

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0002717	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Concord Hospital - Franklin	Street Address, City, State 15 Aiken Ave, Franklin, NH	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to verify the accuracy of direct antiglobulin test (DAT) in 2023 and 2024. Findings include: 1. Review on 11/19/2024 of proficiency testing (PT) records from 2023 and 2024 revealed no PT enrollment for DAT. 2. Interview on 11/19/2024 with the Director of Lab Services at 12:15 a.m. confirmed the above finding and revealed the lab did not verify accuracy for DAT using other methods.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's (lab) bacteriology procedures were not approved, signed, and dated by the Laboratory Director in 2024. Findings include: 1. Review on 11/19/2024 of the lab's new procedures for Clostridium difficile (Cdiff); SARS-COV-2, Influenza A/B, and Respiratory Syncytial Virus (COV-2/Flu, RSV); SARS-CoV-2 (SARS-CoV-2 Plus); Methicillin Resistant Staphylococcus aureus and Staphylococcus aureus (MRSA/SA); Microorganisms Associated with Vaginitis and Bacterial Vaginosis Panel (MVP), revealed 4 (Cdiff,</p>

COV-2/Flu/RSV, SARS-CoV-2 Plus, and MRSA/SA) of the 5 procedures were not signed and dated for approval by the Lab Director. 2. Interview on 11/19/2024 at 10:00 a.m. with the microbiology Technical Supervisor confirmed the above finding and revealed testing for these procedures began September 8, 2024.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory (lab) failed to verify calibration every 6 months for 12 of 32 chemistry analytes performed in October 2024. Findings include: 1. Review on 11/19/2024 and 11/20/2024 of chemistry calibration verification records revealed calibration verification was performed for 32 chemistry analytes in April 2024. Further review revealed calibration verification performed in October 2024 failed to include 12 (chloride, direct bilirubin, creatinine, high density lipoprotein, iron, potassium, sodium, phosphorus, salicylate, total bilirubin, total iron binding capacity, and triglyceride) of the 32 chemistry analytes. 2. Interview on 11/20/2024 at 8:50 a.m. with Testing Personnel confirmed the above finding.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to obtain acceptable routine chemistry and endocrinology control results before reporting patient test results in 2024. Findings include: 1. Review on 11/20/2024 of control testing

performed in October 2024 for free thyroxine (FT4) and troponin revealed control failures for FT4 on 10/11/2024, 10/12/2024, 10/16/2024, and 10/18/2024 and control failures for Troponin on 10/11/2024 and 10/18/2024. 2. Review on 11/20/2024 of patient testing performed in October 2024 for FT4 and troponin revealed 3 patient test results had been reported before control testing failures had been resolved and found acceptable for FT4 on 10/16/2024 (1 patient) and 10/18/2024 (1 patient) and for troponin on 10/11/2024 (1 patient). 3. Interview on 11/20/2024 at 10:20 a.m. with the Chemistry Technical Supervisor confirmed the above findings.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory (lab) failed to perform comparison of test results for the i-STAT and Vista Dimension 500 chemistry instruments twice in 2023 and 2024. Findings include: 1. Review on 11/20/2024 of comparison studies between the i-STAT and Vista Dimension 500 revealed the last comparison study for i-STAT Chem8+ analytes (sodium, potassium, chloride, total carbon dioxide, glucose, blood urea nitrogen, and creatinine) performed on the Vista had last been performed in August 2023. There was no documentation of a second comparison for these analytes in 2023 and no documentation for any comparison done in 2024. 2. Interview on 11/20/2024 at 11:00 a.m. with Testing Personnel confirmed comparison studies had been performed 1 time in 2023 and not at all in 2024.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Supervisor failed to document semi-annual competency assessments for 1 of 2 new testing personnel in 2024. Findings include: 1. Review on 11/19/2024 of personnel records revealed 1 (TP1) of 2 new testing personnel failed to include documentation of a second semi-annual competency assessment in the first year. TP1 was hired 3/21/2023 and trained by the end of April 2023. TP1 had a semi-annual competency assessment for chemistry, hematology and immunochemistry in October 2023 and for microbiology in November 2023. There was no documentation of a second competency assessment, due by April 2024, for TP1. 2. Interview on 11/19/2024 at 10:45 a.m. with the microbiology Technical Consultant confirmed the above finding.