Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0683984	03/17/2023
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on record review, observation, and staff interview, the laboratory (lab) failed to perform quality control (QC) testing following written procedures for Bacteriology, Virology, Hematology, and Routine Chemistry testing in 2023. Findings include: 1. Review on 3/16/2023 of the lab's Quality Control Plan for the Biofire Filmarray System (Biofire) revealed QC was to be performed on each new lot/shipment of test panel kits and monthly. Test panel kits used on the Biofire include blood culture identification panel (BCID2), gastrointestinal (GI) panel, and a respiratory panel. 2. Observation on 3/16/2023 at approximately 3:00 p.m. of the lab's Biofire instrument and testing area revealed two opened lots of BCID2 panels, lot# 2GZE22 and lot# 2M1222. 3. Review on 3/16/2023 of BCID2 QC records from January 2023 to March 2023 revealed monthly QC had been performed for lot# 2GZE22 on January 21, 2023 and monthly QC had been performed for lot# 2M1222 on February 21, 2023. There were no records that QC was performed for lot# 2M1222 prior to being put into use. Review of GI QC records on 3/16/2023 from January 2023 to March 2023 revealed monthly QC had been performed for three lots, lot# 2MUY22, lot# 2KSR22, and lot# 2QTT23. QC had been performed for lot# 2MUY22 on January 23, 2023 and was labeled as monthly and lot QC. Monthly QC had been performed for lot# SKSR22 on February 12, 2023, and for lot# 2QTTT23 on March 10, 2023. The lab could not provide documentation that QC was performed for lot# 2KSR22, and lot# 2QTT23 before being put into use. 4. Interview with the Technical Supervisor on 3/16/2023 at 3:20 p.m. confirmed the above findings. 5. Review on 3/17/2023 of the lab's Quality

	Control Plan for the Cepheid GeneXpert Test System (Cepheid) revealed instruction to perform external QC for each new lot or shipment and monthly. The Cepheid is used to perform testing to identify Sars-CoV-2, Influenza A and B, and Respiratory Syncitial Virus (collectively referred to as the multiplex respiratory panel by the manufacturer when included in the same test cartridge). 6. Review on 3/16/2023 of QC records from January 2023 to March 2023 revealed QC for the current multiplex respiratory panel lot# 1000613575 was performed on January 13, 2023. There was no record of monthly QC for lot# 1000613575 after January 13, 2023 and the lot was still in use. There was no documentation of monthly QC for Sars-CoV-2 test lot# 10005455146 currently in use. 7. Interview with the Technical Supervisor on 3/16 /2023 at 2:30 p.m. confirmed QC had not been performed monthly on the Cepheid instrument. 8. Review on 3/16/2023 of the lab's policy titled "Quality Control - General" revealed the lab's acceptable QC ranges for Prothrombin Time (PT), activated Partial Thromboplastin Time (aPTT), Fibrinogen (Fib), and Troponin were the manufacturer's assayed ranges. 9. Review on 3/16/2023 of the manufacturer's package inserts for PT, aPTT and Fibrinogen QC material revealed the manufacturer's ranges for Level 1 normal control (lot# N0925618) was PT = 9.8 - 13.8 seconds, aPTT = 24.1 - 32.1 seconds, Fib = 238 - 358 mg/dL. The manufacturer's ranges for Level 3 abnormal control (lot# N0925458) was: PT = 30.6 to 45.8 seconds, and aPTT = 49.3 - 66.7 seconds (Fib not tested with Level 3). 10. Review on 3/16/2023 of the lab's Coagulation QC revealed the acceptable ranges for Level 1 normal control (lot# N0925618) was: PT = 9.6 - 13.6 seconds, aPTT = 25.5 - 33.5 seconds, and Fib = 237 - 357 mg/dL and the ranges entered for Level 3 abnormal control (lot# N0925458) was: PT = 31 - 45.4 seconds, and aPTT = 49.0 - 67.0 seconds. Further review revealed the target values (means) entered into the instrument did not match the manufacturer's state target values which resulted in the ranges not matching the manufacturer's. 11. Interview with the Technical Supervisor on 3/16/2023 at 1:45 p.m. confirmed the manufacturer's stated values for the coagulation QC specified above had not been entered correctly. 12. Review on 3/16/2023 of the manufacturer's package insert for the current Troponin QC lot# 67680 revealed the following acceptable ranges: Level 2 = 3,974 - 7,671 pg/mL, and Level 3 = 11,844 - 22, 894 pg/mL. 13. Review on 3/16 /2023 of the Troponin QC ranges set for 1 of 2 chemistry instruments (serial# ending in 616) revealed Level 2 set to 4,503 - 7,202 pg/mL and Level 3 set to 16,316 - 20,081 pg/mL. 14. Review on 3/16/2023 of the lab's QC lot change log revealed the current QC lot# 67680 was changed on 1/4/2023. 15. Interview with the Technical Supervisor on 3/16/2023 at 2:00 p.m. confirmed the manufacturer's ranges for the current Troponin QC had not been entered correctly on 1 of 2 chemistry instruments.