Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385322	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
June E Nylen Cancer Center	230 Nebraska Street, Sioux City, IA	

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
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: Based on review of coagulation reagent verification records, observations of the coagulation instrument, review of coagulation analyzer performance specification records, review of chemistry quality control records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10: 45 am on 11/29/2022, the laboratory failed to meet the analytic systems requirements for: test system/equipment/reagent verification as specified in the standard D5411; establishment of test system performance specifications as specified in the standard D5423; and performing two control materials of different concentrations as specified in the standard D5447.
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: A. Based on observation of the coagulation instrument and reagents in use, review of the laboratory's Test System List and the Cascade M Operator's Manual, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 11/29/2022, the laboratory failed to use the correct prothrombin time reagent as indicated by the manufacturer's instructions for the Helena Laboratories Cascade M coagulation instrument. The findings include: 1. Review of the laboratory's Test System List and observation of the coagulation instrument indicated the laboratory performs prothrombin time (PT) testing on the Helena Laboratories Cascade M coagulation instrument. 2. The Helena Laboratories Cascade M Operator's Manual stated to "Use only Helena reagents designed for use with the Cascade system." 3. At the time of the survey, the laboratory had in use Siemens Dade Innovin prothrombin time reagent (lot number 549769, expiration 01/30 /2023). Personnel identifier #1 confirmed that the laboratory did not have Helena Laboratories reagents for use with the Cascade M coagulation instrument. B. Based on review of coagulation reagent verification records, observation of the coagulation instrument, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 11/29/2022, the laboratory failed to program the correct normal patient mean into the coagulation instrument and to verify the manual calculation of the international normalized ratio (INR) for one out of one lot number of prothrombin time reagent (lot number 549769, expiration 01/30/2023). The findings include: 1. The laboratory began using prothrombin time reagent lot number 549769 (expiration 01/30/2023) on 10/24/2022. 2. Review of the coagulation reagent verification records for prothrombin time reagent lot number 549769 (expiration 01/30/2023) indicated that the laboratory established a normal patient mean of 9.9 seconds. 3. Observation of the coagulation instrument indicated that the laboratory programmed a normal patient mean of 10.1 seconds in for prothrombin time reagent lot number 549769 (expiration 01/30/2023). 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory had the wrong normal patient mean programmed into the coagulation instrument. In addition, the laboratory did not have documentation of a manual check of the INR.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's Test System list, the Cascade M Operator's Manual, the Cascade M performance specification records, observation of the coagulation instrument, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 11/29/2022, the laboratory failed to establish the performance specifications of analytical sensitivity

	and analytical specificity for the Helena Laboratories Cascade M coagulation instrument. The findings include: 1. Review of the laboratory's Test System list and observation of the coagulation instrument indicated the laboratory performs prothrombin time (PT) testing on the Helena Laboratories Cascade M coagulation instrument. 2. The Helena Laboratories Cascade M Operator's Manual stated to "Use only Helena reagents designed for use with the Cascade System." 3. At the time of the survey, the laboratory had in use Siemens Dade Innovin PT reagent. Refer to D5411. 4. Review of the Cascade M performance specification records indicated that the laboratory used Innovin PT reagent to establish performance specifications for the test system. 5. Personnel identifier #1 confirmed that the Helena Laboratories Cascade M instrument performance specification records did not include establishment of analytical sensitivity or analytical specificity.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Vitros XT 7600 quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:50 am on 11/29/2022, the laboratory failed to perform two levels of QC each day of patient testing for the analyte, iron, for eight out of 22 days of patient testing reviewed from 06/01/2022- 06/30/2022. The findings include: 1. Review of QC records for the analyte, iron, indicated that the laboratory only performed one level of QC (level 1) on the following days of patient testing in June 2022: 06/03, 06 /06, 06/07, 06/08, 06/09, 06/10, 06/13, and 06/14. 2. The laboratory performed iron testing on a total of 33 patients during this time period. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional QC records for the analyte, iron, for the dates listed above.