Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0648241	04/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Nemaha Valley Community Hospital	1600 Community Drive, Seneca, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the policy "Normal Reference Ranges" and interview with general supervisor (GS) #1, the laboratory failed to include five of the 24 of the reference ranges (normal values) for complete blood count (CBC) that are reported and listed one incorrect reference range in the policy. Findings: 1. Review of the normal reference ranges policy revealed the procedure did not include accurate lymphs % for male patients. a. Policy lists range of 21.8-23.1%. Test report lists 21.8-53.1%. b. Surveyor asked GS #1 which value is correct. GS #1 confirmed that 53.1%

	is the correct value, based on verification study. 2. Review of normal reference ranges policy revealed the mean corpuscular volume (MPV), red cell distribution width coefficient of variation (RDW-CW), red cell distribution width standard deviation (RDW-SD), automated immature granulocytes % and immature granulocytes auto were not present in the policy. a. Surveyor asked GS #1 about the missing ranges. GS #1 confirmed they were missing from the policy. 3. Interview with GS #1 04/02/2025 at 3:45 p.m. confirmed the laboratory failed to include five of the 24 of the reference ranges (normal values) for complete blood count (CBC) that are reported and listed one incorrect reference range in the policy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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: Based on review of instrument type and test settings, current reagent lot package insert, lack of current reagent lot evaluation data, and interview, the laboratory failed to provide documentation to prove they followed manufacturer's instructions for the patient normal geometric mean instrument settings in prothrombin time testing prior to reporting patient results. Findings: 1. Prothrombin time testing is performed on the ACL top using thromboplastin reagent. 2. ACL top instrument settings for prothrombin time testing showed thromboplastin reagent lot #N0148424, expiration 01 /31/2026, ISI setting of 0.99 and normal patient geometric mean set at 11.5 seconds. The last modification date was 06/01/2024. 3. The surveyor requested documentation of the normal patient geometric mean for lot # N0148424. No documentation of the determination of the normal patient geometric mean was provided at the time of survey. 4. Review of patient data revealed 845 patient results were reported from 06/01 /2024 to 04/02/2025. 5. Interview with General Supervisor (GS) #1 on 04/02/2025 at 3:25 p.m. confirmed, the laboratory failed to provide documentation to prove they followed manufacturer's instructions for the patient normal geometric mean instrument settings in prothrombin time testing prior to reporting patient results.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with GS #1, the laboratory failed to include the test report date and units of measure for mean corpuscular volume

	(MCV) on the patient test reports. Findings: 1. Review of a three patient test reports revealed the performing laboratory's test report date was not on the patient test reports. 2. Review of two patient test reports revealed the performing laboratory's test report did not include a unit of measure for MCV. 3. Interview with GS #1 on 04/02 /2025 at 3:45 p.m. confirmed, the laboratory failed to include the test report date and units of measure for mean corpuscular volume (MCV) on the patient test reports.
D5807	TEST REPORT CFR(s): 493.1291(d) (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 policy "Normal Reference Ranges" and interview GS#1, the laboratory failed to ensure the test report included correct normal ranges as determined by the laboratory policy. Findings: 1. Review of the patient reports from the Laboratory Information System (LIS), revealed four out of 24 parameters for normal ranges did not correctly match those reference ranges for the complete blood count (CBC) test in the laboratory "Normal Reference Range" policy. Patient report: (Male) WBC 4.23-9.00 MONO ABS 0.300-82.00 BASO ABS 0.10-0.80 Ranges stated in policy: (Male) WBC 4.23-9.07 MONO ABS 0.30-0.82 BASO ABS 0.01-0.08 Patient report: (Female) BASO ABS 0.00-0.80 Range stated in policy: BASO ABS 0.01-0.08 2. Interview with GS #1 on 04/02/2025 at 3:45 p.m. confirmed, the laboratory failed to ensure the test report included correct normal ranges as determined by the laboratory policy.