Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0242239	09/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ecu Health Multispecialty Clinic	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the TS 9/12/24, the laboratory failed to establish and follow a competency assessment policy for the TS (technical supervisor) and GS (general supervisor). Findings: Review of the laboratory's "Employee Competency Assessment and Performance Appraisals" policy revealed "... Scope: This procedure applies to competency assessment of phlebotomists, MLT/MT, Lead Techs. ... Procedure: ... The lab manager and the lead tech will be responsible for documenting and updating competencies. ..." The policy included instructions for evaluating technical competency, but did not include instructions for evaluating the competency of the TS and GS for their supervisory duties. Review of personnel records revealed the TS was evaluated for technical competency in 2023 and 2024, but supervisory duties were not included in the evaluations. Review of personnel records revealed the GS was evaluated for technical competency in 2022 and 2023, but supervisory duties were not included in the evaluations. During interview at approximately 11:35 a.m., the TS confirmed supervisory duties had not been evaluated.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation, and interview with the TS and GS 9/12/24, the laboratory failed to establish a function check protocol that ensured centrifuge speed obtained was consistent with the laboratory's requirements for microscopic urine sediment examinations. Findings: Review of the laboratory's "Urinalysis using the CLINITEK Advantus Analyzer" procedure revealed "... Microscopic Procedure: Perform microscopic on urines with positive protein, blood, nitrite or leukocytes. 1. Centrifuge the plastic tubes (each containing 10mls of specimen) at a speed of 1700rpms using the Urine Centrifuge for 6 minutes. ..." During a tour of the laboratory at approximately 4:15 p.m., the surveyor observed a sticker on the back of the "Urine Centrifuge" which stated "SPEED: 3340 (RPM at Rated Voltage)". The sticker included the initials of the person who checked the speed and the date the check was performed (4/9/24). During interview at approximately 4:45 p.m., the TS and GS stated that the urine centrifuge was provided for them by a laboratory they use for send-out testing. They stated centrifuge RPM (revolutions per minute) checks are performed by someone from outside the laboratory, and they were unaware the speed was not consistent with the speed specified in the urine microscopic procedure.