Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2135929	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Carolinaeast Hematology/Oncology	1010 Medical Park Avenue, New Bern, NC	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and staff interview on 8/21/19, the laboratory failed to follow the manufacturer's instructions for proper storage of Iron Calibrator Kits. Findings. 1. At 1:45 p.m. on 8/21/19, the surveyor observed several boxes of Siemens Dimension Iron Calibrator on the door of Refrigerator #5 in the laboratory. The daily temperature monitoring log referenced the refrigerator's acceptable temperature range as 2-8 Degrees Celsius (C). 2. The manufacturer's storage requirements for proper storage of the Iron Calibrator Kits is 15-25 Degrees Celsius (C). 3. The surveyor found stored under these conditions one box of Iron Calibrator, Lot #: 8JN060, with Exp. Date: 2020-03-01; and, 3 boxes of Lot #: 9BN054, with Exp. Date: 2020-08-01. During interview at 1:50 p.m. with laboratory manager revealed that the laboratory was not aware of the manufacturer's specific storage requirements for Iron Calibrators.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information

	required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of a random patient test report, and interview with staff on 8/21/19, the laboratory director failed to ensure that the laboratory's Total Prostatic Specific Antigen (TPSA) test reports included the identity of the assay used. Finding: The laboratory performed Total Prostatic Specific Antigen (TPSA) testing using a Heterogeneous Immunoassay Module for Siemens Dimension clinical chemistry system. The manufacturer's product insert (REF RF451) for this test reads in the section entitled, "WARNING: ...The concentration of TPSA in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physicians must include the identity of the PSA assay used...". Review of a random computer generated patient test report (EMRN #: 137807) revealed that the test report referenced the Siemens EXL 200 analyzer, but it did not include the test method used for PSA in the report. During interview at approximately 1:00 p.m., the laboratory manager confirmed that the TPSA method was not included in patient test reports.