

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0660960	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier University Of Vermont Medical Center-Mchv Campus	Street Address, City, State 111 Colchester Ave, Burlington, VT	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) 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 (LD) failed to ensure 2 of 5 contracted high complexity testing personnel hired in 2023 met qualifications requirements. Findings include: 1. Review on 1/10/2024 of 5 contracted high complexity testing personnel files revealed 2 (TP1 and TP2) of 5 files failed to include educational qualifications to meet high complexity testing. TP1's file included an "Associates in Arts - DTA" degree but did not specify the major. TP2's file included an "Associates of Science in Health Science" degree had been earned; but did not indicate whether "Health Science" was in laboratory science or medical laboratory technology. The personnel files for TP1 and TP2 did not include transcripts at the time of the onsite investigation. TP1 was a contracted employee from 4/24/2023 to 10/29/2023 and was trained in Microbiology (high complexity) and Chemistry (moderate complexity). TP2 is a contracted employee and trained in Immunohematology beginning 11/20/2023 and is currently to work to 5/26/2024. 2. Interview on 1/10/2024 at 11:35 a.m. with the Technical Specialist for Immunohematology confirmed TP2 was trained to perform high complexity testing in Immunohematology. 3. Interview on 1/10/2024 at 11:50 a.m. with the Microbiology</p>

Supervisor confirmed TP1 had been trained to perform high complexity testing in Microbiology. 4. Interview on 1/10/2024 at 11:45 a.m. with the Quality Manager confirmed the personnel files for TP1 and TP2 did not include documentation that qualifications for high complexity testing were met. The Quality Manager revealed that the lab had depended on the contracted agency to ensure qualification requirements had been met and the lab did not verify qualifications for the contracted employees.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

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.

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure personnel qualification requirements for high complexity testing were met before patient testing for 1 of 10 testing personnel in 2023 and 2024. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(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 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 (lab) failed to ensure personnel qualification requirements for high complexity testing were met before patient testing for 1 of 10 testing personnel in 2023 and 2024. Findings include: 1. Review on 1/10/2024 of 10 high complexity testing personnel files revealed 1 (TP1) of 10 files failed to include educational qualifications to meet high complexity testing. TP1's file included an "Associates in Arts - DTA" degree but did not specify the major. The personnel file for TP1 did not include transcripts or other documentation that qualification requirements were met at the time of the onsite investigation. TP1 was a contracted employee from 4/24/2023 to 10/29/2023 and was trained in Microbiology (high complexity) and Chemistry (moderate complexity). 2. Interview on 1/10/2024 at 11:50 a.m. with the Microbiology Supervisor confirmed TP1 had been trained to perform high complexity testing in Microbiology. 3. Interview on 1/10/2024 at 11:45 a.m. with the Quality Manager confirmed the personnel file for TP1 did not include documentation that qualifications for high complexity testing were met. The Quality Manager revealed that the lab had depended on the contracted agency to ensure qualification requirements had been met and the lab did not verify qualifications for the contracted employees.