

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2156646	(X3) Date Survey Completed 10/25/2024
Name of Provider or Supplier Ecu Health Healthplex - Wilson	Street Address, City, State 3724 Raleigh Road Parkway West, Wilson, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's user manual for the Medonic M-series hematology analyzer, review of the manufacturer's reference guide for the VITROS XT 3400 chemistry analyzer, review of 2022, 2023, 2024 laboratory maintenance logs, and interview with Manger/Consultant #1 and #2 on 10/25/2024, the laboratory failed to ensure that the established room temperature for the VITROS, and the established relative humidity (RH) ranges for the Medonic and VITROS were within manufacturer's specifications. Findings: Review of the "Medonic M-series User's Manual" Section 11.2, Specifications page 83, revealed "...Humidity (noncondensing) Up to 80%..." Review of the "Reference Guide VITROS XT 3400 Chemistry System" Chapter 1, Environmental Specifications page 1-4, revealed "...Operating temperature: 15-29.5 C (59-85 F)...Site Relative Humidity: 15-75% RH noncondensing..." Review of laboratory maintenance logs, "LAB Vidant Health Plex Wilson," revealed "...Temperatures...Room 20-32c...Humidity 18-85%..." The laboratory's established room temp range "20-32c" and humidity range "18-85%" does not meet the users manual and reference guide specifications for both the Medonic hematology and VITROS chemistry analyzers. During interview at approximately 2:00 p.m., Managers /Consultants #1 and #2 confirmed temperature ranges for the VITROS and humidity ranges for the Medonic and VITROS do not meet manufacturers requirements.</p>

Manager/Consultant #1 stated the ranges were not updated with the introduction of the VITROS in the laboratory. Manager/Consultant #2 stated she was not aware that the ranges were not updated.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of 15 random laboratory patient test reports from 2022, 2023, and 2024, and interview with the Manager/Consultant #1 on 10/25/2024, the laboratory test report failed to include the address where the test was performed. Findings: During interview and review of 1 of 15 test reports (MRN: 5064547) at approximately 1:25 p.m., the Manager/Consultant #1 acknowledged that the address on the patient test report was incorrect, and he confirmed that testing had been performed at this physical address. At the conclusion of the interview, the Manager/Consultant #1 stated, and I quote: ... "my preliminary conclusion about the incorrect address appearing on the patient test report was an Information Technology (IT) programming issue ...".

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of personnel records for 2022, 2023, and 2024, and interview with Manager/Consultant #1 on 10/25/2024, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for the LD, Clinical Consultant (CC), and Technical Consultant (TC) involved in the daily operation of the laboratory. Findings: Review of personnel records revealed the absence of a job description for the following positions: 1. LD 2. CC 3. TC During interview at approximately 1:12 p.m., Manger/Consultant #1 stated he didn't have job descriptions for the required positions.