursing personnel #5 and vitals was taken: Pulse: 104, Blood Pressure: 106/49, Respirations: 18, no temperature was recorded by nursing personnel #5. At 17:22 on 11/15/19 per nursing personnel #5 "patient c/o headache and bodyaches, moaning and groaning loudly." Pain medications administered as ordered." Nursing personnel failed to notify the laboratory or Blood Bank of possible transfusion reaction as per nursing training policy. Patient #80925 received 2 more units of Packed Red Blood Cells: Unit W091019361700 (A positive) transfused on 11/16/19 at 1132 and unit W091019378528 (A positive) transfused at 2147 on 11/16/19. L) Through a review of blood administration records for October and November 2019 involving 20 patients receiving 54 units of packed red blood cell (PRBC) revealed that on 13 of 54 transfusions were missing vital sign recordings as required by policy and procedure. M) The following vital sign changes were noted: Patient ID DATE UNIT # FINDINGS NOTED 83696 11/10/19 wo91019351330 Pre systolic BP 135 15' systolic BP 118 80925 11/15/19 wo91019361687 15' pt complained "I am burning up" 132844 11/1/19 wo91019277649 Pre systolic BP 113 Post systolic BP 145 1396077 11 /20/19 wo91019350548 Presystolic BP 139,15'systolic BP 122 Post systolic BP 109 Because of inconsistencies between laboratory and nursing policy and procedure, inconsistency in understanding of changes in vital signs and other symptoms that might indicate a possible transfusion reaction, missing vital sign measurements as required by policy, and the findings upon reviewing a sample of tranfusion records it was determined that the facility transfusion reaction policies failed to promptly identify, investigate and document transfusion reactions for all blood products. This represents an immediate jeopardy to patients receiving blood and blood products at the facility.
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: Based upon a review of Mena Regional Health System transfusion statistics, lack of documentation, Mena Regional Health System / Laboratory Blood Bank Department

	"Transfusion Reaction Policy", Mena Regional Health System "Blood Components Administration" policy, Perry & Potter current edition "Clinical Nursing Skills & Techniques", MRHS Employee In Service "Skills for Administering Parenteral Fluids and Blood Products" Power-Point slide summary, the Mena Regional Health System "Transfusion Reaction:Request for Investigation" form, Emergency Requests for Uncrossmatched Blood for 2019, patient blood administration records for October and November 2019, and interview it was determined the laboratory failed to meet the requirements for the specialty of Immunohematology. (refer to D5553 and D5559) Failure to meet CLIA Immunohematology requirements is an immediate jeopardy to patient care
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Through a review of the Proficiency Testing records for 2018 and 2019, Survey Exception Reports, lack of documentation, and interviews with staff, it was determined the laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. Survey findings follow: A. A review of the Proficiency testing records for 2018 and 2019 Vaginal Wet Prep proficiency testing results: for the 3rd event of 2018 and 1st event of 2019 (two of two testing events) the laboratory scored 0% for the Urine Sediment test -Vaginal Wet Preparation. B. A review of the Survey Exception Report for the 3rd Vaginal Wet Prep proficiency testing event of 2018 revealed: "Re-educated staff." C. A review of the Survey Exception report for the 1st Vaginal Wet Prep Proficiency testing event of 2019 revealed: "Vaginal Wet Prep Clue Cells-this and the previous event done by MLS and LAB Assistants who are no longer employed here." D. The corrective actions taken by the laboratory in the 3rd Vaginal Wet Prep Proficiency testing event of 2018 failed to prevent the recurrence of problems identified in the 1st Vaginal Wet Prep Proficiency testing event of 2019. E. In an interview on 01/21/2020 at 10:30, laboratory personnel #2 (as listed on form CMS 209) confirmed the action taken failed to prevent the recurrence of failures in two of two Proficiency testing events.
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 laboratory policies and procedures, lack of documentation, manufacturer's ELITE Pro coagulation instrument user manual, laboratory records for

	determining normal patient mean, laboratory temperature records, Annual test volume worksheet, Individualized Quality Control Plan (IQCP) for Cardinal Health Serum Pregnancy Test (S-BHCG), quality control (QC) data, PolyMedco SED-CHEK 2 package inserts, Quality Control (QC) for 2019 records, Microbiology Policy and Procedure Manual and quality control records for bacteriological media, Chemistry Quality Control for March, July, and December of 2019, patient test records for December 2019, Vitek II MIC (minimum inhibitory concentration) quality control documentation, Levy-Jennings Tabular Values for Prothrombin Time assays (PT) for July 2019 , patient result reports, 2019 (12 of 12 months) Vitek 2 Compact QC Log, observations made during a tour of the laboratory, and lack of documentation, it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5403 - the laboratory failed to have step by step instructions for KOH procedures and failed to have written procedures for evaluating patient test results obtained in the unacceptable test run and since the last acceptable test run when corrective actions are taken for quality control failures D5407 - the current laboratory director failed to approve, sign, and date the policies and procedures D5411 - the laboratory failed to establish normal reference mean according to instructions provided by the instrument manufacturer D5413 - the laboratory failed to monitor room temperature in one of five rooms in which supplies with a storage temperature requirement were stored D5445 - the laboratory failed to document and perform S-BHCG QC according to their IQCP guidelines and failed to include the Quality Assessment component in the developing of their IQCPs and failed to specify which external control material will be utilized in the IQCP D5469 - the laboratory failed to establish the criteria for acceptability of Erythrocyte Sedimentation Rate (ESR) control D5477 - the laboratory failed to check each batch of media for the ability to support growth, select or inhibit specific organisms, or produce a biochemical response D5481 - the laboratory reported patient results when quality control was unsuccessful D5507 - the laboratory failed to perform MIC quality control each day tests are performed D5545 - the laboratory failed to ensure two levels of quality control material are performed every eight hours of patient testing D5553 - the requesting physician failed to sign the request for release of uncrossmatched blood as required at 21 CFR 606.160(b)(3)(v). D5783 - the laboratory failed to document corrective actions when quality control failed to meet the laboratory's established criteria and failed to evaluate patient results to the last acceptable quality control performance after unacceptable quality control performance.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, lack of documentation, and an interviews with staff, it was determined the laboratory failed to have step by step instructions for KOH procedures and failed to have written procedures for evaluating patient test results obtained in the unacceptable test run and since the last acceptable test run when corrective actions are taken for quality control failures as required at 493.1282(b)(2). Survey findings include: 1. The laboratory failed to have step by step instructions for KOH procedures. A. The KOH procedure does not include a step for the addition of the KOH solution or the quantity of KOH solution. The procedure includes a step that requires the pH of the KOH solution to be tested to ensure it is acidic. KOH solution is a basic solution and will never be acidic. B. During an interview (3:05 p.m. on 1/22/2020) laboratory employee #2 (as listed on the form CMS-209) confirmed the procedure for KOH was lacked steps and was misleading. 2. The laboratory failed to have written procedures for evaluating patient test results obtained in the unacceptable test run and since the last acceptable test run when corrective actions are taken for quality control failures as required at 493.1282 (b)(2). A. During a review of the Chemistry Policy and Procedure Manual and the Laboratory General Policy and Procedure Manual it was determined the policy for quality control failures and corrective actions did not include procedures for evaluating patient test results since the last acceptable test run. B. In an interview at 11:15 on 1/23/2020, employee #2 (as listed on the form CMS-209) confirmed the laboratory had no written policies and procedures for evaluating patient test results obtained in the unacceptable test run and since the last acceptable test run if corrective actions are taken for quality control failures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Through a review of the General Laboratory Policy and Procedure Manual and the Chemistry Policy and Procedure Manual, lack of documentation, and interviews with laboratory staff, it was determined the current laboratory director failed to approve, sign, and date the policies and procedures. Survey findings include: 1. The current laboratory director failed to approve, sign, and date the General Laboratory Policy and Procedure Manual. A. A review of the General Laboratory Policy and Procedure Manual revealed that the manual was signed and approved by the previous laboratory director but had not been approved and signed by the laboratory director listed on the current CMS-209. B. In an interview at 2:53 p.m. on 1/21/2020 laboratory employee #2 (as listed on the CMS-209) confirmed the current laboratory director failed to approve and sign the Laboratory General Policy and Procedure Manual. 1. The Lactate test procedure was not approved, signed, and dated by the laboratory director. A. A review of the Chemistry Policy and Procedure Manual revealed the procedure for Lactate was not included in the manual although the test was in their test menu and was reported in the Chemistry Proficiency Test Events. B. When the surveyor

	requested a copy of the Lactate procedure, employee #2 stated that they were able to get it from the manufacturer's website. Employee #2 printed the Lactate procedure from the website but the procedure had not been approved, signed, and dated by the laboratory director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Through review of the manufacturer's ELITE Pro coagulation instrument user manual, laboratory records for determining normal patient mean, lack of documentation, and interview it was determined that the laboratory failed to establish normal reference mean according to instructions provided by the instrument manufacturer. Findings follow:. A) The manufacturer's instrument manual for the ACL ELITE coagulation instrument states when determining the normal reference means, "donors should be healthy and have no pathological condition, don't use patients, donors should not be on medication affecting coagulation, donors should span the adult age range, pediatric ranges should be established separately, donors should be equally divided between male and females". B) Review of the 20 samples used to establish the normal reference mean for RecomboPlasTin lot # N0394619 on December 31, 2019 revealed that donors were identified as N-1.....N-20 with no other demographics provided. C) In an interview on 1/21/20 at approximately 3:30 PM the laboratory staff member identified as number 2 on the CMS 209 form stated that the normal donors used to establish the normal reference mean for RecombiPlasTin lot # N0394619 were patients in which an extra blue-topped tube was drawn that were kept totally anonymous and the laboratory failed to document conformance with the test system manufacturer since there is no method to review the patients records to evaluate age, sex, medication history, or possible pathologies.
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 observation, review of laboratory temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor room temperature in one of five rooms in which supplies with a storage temperature requirement were stored: Findings follow: A) Five separate rooms with equipment or supplies with temperature limitations were observed including a phlebotomy room,

	main laboratory room, microbiology room, blood bank room and supply storage room, during a tour of the laboratory on 1/21/20 at approximately 11:30 AM. B) Review of laboratory room temperature records for the calendar year of 2019 revealed records for the main laboratory room, microbiology room, blood bank room and supply storage room. C) Upon request, the laboratory was unable to provide room temperature records for the separate phlebotomy room. D) In a tour of the laboratory on 1/22/20 at approximately 03:00 PM approximately 100 BD Na Citrate blood collection tubes lot # 9260280 expiration date 2020-3-31, approximately 80 BD SST blood collection tubes lot # 9235526 expiration date 2020-8-31, approximately 50 BD Heparin blood collection tubes lot # 9280943 expiration date 2020-10-31, approximately 30 BD EDTA blood collection tubes lot # 9280883 expiration date 2021-01-31, and approximately 70 BD Red Top blood collection tubes lot # 9143847 expiration date 2020-09-30 were observed in the separate phlebotomy room all with a storage temperature requirement of 4 degrees C. to 25 degrees C. E) In an interview on 1/23/20 at approximately 02:30 PM, the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that the temperature in the separate phlebotomy room was not recorded.
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: . 1. Through a review Annual test volume worksheet, Individualized Quality Control Plan (IQCP) for Cardinal Health Serum Pregnancy Test (S-BHCG), quality control (QC) data, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to document and perform S-BHCG QC according to their IQCP guidelines. Survey Findings Follow: A. A review of the Annual test volume worksheet revealed the laboratory performed eighty-one Serum Pregnancy tests annually. B. A review of the IQCP for S-BHCG test revealed "Perform external quality control for serum BHCG testing using the SP HCG Combo kit with each new lot, shipment, or operator and at least every thirty days." C. A review of the Quality Control Data for 2018 and 2019 revealed the laboratory only performed quality control with the change in new lot numbers. In 2018, laboratory documented quality control in April, June, September and December (four of twelve months). In 2019, laboratory performed quality controls in April, May, August and December (four of twelve months). D. Surveyor request documentation of S-BHCG quality controls performed monthly. None was provided. E. In an interview on 1/21/2020 at 13:00, laboratory personnel #3 (as listed on form CMS 209) stated the laboratory only performs quality controls for S-BHCG when changing lot numbers. 2. Through a review of the Individualized Quality Control Plan (IQCP), lack of documentation and interviews with staff, it was determined the laboratory failed to include the Quality Assessment component in the developing of their IQCPs and failed to specify which external control material will be utilized in the IQCP. Survey Findings Follow: A. A

	review of IQCP (eight of ten IQCP) for the following test, Serum Pregnancy Test, Creatine Kinase Muscle/Brain (CKMB), Troponon-1 (TNI), Antimicrobial Susceptibility Testing (AST), Fecal Lactoferrin, Campylobacter Antigen, Clostridium Difficile (C-Diff) and Enterohemorrhagic Escherichia Coli (EHEC) Shiga Toxin revealed the laboratory failed to include the Quality Assessment component in their IQCPs. B. A review of IQCP (eight of ten IQCP) for the following Serum Pregnancy Test, Creatine Kinase Muscle/Brain (CKMB), Troponon-1 (TNI), Antimicrobial Susceptibility Testing (AST), Fecal Lactoferrin, Campylobacter Antigen, Clostridium Difficile (C-Diff) and Enterohemorrhagic Escherichia Coli (EHEC) Shiga Toxin revealed the laboratory failed to specify which external controls will be utilized in the IQCP. C. In an interview at 1430 on 01/21/2020, laboratory personnel #2(as listed on Form CMS 209) confirmed the laboratory failed to include the Quality Assessment component in their IQCP and did not specify what external controls will be used in the IQCP.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of annual test volume worksheet, PolyMedco SED-CHEK 2 package inserts, Quality Control (QC) for 2019 records, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of Erythrocyte Sedimentation Rate (ESR) control. Survey Findings Follow: A. The laboratory utilizes an automatic analyzer to preform ESR assay with an annual test volume of 600 assays. A review of package insert for PolyMedco SED-CHEK 2 for automated Sedimentation Rate states: "The assay values are derived from replicate analysis on both automated and manual methods. A laboratory should establish its own acceptable ranges. B. In a review of ESR quality control data, it was determined the mean and acceptable range in nine of nine months (January-September 2019) reviewed matched the expected range as listed on the PolyMedco SED-CHEK 2 package insert: January 2019 Lot # 11502181N (expiration date 9/30/19) range (1-19 mm/hr) and Lot #11503181A range (48-88 mm /hr): February-March 2019 Lot #11504181N (expiration date 3/31/19 range (1-19 mm /hr) and Lot #11504181A range (48-88 mm/hr): April-August 2019 Lot #11502191N (expiration date 12/31/19) range (1-18 mm/hr) and Lot #11501191A range (44-85 mm /hr): September 2019 Lot #11502191N (expiration date 9/30/2020) range (1-18 mm /hr) and Lot #11502191A range (44-79 mm/hr). C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 01/22/2020 at 1300, laboratory employee #2 (as listed on CMS-

	209) confirmed that the laboratory had not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the Microbiology Policy and Procedure Manual and quality control records for bacteriological media, observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory failed to check each batch of media for the ability to support growth, select or inhibit specific organisms, or produce a biochemical response. Survey findings include: A. The Microbiology Policy and Procedure Manual included policies for in-house quality control on Chocolate Agar, Campy Agar, and CPS3 Chrom Agar. There were no policies for in-house quality control for other bacteriological media. B. In a review of the laboratory binder of quality control documentation for bacteriological media the surveyor determined in-house quality control was documented for Chocolate Agar, Chrom ID Agar, MacConkey Sorbitol Agar, and Campy Agar. C. During a tour of the Microbiology laboratory at 2:35 on 1/22/2020 the surveyor observed the following bacteriological media available for use in the laboratory: Tryptic Soy with 5% Sheep Blood; MacConkey II; Chocolate Agar; Chrom ID Agar, MacConkey Sorbitol; Campy Agar; XLD agar, and GN Broth. D. The surveyor requested quality control for the media that was not included in the binder of in-house quality control and was provided with documentation of media physical inspection and manufacturer's quality control for each lot and shipment of media but no in-house quality control for GN Broth, XLD Agar, Tryptic Soy with 5% Sheep Blood Agar, and MacConkey II Agar. E. In an interview at 2:45 on 1/22/2020, laboratory employee #3 (as listed on the form CMS-209) confirmed the laboratory did not perform in-house quality control for GN Broth, XLD Agar, Tryptic Soy with 5% Sheep Blood Agar, and MacConkey II Agar. F. In an interview at 3:05 on 1/22/2020, laboratory employee #2 (as listed on the form CMS-209) stated that the laboratory does not have an IQCP for in-house quality control on GN Broth, XLD Agar, Tryptic Soy with 5% Sheep Blood Agar, and MacConkey II Agar.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Through a review of Chemistry Quality Control for March, July, and December of 2019, patient test records for December 2019, and interviews with laboratory staff, it was determined the laboratory reported a patient Ferritin result when quality control was unacceptable. Survey findings include: A. Through a review of quality control results for 19 different chemistry tests performed on the two Vitros 5600 chemistry instruments in March, July, and December of 2019, it was determined that on 12/13 /2019 both Ferritin controls (one of nineteen tests reviewed) were unacceptable. Control 1DI - Immunoassay 1-V/5600 (lot # 40971) was reported as 20.3 with an acceptable range of 14.0 to 20.0 and Control 1EI - Immunoassay 3-V/5600 (lot # 40973) was reported as 299.9 with an acceptable range of 210 to 290. Both results were flagged with 2-2s rules violated and a note stating, "SUPERVISOR OKAYED RESULT". B. A review of the laboratory test reports for patient #1398393 revealed a Ferritin result reported at 9:54 a.m. on 12/13/2019 (the date that the Ferritin controls were unacceptable). C. In an interview of 12/22/2020 at 1:10 p.m. laboratory employee #2 (as listed on the form CMS-209) confirmed a Ferritin result for patient #1398393 was reported on 12/13/2019 when quality control was unacceptable. 35659 Through review of the laboratory's policy and procedure for quality control of the Elite Pro coagulation instrument, review of the Levy-Jennings Tabular Values of quality control of Prothrombin Time (PT) assays, patient result reports and interview it was determined that the laboratory reported patient results when quality control was unsuccessful in one of three months reviewed. Findings follow: A) Review of the laboratory's policy and procedure for quality control of the Elite Pro coagulation instrument revealed two levels of control must be within plus or minus two standard deviations (SD) to be acceptable. B) Review of the laboratory's Levy-Jennings Tabular Values report revealed that the laboratory ran two levels (Level 1 and Level 3) on each shift of laboratory operation. C) Review of the Levey-Jennings Tabular Values report revealed that level three of PT Hemosil quality control material, lot # N0286060, acceptable range (34.5 to 39.7) was reported as: * 44.8 + 3.4 SD at 01:21 PM on 7/3/19 * 43.0 +2.5 SD at 01:55 PM on 7/3/19 * 36.6 -0.7 SD at 20:15 PM on 7 /3/19 (successful) Therefore only one level of quality control was acceptable until 20: 15 PM on 7/3/19. D) Review of patient results revealed that fifteen patients, identified as numbers 1 through 15 on a separate patient identification list, were performed and reported from 11:00 AM to 20:15 PM on 7/3/20. E) In an interview on 1/22/20 at approximately 10:45 AM the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that PT assay results were reported on the patients identified above prior to acceptable quality control results.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 Microbiology Policy and Procedure Manual and the Vitek II MIC (minimum inhibitory concentration) quality control documentation, lack of

	documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform MIC quality control each day tests are performed. Survey findings include: A. During a review of the Microbiology Policy and Procedure Manual it was revealed the policy for quality control of the Vitek II MIC states that sensitivity quality control will be performed every Monday (once per week). B. Through a review of Vitek II MIC quality control documentation for March, July, and December 2019 it was determined the quality control was performed weekly with additional quality control only documented when there was a quality control failure. Examples of quality control frequency are as follows: AST-ST02 tested on 7/1/19, 7/7/19, 7/8/19 (repeat), 7/14/19, 7/15/19 (repeat), and 7/21/19; AST-XN06 tested on 12/1/19, 12/8 /19, 12/15/19, 12/22/19, and 12/29/19; and AST-GP75 tested on 12/1/19, 12/8/19, 12 /15/19, 12/22/19, 12/23/19 (repeat), and 12/29/19. C. In an interview at 3:05 on 1/22 /2020, laboratory employee #2 (as listed on the form CMS-209) confirmed the MIC quality control is documented weekly and stated that the laboratory does not have an IQCP for MIC quality control.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 manufacturer's user's manual of the Elite Pro coagulation instrument, Levy-Jennings Tabular Values for Prothrombin Time assays (PT) for July 2019 , patient result reports and interview it was determined that the laboratory failed to ensure two levels of quality control material are performed every eight hours of patient testing in one of three months reviewed. Findings follow: A) The manufacturer's user's manual of the Elite Pro coagulation instrument states "controls should be analyzed at least once every 8 hour shift in accordance with good laboratory practice". B) Review of the Levy Jennings Tabular Values report revealed that quality control for PT assays was performed at 08:10 PM on 7/2/19 and not attempted again until 01:21 PM on 7/3/19, a period of over seventeen hours. Quality control was due to be performed by 04:10 AM on 7/3/19. C) Review of patient result reports revealed that PT assays were performed and reported on four patients, identified as numbers 1 through 4 on a separate patient identification list between 04:10 AM on 7/3/19 and 1: 21 PM on 7/3/19. D) In an interview on 1/22/20 at approximately 10:45 AM, the laboratory staff member identified as number 2 on the CMS 209 form confirmed that the PT assays identified above were performed and reported greater than eight hours since the last succesful performance of quality control.
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 Emergency Requests for Uncrossmatched Blood for 2019, and interview it was determined that the request for release of uncrossmatched blood in two of nineteen units released in 2019 were not signed by the requesting physician as required at 21 CFR 606.160(b)(3)(v). Survey Findings follow: A. A review of Emergency Requests for Uncrossmatched Blood Request Forms (nineteen of nineteen) for the calendar year 2019 revealed that two units of uncrossmatched blood products (Units #W0910 19 127317 and W0910 19 128619) were released for patient #1366962 on 03/01/2019 and that requests were not signed or counter signed by the requesting physician but were only signed by nursing personnel. B. In an interview on 01/23/2020 at 11:00 am., laboratory employee #2 (as listed on the CMS 209 form) confirmed that the request for emergency release of uncrossmatched blood forms had been signed by nursing staff and not by the physician.
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: Based upon a review of Mena Regional Health System provided statistics, lack of documentation, Mena Regional Health System / Laboratory Blood Bank Department "Transfusion Reaction Policy", Mena Regional Health System "Blood Components Administration" policy, Perry & Potter current edition "Clinical Nursing Skills & Techniques", MRHS Employee In Service "Skills for Administering Parenteral Fluids and Blood Products" Power-Point slide summary, the Mena Regional Health System "Transfusion Reaction:Request for Investigation" form, patient blood administration records for October and November 2019, and interview the laboratory failed to ensure transfusion reaction policies promptly identified, investigated and documented transfusion reactions for all blood products. A) Review of the Mena Regional Health Systems transfusion statistics revealed that 438 units of blood products were transfused in 2018 and 397 units of blood products were transfused in 2019. B) Upon request, the laboratory could not provide records of transfusion reaction investigations and, in an interview on 1/22/20 at approximately 02:00 PM, the laboratory staff member, identified as number 2 on the CMS 209 form, stated there were no possible transfusion reactions reported in 2018 or 2019. C) Review of the Mena Regional Health System/Laboratory Blood Bank Department "Transfusion Reaction Policy" revealed "in event that the reaction involves a rise in the patient's temperature of 2 degrees C or higher the following protocol must be followed: a. The RN shall immediately notify patient's physician and the blood bank, b. The registered nurse will complete the patient information portion of the transfusion reaction form and return it to the Blood Bank along with blood component bag, the attached transfusion set and

IV solutions when possible, c. The registered nurse will order and collect the urine specimen for a post transfusion urinalysis and send it to the Clinical Laboratory. d. The Clinical Laboratory will collect a new, properly labeled, blood sample from the patient. D) Review of the Mena Regional Health System nursing policy and procedure for "Blood Components Administration" reveals that it refers for procedure to Potter & Perry current edition " Clinical Nursing Skills and Techniques" and "if a patient experiences a reaction at any time, STOP the transfusion immediately, stay with the patient, and notify the physician". That vital signs should be recorded prior to the transfusion, at 15 minutes, 30 minutes, and hourly until the transfusion is completed. E) Review of the MRHS In-Service "Skills for Administering Parenteral Fluids and Blood Products" Power Point presentation reveals that nursing staff is informed to "stay with pt for at least the first 15 minute (50 ml) of infusion, reaction can occur at any time, even afterwards, but usually occur in the first 15 minutes (if reaction = STOP stat), Monitor VS after first 15 minutes, then every 30 minutes after increasing rate, then every hour, Any reaction: STOP the blood, run in NS to slow KVO and notify the physician and the lab" F) In an interview on 1/22/20 at approximately 1:40 PM, the hospital staff member, identified as number 1 on the separate hospital staff list who holds the position of QA Director, stated that she would recognize a possible transfusion reaction if there was a temperature increase 1 degree C above baseline, that the official nursing policy and procedure is Perry & Potter "Clinical Nursing Skills and Techniques" 9th edition, that she "doesn't know what the lab side looks like" and she "knows we have had some (possible transfusion reactions), we cut pig tails off and sent them to the lab" but she couldn't tell the number. She then called the hospital staff member, identified as number 2 on the separate staff identification list who holds the position of Nursing IT supervisor, who stated they knew of no definitions of changes in blood pressure that would trigger a possible transfusion reaction investigation. Asked if the laboratory would have access, in any form, to the vital signs registered during a transfusion the hospital staff member, identified as number 1 on the separate staff identification list, said that they didn't know. They then called the hospital staff member, identified as number 3 on the separate staff identification list who holds the position of CNO, who stated that they knew they had a possible transfusion reaction in October or November of 2019 because they were called at home and informed and they instructed staff to stop the transfusion and collect blood and urine specimens and send to lab for investigation but they couldn't remember the date or name of the patient. Surveyors requested the hospital staff member to try to identify the patient and date of the incident. G) In an interview on 1 /23/2020 at 12:48 p.m. facility staff member, identified as number 6 on the staff identification list, who is a registered nurse in ICU, was asked to explain her processes when administering blood and blood products to a patient and to explain what she consider signs and syptoms of a transfusion reaction. She stated that if the patient's temperature went over 100 degrees Fahrenheit or if a significant increase or decrease in the blood pressure occurred she would suspect a transfusion reaction. When asked what a "significant" change would be she stated that there is not anything definite. She further stated that she would stop the transfusionand call the hospitalist but not the laboratory and that she would let the hospitalist decide whether to call the lab. On 1/23 /2020 at 1:05 p.m. the surveyor interviewed a facility staff member identified as number 7 on the staff identification list, who is a registered nurse (charge nurse) in the med/surg unit. In the interview she stated that she would suspect a transfusion reaction if the patient's temperature changed by a degree or if the blood pressure increased or decreased by 20. She stated that she would notify the laboratory and the physician and that the laboratory would come draw blood from the patient and get a "tag" from the blood. Due to lack of specific written policies for monitoring patients during transfusion the nursing staff did not make consistent statements regarding transfusion

reaction signs and symptoms. H) In an interview on 1/22/20 at approximately 02:30 PM, laboratory testing personnel, identified as number 5 on the CMS 209 form, stated that they had not received a request for transfusion reaction investigation, that they remember an instance when a unit was brought back to the laboratory but there was no transfusion reaction investigation initiated. I) In an interview on 1/23/20 at approximately 08:45 AM, the hospital staff member, identified as number 3 on the separate staff identification list, stated that they were not able to identify the possible transfusion reaction that they had mentioned on the previous day but they thought is was a outpatient who declined the transfusion and no blood was given. When shown the "Transfusion Reaction: Request for Investigation" form, they indicated that it was not an official form and made a copy. J) A review of the Mean Regional Health System (MRHS) policy Skills for Administering Parenteral Fluids and Blood Products revealed the nursing personnel training in-service on Blood Administration and Blood Transfusion Reactions:" 1. Sign and Symptoms of Reaction: Statement of "not feeling right" Chills Fever Low back pain Pruritis Hypotension N/V (Nausea/Vomiting) Decreased urine output Chest pain "Dyspnea" 2. If you suspect a reaction: STOP infusion immediately KVO (Keep vein open) with NS (Normal Saline) and notify doctor and blood bank immediately Monitor VS (Vital Signs) and urine output q15m (every 15 minutes) Provide reassurance to the patient Watch for S&S (Signs and Symptoms) of shock K) Transfusion History of Patient #80925: Source Nursing Notes from Nursing Personnel #5 On 11/14/19 patient #80925 was admitted to the hospital. On 11/15/19 at 0707 patient #80925 had a Hemoglobin of 9.4 g/dl and Hematocrit of 30%. At 0847 on 11/15/19 patient's Hemoglobin was 6.1 g/dl and Hematocrit 20%. The physician was notified by nursing personnel #4 (as identified on personnel worksheet #1) and a- Crossmatch for three units of Packed Red Blood Cells was ordered. On 11/15/19 at 1408 unit W091019361687 (A positive) was started with pre-transfusion vitals: Temperature 98.3, Pulse: 100, Blood pressure 104/61 and Respirations: 18. At 1414 on 11/15/16 patient #80925 stated "I'm burning up". Nursing personnel #5(as listed on staff identificatin list) stated" patient emphatically c /o being hot and burning up. Temperature is increased from start of transfusion. Physician notified. Blood Stopped. At 15:10 on 11/15/19 blood was restarted by nursing personnel #5 and vitals was taken: Pulse: 104, Blood Pressure: 106/49, Respirations: 18, no temperature was recorded by nursing personnel #5. At 17:22 on 11/15/19 per nursing personnel #5 "patient c/o headache and bodyaches, moaning and groaning loudly." Pain medications administered as ordered." Nursing personnel failed to notify the laboratory or Blood Bank of possible transfusion reaction as per nursing training policy. Patient #80925 received 2 more units of Packed Red Blood Cells: Unit W091019361700 (A positive) transfused on 11/16/19 at 1132 and unit W091019378528 (A positive) transfused at 2147 on 11/16/19. L) Through a review of blood administration records for October and November 2019 involving 20 patients receiving 54 units of packed red blood cell (PRBC) revealed that on 13 of 54 transfusions were missing vital sign recordings as required by policy and procedure. M) The following vital sign changes were noted: Patient ID DATE UNIT # FINDINGS NOTED 83696 11/10/19 wo91019351330 Pre systolic BP 135 15' systolic BP 118 80925 11/15/19 wo91019361687 15' pt complained "I am burning up" 132844 11/1/19 wo91019277649 Pre systolic BP 113 Post systolic BP 145 1396077 11 /20/19 wo91019350548 Presystolic BP 139,15'systolic BP 122 Post systolic BP 109 Because of inconsistencies between laboratory and nursing policy and procedure, inconsistency in understanding of changes in vital signs and other symptoms that might indicate a possible transfusion reaction, missing vital sign measurements as required by policy, and the findings upon reviewing a sample of tranfusion records it was determined that the facility transfusion reaction policies failed to promptly identify, investigate and document transfusion reactions for all blood products. This

	represents an immediate jeopardy to patients receiving blood and blood products at the facility.
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 2019 (12 of 12 months) Vitek 2 Compact QC Log, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when quality control failed to meet the laboratory's established criteria. Survey findings include: A. A review of the corrective actions documented for weekly MIC (minimum inhibitory concentration) on the Vitek 2 Compact QC Log for 2019 revealed that on 3/25/2019 Strep pneumo (ATCC49619) failed. It was repeated on 3/26/2019, 3/27/2019, and 3/28/2019. There was no corrective action documented for the failures. The only action documented was "reset-up" until the quality control passed on the fourth run. On 10/20/2019 E. faecalis (ATCC51299) failed. It was repeated three times on 10/21/2019, 10/22/2019, and again on 10/22/2019. There was no corrective action documented for the failures other that "re set-up". On 11/25/2019 Strep pneumo (ATCC49619) failed. It was repeated on 11/26/2019, 11/27/2019, 11/28/2019, and 11/29/2019. There was no corrective action documented for the failures. The only action documented was "reset-up" until the quality control passed on the fifth run. Weekly Quality Control for MIC failed multiple times without documented corrective actions in three of 12 months reviewed. B. In an interview at 2:45 on 1/22/2020, laboratory employee #3 (as listed on the form CMS-209) confirmed the Vitek 2 Compact QC Log was the only documentation of corrective actions and that no other corrective actions are documented for the MIC failures. 35659 Through review of the laboratory's Levy-Jennings Tabular Value reports, patient result reports, lack of documentation and interview it was determined that the laboratory failed to evaluate patient results to the last acceptable quality control performance for fifteen of fifteen patients tested for Prothrombin Time (PT) assays after unacceptable quality control performance. Findings follow: A) Review of the Levy-Jennings Tabular Value report for PT assays revealed the following findings for level 3 of Hemosil quality control material lot # N0286060 with an acceptable range of 34.5 to 39.7: * 08:10 PM on 7/2/19, result 38.4, + 0.2 SD acceptable, *01:21 PM on 7/3/19, result 44.8, +3.4 SD, unacceptable, * 01:55 PM on 7/3/19, result 43.0 + 2.5 SD, unacceptable, * 08:15 PM on 7/3/19, result 36.6 - 0.7 SD, acceptable. B) Review of patient result reports revealed that PT assays were performed and reported on fifteen patients, identified as numbers 1 through 15 on a separate patient identification list, between 7/2/19 at 08:10 PM and 7/3/19 at 08: 15 PM. C) Upon request, the laboratory was unable to provide records documenting the evaluation of the PT results identified above. D) In an interview on 1/22/19 at approximately 10:45 AM, the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that the PT results on the patients identified above had not been evaluated.

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 stff interviews, it was revealed the laboratory director failed to provide overall management for the laboratory (refer to 6096, 6103, 6106, and 6107) Failure of the Laboratory Director to provide overall management for the laboratory is an immediate jeopardy to patient care.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on a review of Mena Regional Health System provided statistics, lack of documentation, Mena Regional Health System / Laboratory Blood Bank Department "Transfusion Reaction Policy", Mena Regional Health System "Blood Components Administration" policy, Perry & Potter current edition "Clinical Nursing Skills & Techniques", MRHS Employee In Service "Skills for Administering Parenteral Fluids and Blood Products" Power-Point slide summary, the Mena Regional Health System "Transfusion Reaction:Request for Investigation" form, patient blood administration records for October and November 2019, and interview the facility failed to ensure transfusion reaction policies promptly identified, investigated and documented transfusion reactions for all blood products, it was revealed the laboratory director failed to ensure problems were resolved for incomplete blood transfusion records and notification of possible transfusion reactions (refer to D3025)
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 reported on the CMS-209 form as well as interviews with staff, it was determined the laboratory director failed to assure that testing personnel are competent and maintain their competency to perform test procedures for two of five testing personnel reported on the CMS 209 form. Survey findings follow: A) Review of the personnel files for the testing

	personnel, identified as number 7 on the CMS 209 form, revealed that the competency evaluation dated as performed on 1/19/20 was not initialed by a preceptor and was not signed by the laboratory director or technical consultant. B) Review of the personnel files for the testing personnel, identified as number 5 on the CMS 209 form, revealed that competency is indicated by the letter "C" on a spreadsheet and there is no indication of the six required competency assessment criteria. C) In an interview on 1 /21/20 at approximately 02:00 PM, the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that the preceptor "HBT" is not the laboratory director or technical consultant and that neither competency evaluations identified above were signed by the laboratory director or technical consultant and did not indicate the six required competency assessment criteria. .
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Through a review of the General Laboratory Policy and Procedure Manual and the Chemistry Policy and Procedure Manual, lack of documentation, and interviews with laboratory staff, it was determined the current laboratory director failed to approve, sign, and date policies and procedures. Survey findings follow: The current laboratory director failed to approve, sign, and date the General Laboratory Policy and Procedure Manual and failed to approve sign and date the lactate test procedure as cited at D5407.
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 identified on the CMS 209 form. Findings follow: 1. Upon review, personnel files for testing personnel identified as numbers 3 through 7 inclusive on the CMS 209 form did not contain written authorization by the laboratory director to perform procedures and examinations. 2. 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 3 through 7 inclusive on the CMS 209 form. 3. In an interview on 1/21/20 at approximately 1027, the laboratory

	staff member, identified as number 2 on the CMS 209 form, confirmed that no written authorization to perform procedures or examinations was present and indicated a lack of knowledge of the requirement.