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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>30D0652824 | <b>(X3) Date Survey Completed</b><br><br>09/21/2023 |
| <b>Name of Provider or Supplier</b><br><br>Upper Connecticut Valley Hospital   | <b>Street Address, City, State</b><br><br>181 Corliss Ln, Colebrook, NH    |   |
| 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>  |
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| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, record review, and staff interview, the laboratory (lab) failed to follow their procedure for performing microscopic examinations of urine sediment in 2023. Findings include: 1. Observation on 9/20/2023 at 1:30 p.m. of the centrifuge used to spin urine specimens for microscopic examination of urine sediment revealed the centrifuge was set to spin at 3,300 revolutions per minute (rpm). 2. Review on 9/20/2023 of the lab's procedure titled "Urinalysis, Routine and Microscopic" effective 11/10/2021 revealed instruction on page 3 to centrifuge urine specimens at 1,500 rpm with a note stating "At greater speeds, or after prolonged centrifuging, microscopic structure tends to disintegrate." 3. Interview on 9/20/2023 at 1:30 p.m. with Testing Personnel confirmed the centrifuge was set to 3,300 rpm and the procedure states to spin at 1,500 rpm.</p> |
| <b>D5439</b>              | <p>CALIBRATION AND CALIBRATION VERIFICATION<br/>CFR(s): 493.1255(b)</p> <p>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</p>  |

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 perform calibration verification for Lithium in 2023 and calibration verification procedures completed in April 2023 for Chloride failed to cover the reportable range. Findings include: 1. Review on 9/20/2023 of calibration verifications from 2023 revealed 2 of the 5 standards used for CL calibration verification, performed in April 2023, failed to meet acceptable criteria resulting in a verified range of 115.2 to 306.1 mmol/L. There was no documentation of calibration verification procedures for Lithium in 2023. 2. Review on 9/20/2023 of the lab's reportable range for CL revealed the range in use is 15 to 400 mmol/L. 3. Interview on 9/20/2023 at 4:15 p.m. with the Lab Director and Technical Supervisor confirmed the above findings.

D5469

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 (lab) failed to document control procedures performed to establish acceptable ranges for routine chemistry and toxicology tests in 2022 and 2023. Findings include: 1. Review on 9/21/2023 of the package inserts for brain natriuretic peptide (BNP) and high density lipoprotein cholesterol (HDL) control material revealed ranges for assayed BNP control material and the target values for unassayed HDL control material: BNP Level 1 = 77.9 - 115 pg/mL BNP Level 3 = 1,391 - 1,857 pg/mL HDL Level 1, target value = 37.5 mg/dL HDL Level 3, target value = 92.5 mg/dL 2. Review on 9/21/2023 of the control

acceptability ranges for brain natriuretic peptide (BNP) and high density lipoprotein cholesterol (HDL) revealed the following acceptable ranges: BNP Level 1 = 79 - 115 pg/mL BNP Level 3 = 1,390 - 1,858 pg/mL HDL Level 1 = 24.10 - 32.10 mg/dL HDL Level 3 = 66.72 - 78.08 mg/dL 3. Review on 9/21/2023 of the lab's procedure titled "Quality Control Lot Number Change" effective 9/1/2009 revealed instruction for using and implementing assayed and unassayed controls. Instruction included how to establish ranges for unassayed control materials. 4. The lab could not provide documentation of the studies used to establish ranges in use for BNP and HDL at the time of survey. 5. Interview on 9/21/2023 on 8:30 a.m. with the Lab Director and Technical Supervisor confirmed the above findings.

**D6128**

**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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Technical Supervisors (TS) failed to perform annual competency assessments for 4 of 4 Testing Personnel (TP) in 2021, 2022 and 2023. Findings include: 1. Review on 9/20/2023 of personnel records revealed 4 TP performing high complexity testing for more than 2 years. Review of competency assessments revealed 1 of 4 TP did not receive competency assessments in 2021, 2022 or 2023; and the remaining 3 of 4 TP did not have competency assessments in 2022 and 2023. 2. Interview on 9/20/2023 at 10:15 a.m. with 2 of 2 TS confirmed the above finding.