

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 30D0652824	<b>(X3) Date Survey Completed</b> 07/26/2019
<b>Name of Provider or Supplier</b> Upper Connecticut Valley Hospital	<b>Street Address, City, State</b> 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>
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's blood gas analyzer failed to document automatic quality control (AQC) results in June and July 2019. Findings include: 1) Review on 7/26/2019 of ABL 80 Flex Co-Ox (ABL 80) analyzer quality control logs from May, June and July 2019 revealed AQC was run and results documented every 8 hours in May through June 20, 2019. Documentation of AQC results on June 21, 2019 included results at 5:00 a.m. and 1:00 p.m. but no results at 9:00 p.m. There were no AQC results documented from the June 21, 2019 at 9:00 p.m. through July 26, 2019. 2) Observation on 7/26/2019 at 9:40 a.m. of the ABL 80 analyzer revealed the analyzer was in "green" status, indicating the analyzer was in good working order. 3) Interview on 7/26/2019 at 9:40 a.m. with the General Supervisor confirmed the above findings.</p>
<b>D6051</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor failed to ensure</p>

	<p>competency assessments included assessment of test performance for 7 of 7 testing personnel performing microbiology, diagnostic immunology, chemistry, hematology, and immunochemistry testing in 2018. Findings include: 1) Review on 7/25/2019 of competency assessments for 7 testing personnel in 2018 revealed no documentation of an assessment of test performance. 2) Interview with the General Supervisor on 7/25/2019 at 12:00 p.m. confirmed the above findings and revealed the 7 testing personnel perform some testing within all specialties of testing; microbiology, diagnostic immunology, chemistry, hematology, and immunochemistry specialties.</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure that 1 of 4 new testing personnel met educational qualification requirements prior to testing patient results. Findings include: 1) Review on 7/25/2019 of personnel records revealed 1 of 4 new personnel (Staff A) had a bachelor's degree from Jamaica. Staff A's personnel record did not include an assessment of equivalency for the foreign education. 2) Interview on 7/26/2019 at 1:00 p.m. with the General Supervisor revealed the laboratory did not obtain an assessment of equivalency for Staff A's foreign education.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure 1 of 4 new testing personnel met qualifications requirements prior to performing high complexity testing. Refer to tag D6171.</p>
<p><b>D6171</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60</p>

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to provide documentation that 1 of 4 Testing Personnel met educational qualification requirements for performing high complexity testing. Findings include: 1) Review on 7/25/2019 of CMS-209 Personnel Form revealed 4 new testing personnel. 2) Review on 7/25/2019 of personnel records revealed 1 of 4 new testing personnel (Staff A) earned a Bachelor's degree from Jamaica. Staff A's personnel record failed to include an assessment of equivalency for the foreign education. 3) Interview on 7/26/2019 at

1:00 p.m. with the General Supervisor confirmed the laboratory did not obtain equivalency assessment for Staff A's foreign education.