Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047176	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Health System	511 Ne 10th St, Abilene, KS	

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
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: Based on review of laboratory policies/procedures, lack of quality control (QC) results and interview, the laboratory failed to check each shipment of blood culture media with controlled organisms to ensure the media supported intended growth and/or the intended response. Findings: 1. A review of the laboratory's procedure for Automated Blood Cluture Bactec 9050 under section IV Quality Control (QC) revealed the following statement: Test each shipment of media for performance through the use of a postive and negative vial test. Two positive vials should be inoculated with 1.0 mL of a 0.5 McFarland Standard of Escherichia coli and Staphylococcus aureus prepared from a fresh 18 - 24 h culture. These vials and an uninoculated vial should be logged into the instrument and tested. The inoculated vials should be detected as positive by the instrument within 72 hours. The negative control vials should remain negative throughout the entire testing protocol. This verifies that the media were not subject to adverse storage or shipping conditions prior to receipt in the laboratory. 2. No documentation of new shipment media QC testing was made availible at the time of survey. 3. Interview with Technical Supervisor (TS) #2 on April 21, 2021 at 1:30 p.m. confirmed the lab was not performing quality control on each batch of media with controlled organisms to ensure the media supported intended growth and/or the intended response.

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: Based on review of immunohematology crossmatch procedures, transfusion service testing record, blood bank quality assessment monitor documents, emergency transfusion requests, transfusion reaction investigation report and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system immunohematology. Findings: 1. Review of the Antiglobulin crossmatch procedure, Interpretation of Results states: Incompatible Crossmatches will be repeated. If still incompatible the specimens will be referred to Red Cross in Wichita. 2. Review of the transfusion service testing record page (8/26/2020 to 9/1/2020) for blood type, antibody detection, and compatibility testing for a patient documented for a suspect transfusion reaction revealed one of three units crossmatched as incompatible with a 2+ reaction. No repeat crossmatch is documented. Additional comment listed as: Not Given. No documentation of specimen referral to Red Cross. No documentation of quarenteen or sequestering of incompatible unit. No documentation of review by Technical Supervisor (TS)#1, who is also the Laboratory Director is present on this testing record page. 3. Patient was trasnfused with the 2 compatible units on 2 different dates: 8/30/2020 and 9/2/2020. Both transfusions were stopped before completion due to suspected transfusion reaction. Documentation for each suspected transfusion reaction laboratory investigation form revealed no documentation of suspect unit (not given), incompatible testing results, or Red Cross results for referral required per procedure. 4. Both investigational documents include an interpretation which states: No evidence of a hemolytic transfusion reaction and are signed by Clinical Consultant (CC) #3. 5. Review of the transfusion service testing record page (9/4/2020 to 9/9/2020) for blood type, antibody detection, and compatibility testing for a patient documented for emergency release of uncrossmatched blood revealed a notation: Type/screen & X-match not performed Emergency Release forms signed. No documentation of why testing was not performed was made available at the time of survey. No documentation of review by Technical Supervisor (TS)#1, who is also the Laboratory Director is present on this testing record page. 6. General supervisor (GS) stated that the laboratory was unable to obtain a specimen from the patient, who expired. 7. No documentation of investigational follow up for this emergency release was made available at the time of survey. 8. Review of the Blood Bank Quality Assessment Monitors log for 2020 contained check marks for all quality indicators. Included in the indicators listed were: BB log/worksheet checked for accuracy and completeness, Transfusion reaction work-ups reviewed for completeness and pathologist review, and Emergency transfusion documentation reviewed for completeness. No documentation was availible at the time of survey for investigation into failures to follow procdure or incomplete testing documention No documentation of review by TS#1 is present on this log. 9. Interview with GS April 21, 2021 at 2 p.m. confirmed, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system immunohematology.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, review of laboratory records, observation, and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791