Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0662367	03/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Carolina Medical Center	One Medical Drive, Benson, 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
D0000	A validation survey was conducted March 11, 2026, with standard level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient records, and confirmed in an interview with the Technical Consultant, the laboratory failed to follow their own policy and procedure for 3 of 4 patients with abnormal complete blood count (CBC) results. Findings: 1. The laboratory policy titled "Abnormal Differential Policy" stated " ...It is the policy of Eastern Carolina Medical Center to address abnormal differential counts and to take appropriate action ...Abnormal differentials will be repeated. If repeat is abnormal the specimen will be confirmed by microscopic by sending the specimen to the reference laboratory. The attending physician will make the informed decision as to send the specimen to the reference laboratory ..." 2. The laboratory procedure titled "Sysmex Procedure" stated " ...VIII. Reporting Abnormal Results to Physicians: All specimen {sic} resulted with a positive alert or with a panic value will be ran again for confirmation of results. If deemed necessary by the Physician, the sample will be sent out to reference lab for verification ..." 3. Review of patient CBC test records from 03/09/2026 and 03/10/2026 revealed the following 3 patients with a "positive alert" (abnormal) result: a. Patient ID 10400330 Test results directly from the Sysmex XN-1000 revealed: Specimen tested 03/09/2026 at 10:02 am with a positive "Macrocytosis" alert. Specimen repeated 03/09/2026 at 10: 06 am with the same alert. Test results from the laboratory's information system (LIS)

	did not indicate a positive or abnormal result. b. Patient ID 10400362 Test results directly from the Sysmex XN-1000 revealed: Specimen tested 03/09/2026 at 11:38 am with a positive "Lymphopenia" alert. Specimen repeated 03/09/2026 at 11:39 am with the same alert. Test results from the laboratory's information system (LIS) did not indicate a positive or abnormal result. c. Patient ID 10400622 Test results directly from the Sysmex XN-1000 revealed: Specimen tested 03/10/2026 at 03:07 pm with a positive "Microcytosis and Hypochromia" alert. Specimen repeated 03/10/2026 at 03: 13 pm with the same alert. Test results from the laboratory's information system (LIS) did not indicate a positive or abnormal result. 4. In an interview on 03/11/2026 at 11: 56 am, the Technical Consultant (TC) was asked how the providers received CBC results. The TC stated that the providers see testing results from the LIS. The TC was asked how positive or abnormal CBC results were communicated to the providers in order to make an "informed decision" about sending the specimen to a reference laboratory. The TC stated that the providers were not aware of the positive or abnormal results. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and confirmed in an interview with the Technical Consultant, the laboratory failed to ensure manufacturer's room temperature specifications for 30 of 30 blood collection tubes. Findings: 1. During a tour of the laboratory's "drawing room" on 03/11/2026 at 10:03 am, the following blood collection tubes were observed stored in racks: a. 12 Becton Dickinson serum separator tubes (SST) collection tubes; Lot number 5160812; Expiration date 05/31/2026. b. 6 Becton Dickinson Sodium Citrate (blue top) collection tubes; Lot number 5169796; Expiration date 03/31/2026. c. 12 Becton Dickinson serum (red top) tubes; Lot number 5241150; Expiration date 08/31/2027. 2. Review of the manufacturer's instructions for storage, indicated on the label of each tube, revealed a specified room temperature of 4C-25C. 3. In an interview on 03/11 /2026 at 10:10 am, the Technical Consultant was asked to provide documentation of room temperature monitoring for the area. No documentation was provided. The Technical Consultant confirmed that the temperature of the area was not monitored or documented.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent

	information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and confirmed in an interview with the Technical Consultant (TC), the laboratory failed to label 5 of 5 vials of control material with the revised expiration date. Findings: 1. During a tour of the laboratory area on 03/11/2026 at 10:03 am, observed in the TOSOH room refrigerator were two in-use vials (Level 1 and 2) of TOSOH Hemoglobin A1c control material, Lot number 7156. Written on each vial was "22526". Observed in the main laboratory were 3 vials of discarded XN Check complete blood count control material: Level 1; Lot number 602271101 Level 2; Lot number 602271102 Level 3; Lot number 602271103 Written on each vial was "3426". 2. The manufacturer's instructions for TOSOH Hemoglobin A1C control material stated " ...Once the control is reconstituted it can be used for 60 days when stored tightly ..." The manufacturer's instructions for XN Check control material stated " ...Open vials and vials which have been sampled by cap piercing will retain stability for 7 days ..." 3. In an interview on 03/11/2026 at 10:39 am, the TC was asked what the numbers written on the vials designated. The TC stated that the numbers were open dates for the control material. The TC confirmed that the laboratory failed to label each vial with a revised expiration date per manufacturer's instructions.