Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449946	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Healthcare	708 N 18th Street, Marysville, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of performance verification documentation for the Ortho Clinical Diagnostics Vitros 5600 chemistry analyzer, non-waived test list and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of the verification documentation of the Ortho Clinical Diagnostics Vitros 5600 chemistry analyzer, S/N 56004074, revealed the laboratory performed an instrument verification in July 2021. The laboratory started reporting patient test results in August 2021 2. The KS-CLIA-PS01, non-waived test list provided at the time of survey, listed 48 analytes as performed on the Ortho Clinical Diagnostics Vitros 5600. Annual test volumes for the 48 analytes listed as 143,379 tests. 3. No documentation for verification of the manufacturer's normal values were available for 48 of 48 analytes at the time of survey. 4. Interview with General Supervisor #1 (GS#1) on 4/13/22 at 1:15 p.m. confirmed, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

	(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Review of 2020, 2021 and to date of survey blood bank temperature monitoring records, lack of procedure, lack of alarm check records, and interview, the laboratory failed to regularly inspect the alarm system for the storage of blood products. Findings: 1. Review of monitoring records found 24 hour monitoring system in place with computerized graphs for temperature records. Records reviewed showed acceptable temperatures were maintained. 2. GS #1 stated that the system monitored the temperatures and would send laboratory staff a text alert if the temperature went out of range. 3. Surveyor requested records of high and low alarm checks. GS#1 stated the alarm system was not regularly checked. 4. Surveyor asked for policy for temperature alarm checks. GS#1 stated the laboratory did not have a policy for testing the blood bank storage alarm system. No documentation of an alarm check was provided from 1/10/2020 to 4/13/2022. 5. Interview with GS #1 on 4/13/22 confirmed, the laboratory failed to regularly inspect the alarm system for the storage of blood products.