Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047368	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Morton County Hospital	445 Hilltop, Elkhart, 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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of quality control (QC) records, lack of documentation and interview with the technical consultant #1 (TC#1), the laboratory failed to document QC for Gram Stains for positive and negative reactivity prior to use for patient testing. Findings: 1. Review of the QC records for Gram Stain revealed no QC testing had been performed since 5/20/21. Exact date not available. 2. The current documentation for the Gram Stain QC was not made available at the time of survey. 3. Interview with TC#1 on 2/8/23 at 10:45 a.m. confirmed, the laboratory failed to document QC for Gram Stains for positive and negative reactivity prior to use for patient testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by:

	Based on review of approved reference ranges in the laboratory "Hematology Reference Range" procedure manual and interview with the technical consultant #1 (TC#1), the laboratory failed to ensure the test report included correct normal ranges and unit of reports as determined by the laboratory "Reference Range" policy at time of survey. Findings: 1. Review of the patient reports from the Laboratory Information System (LIS) revealed 18 out of 18 parameters for normal ranges and unit of reports did not correctly match those reference ranges for the complete blood count (CBC) test in the laboratory "Reference Range" procedure manual. LIS patient report (Unisex): WBC 3.6 - 10.7 10*3/uL RBC 4.4 - 5.9 10*6/ul HGB 13.0 - 18.0 g/dL HCT 40 - 52 % MCV 80.0 - 98.0 fL MCH 26.0 - 34.0 pg MCHC 31 - 37 g/dL PLATELETS 140 - 440 10^3/uL NEUT % None % LYMPH % None % MONO % None % EOS % None % BASO% None % NEUT # None, No Unit of Report LYMPH # None 10^9/L MONO # None 10^9/L EOS # None, No Unit of Report BASO # None, No Unit of Report Procedure Manual Parameters (Unisex): WBC 2.5 - 20,000/cumm RBC 3.0 - 6.0 mil/cumm HGB 8.0 - 18.0 gm/dL HCT 24.0 - 54.0 % MCV 72.0 - 105.0 cumm MCH 30.0 - 36.0 pg MCHC 30.0 - 36.0 gm/dL PLT 75 - 500,000/mm3 Neut 30.0 - 90.0 % Lymph 10.0 - 45.0 % Mono 1.0 - 10.0 % Eos 0.5 - 10.0 % Baso 0.1 - 3.0 % LUC 0.0 - 3.5 % Neut# None Listed Lymph# None Listed Mono# None Listed Eos# None Listed Baso# None Listed 2. Interview with TC#1 on 2/8/2023 at 11:20 a.m. confirmed, the laboratory failed to ensure the correct reference ranges and unit of reports approved in the "Reference Range" procedure manual were in correlation with the LIS patient report.