Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0683984	04/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gifford Medical Center	44 South Main St, Randolph, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor (TS)/General Supervisor (GS) in 2017 and 2018. Findings include: 1) Review on 4/11/2019 of the laboratory's "Competency Assessment Program" procedure signed and dated by the laboratory director on 5/1/2017 revealed no policies and procedures to assess the TS/GS to ensure delegated and assigned responsibilities are met. 2) Interview on 4/11/2019 at 8:15 a.m. with the TS/GS confirmed the laboratory did not have policy and procedure in place to assess the competency of the TS/GS.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform testing using at least one control material every 8 hours for high complexity manual cell

	counts in 2017, 2018, and 2019. Findings include: 1) Review on 4/11/2019 of two cerebral spinal fluid (CSF) manual cell counts performed February 2019 revealed no control testing documentation. 2) Review on 4/11/2019 of the laboratory's procedures "Cell Count on Body Fluids" dated 4/3/2013 and "Semen Analysis - Fertility" dated 12 /21/2017 revealed the laboratory used a hemocytometer for CSF and semen cell counts. The procedures failed to include instruction to perform manual cell counts using a control material. 3) Interview on 4/11/2019 at 11:25 a.m. with the Technical Supervisor and Staff A (testing personnel) confirmed the laboratory did not perform manual cell counts with a control material when performing manual cell counts on patient semen and CSF specimens. 4) The laboratory performed 5 semen analysis and approximately 10 CSF cell counts in 2018.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) failed to ensure all staff performing blood gas and co-oximetry analysis were included in procedures for evaluation of competency in 2017 and 2018. Findings include: 1) Review on 4/11/2019 of personnel records revealed 5 of 5 testing personnel from the respiratory department failed to be evaluated for competency of blood gases (hydrogen concentration, partial pressure of oxygen and partial pressure of carbon dioxide) and co-oximetry (carboxyhemoglobin) analysis. 2) Interview on 4/11/2019 at 8:15 a.m. with the TS confirmed the 5 respiratory department personnel performed blood gas and co-oximetry analysis and these 5 testing personnel were not evaluated for competency for these test procedures.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisors (TS) failed to ensure competency assessments of testing personnel conducted in 2018 included assessment of test performance. Findings include: 1) Review on 4/10/2019 of proficiency testing (PT) records from 2018 revealed all PT specimens from each PT event was performed by one testing personnel. Assignments for each PT event were rotated amongst testing personnel. 2) Review on 4/10/2019 of personnel records and PT records revealed PT was the only method used for competency assessment of test performance for testing personnel in 2018. The following were not assessed for test performance of specific test systems/specialties: 10 of 13 testing personnel for

	complete blood counts, 11 of 13 testing personnel for sperm counts, 10 of 13 testing personnel for immunohematology, 11 of 13 testing personnel for fetal fibronectin, 10 of 13 testing personnel for coagulation (protime, prothrombin time, and fibrinogen), 11 of 13 testing personnel for d-dimer, 11 of 13 testing personnel for mononucleosis, 10 of 13 for serum pregnancy, and 15 of 18 for blood gases and co-oximetry. Testing personnel who did not participate in a PT even for a given test system/specialty were not assessed for test performance through alternate methods (testing previously analyzed specimens or internal blind testing). 3) Interview on 4/10/2019 at 10:00 a.m. with the TS confirmed PT was the sole source for assessment of test performance and not all testing personnel participated in PT in 2018. 4) This is a repeat deficiency from the recertification survey completed on 4/4/2017.
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 (TS) failed to evaluate the competency of one of one new testing personnel performing hematology, chemistry and microbiology testing semiannually within the first year in 2018. Findings include: 1) Review on 4/10/2019 of personnel records revealed one new testing personnel (Staff B) hired in January of 2018 and completed training for hematology, chemistry and microbiology by April 2018. There was no documentation that Staff B was evaluated for competency for test procedures in hematology, chemistry or microbiology semiannually from April 2018 to April 2019. 2) Review on 4/10/2019 of the laboratory's "Competency Assessment Program" procedure signed and dated by the laboratory director on 5/1/2017 revealed new employees will complete competency assessments within the first six months from the first day of employment. 3) Interview on 4/10/2019 at 10:00 a.m. with the TS confirmed a semiannual competency assessment had not been performed within the first year for Staff B.
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 one of one new testing personnel performing high complexity testing in 2018 and 2019 met qualification requirements. Findings include: 1) Review on 4/10/19 of personnel records revealed one of one new testing personnel hired in January 2018 failed to include documentation of qualifications for high complexity testing. 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, one of one new testing personnel failed to meet qualification requirements for performing high complexity testing in 2018 and 2019. Findings include: 1) Review on 4/10/2019 of personnel records revealed one of one new testing personnel (Staff B) hired in January 2018 obtained a Bachelor of Arts in "Communications Disorders." Further review of personnel records revealed Staff B was trained in all specialties of the laboratory including high complexity hematology, immunohematology and microbiology (gram stains and planting only). The laboratory failed to provide, at the time of survey, documentation of Staff B's qualifications for performing high complexity testing. Staff B completed training and began patient testing for hematology and microbiology by April 2018 and immunohematology by August 2018. 2) Interview on 4/10/2019 at 9:30 a.m. with the Technical Supervisor (TS) revealed Staff B had completed courses to sit for a medical technologist certification exam and was certified as a medical technologist through a nationally recognized organization. TS confirmed the laboratory did not obtain documentation of qualifications for Staff B to perform high complexity testing.