

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0242239	<b>(X3) Date Survey Completed</b>  04/09/2019
<b>Name of Provider or Supplier</b>  Ecu Health Multispecialty Clinic	<b>Street Address, City, State</b>  101 Clinic Drive, Tarboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer package inserts and testing personnel (TP) interview 04/09/19, the laboratory failed to label expiration dates on opened and in use quality control (QC) material. During tour of laboratory at approximately 3:30 p.m. surveyor observed multiple bottles of opened and in use QC material in laboratory refrigerator located in main laboratory area. The bottles of QC material were not labeled with expiration dates. Review of manufacturer package inserts revealed QC material expiration dates change once the bottle of QC material is thawed and/or opened. For example: 1. Package insert for Bio-Rad Liquid Assayed Multiqual Quantify Control Levels 1, 2 and 3 states "Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius (C), this product will be stable as follows: All analytes: 14 days Except: Alkaline Phosphatase, ...9 days....Phosphorus....7 days..." 2. Package insert for Bio-Rad Lyphochek Diabetes Control Levels 1 and 2 states "Once the control is reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 to 8 degrees C." 3. Package insert for Bio-Rad Liquichek Cardiac Markers Plus Control Levels 1, 2 and 3 states "Once thawed, opened, and stored tightly capped at 2 to 8 degrees C, this product will be stable as follows: ...20 days Except:...and B-type Natriuretic Peptide (BNP); 8 days." Interview with TP#2 at approximately 3:30 p. m. confirmed the QC and calibration bottles observed by the surveyor were open and in use.</p>

<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>  CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor observation and testing personnel (TP) interview 04/09/19, the laboratory failed to discard quality control (QC) material that had expired, but was available for use. During tour of laboratory at approximately 3:30 p.m. surveyor observed the following expired QC material in laboratory refrigerator located in main laboratory area: 1. Stanbio human chorionic gonadotropin (HCG) serum control, Lot #01772, expired 01/31/19. 2. Stanbio HCG serum control, Lot #01773, expired 01/31/19. 3. Stanbio HCG serum control, Lot #01774, expired 01/31/19. Interview with TP#2 at approximately 3:30 p.m. confirmed the 3 bottles of HCG serum controls had expired and stated they don't use them often, only when a new lot number or shipment arrives. The 3 bottles of serum controls were properly disposed of.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b>  CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:  Based on review of manufacturer's instructions and review of 2017, 2018, and 2019 hematology maintenance logs 4/9/19, the laboratory failed to perform and document maintenance as required for the Sysmex XT-2000i hematology analyzer. The manufacturer specifies daily, weekly, and "Other Maintenance" which is required at specific intervals for the Sysmex XT-2000i hematology analyzer. "Other Maintenance" includes "Clean Sample Rotor Valve" at 15,000 cycles and "Replace Piercer" at 30,000 cycles. Review of 2017, 2018, and 2019 hematology maintenance logs revealed the laboratory documented "Clean Sample Rotor Valve" maintenance 12/31/18, 1/23/19, and 3/27/19. There was no documentation of "Clean Sample Rotor Valve" maintenance from 5/1/17 - 12/30/18. Review of 2017, 2018, and 2019 hematology maintenance logs revealed no documentation of "Replace Piercer" maintenance from 5/1/17 - 4/8/19.</p>
<p><b>D6091</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by:  Based on review of 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records, review of laboratory PT policy and exit interview with general</p>

supervisors (GS) 04/09/19, the laboratory director failed to ensure all PT results were reviewed to evaluate the laboratory's performance and failed to identify any problems requiring correction action. 1. Review of 2017 and 2018 API PT records revealed the following PT events had "Not Graded" results which were not reviewed or evaluated by the laboratory. a. 2017 Hematology/Coagulation - 1st event; Sample UA-02, Urobilinogen. b. 2017 Chemistry Core - 1st event; Sample CH-01, Triglycerides. c. 2017 Hematology/Coagulation - 2nd event; Sample UA-03, Urobilinogen. d. 2018 Hematology/Coagulation - 1st event; Sample BC1-01, Blood Cell Identification. e. 2018 Hematology/Coagulation - 2nd Event, Samples BC1-10, BC1-13 and BC1-14, Blood Cell Identification f. 2018 Hematology/Coagulation - 3rd event; Sample UA-06, Urobilinogen. Review of laboratory procedure "Proficiency Testing Policy and Procedure" revealed the policy did not include a mechanism for the review of ungraded proficiency testing results. For example; the policy states "When results are received back from API, all erroneous results are repeated and reviewed." The policy fails to define "erroneous results" and fails to include review of ungraded results. Exit interview with GS #1 and GS #2 at approximately 5:30 p.m. confirmed the "Not Graded" APT PT results were not reviewed or evaluated. They stated they were unaware not graded API results required review. 2. Review of 2017 and 2018 API PT records revealed the following PT event had an "Unacceptable" result that was not reviewed or evaluated by the laboratory. a. 2017 Chemistry Core - 1st event; Sample CH-01, Cholesterol, Total. Exit interview with GS #1 and GS #2 at approximately 5:30 p.m. confirmed the unacceptable PT result was not reviewed by the laboratory. 3. Review of 2017 and 2018 API PT records revealed the following PT events had acceptable results that were not reviewed by the laboratory. 1. 2017 Chemistry - Miscellaneous - 2nd event. 2. 2017 Immunology/Immunochemistry - 2nd event. Exit interview with GS #1 and GS #2 at approximately 5:30 p.m. confirmed the PT events had no documentation of review.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of Federal Drug Administration (FDA) database, review of laboratory procedure, review of quality control records and testing personnel (TP) and general supervisors (GS) interviews 04/09/19, the laboratory director failed to establish accurate quality control policies for serum hCG testing. The laboratory utilizes the Alere hCG Combo Cassette for serum and urine HCG testing. Review of the FDA website revealed serum HCG testing with the Alere hCG Combo Cassette is classified as moderate complexity. Review of laboratory procedure "Alere hCG Urine /Serum Test" revealed "...An external positive and negative control is required with each new lot, each new shipment, monthly as a check on storage, each new box, and each new untrained operator." The laboratory procedure fails to indicate serum HCG testing requires a positive and negative quality control each day of patient testing. Review on quality control records revealed the laboratory is performing quality control as stated in the laboratory procedure. Surveyor was unable to determine the number of patients tested for serum HCG that may have been affected. Interview with TP#2 at approximately 3:30 p.m. confirmed the laboratory performs quality control for serum and urine HCG testing as per laboratory procedure. Exit interview with GS

#1 and GS #2 at approximately 5:30 p.m. confirmed the laboratory was not aware that the serum hCG testing was moderate complexity and required quality control to be performed each day of patient testing (see D5449).

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of 2017 and 2018 proficiency testing (PT) records and review of quality assurance (QA) records 04/09/19, the laboratory director failed to ensure the laboratory's QA program was able to identify proficiency testing deficiencies found at time of survey. Review of laboratory "Quality Assurance Review - System 9: Proficiency and Split Sample Testing" revealed an annual checklist signed by the laboratory director that includes the following: 1. "Appropriate proficiency testing is done for all testing performed in the lab." 2. " Each employee who performs patient testing participates in the proficiency testing process." 3. "There are documented reviews of the graded results." The annual checklist failed to identify the following proficiency testing deficiencies found at time of survey. 1. All "unacceptable" PT results were reviewed and evaluated. See D6091. 2. "Ungraded" PT results were reviewed and evaluated. See D6091. 3. All acceptable PT results were reviewed. See D6091.