Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0683984	07/03/2025
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
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) (b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to demonstrate test systems used for bacteriology, mycology, parasitology, and virology testing are stabile and support the quality control plan (QCP) to perform quality control (QC) monthly. Findings include: 1. Review on 7/3/2025 of the lab's QCPs, signed by the Lab Director on 7/1/2025, for Chlamydia trachomatis and Neisseria gonorrhoeae (CT /NG) and for multiplex vaginal panel (MVP; includes bacterial vaginosis, Candida group, Candida glabrata, Candida krusei, and Trichomonas vaginalis) revealed instruction to perform QC using two levels of controls for each new lot number and shipment and monthly. 2. Review on 7/3/2025 of the lab's individualized quality control plan (IQCP) risk assessments for CT/NG and MVP revealed the lab performed in house quality control (QC) testing over the course of 32 days (4/16/2025 through 5 /17/2025) using two different lot numbers (lots 43312 and 43605) of test cartridges for CT/NG and two different lot numbers (lots 03801 and 03807) of test cartridges for MVP. Further review revealed the lab demonstrated CT/NG lot 43312 was stabile for 13 days, and CT/NG lot 43605 was stabile for 18 days through it's in-house QC testing. No CT/NG QC data was provided for 4/29/2025. The lab's in-house QC testing for MVP revealed the lab demonstrated both lots 03801 and 03807 was stabile for 16 days each. There was no data to demonstrate a lot number of CT/NG or MVP test cartridges can be stabile for 31 days. 3. Interview by electronic mail on 7/3/2025 with the Technical Supervisor confirmed the lab used two different lot numbers for

	both CT/NG and MVP risk assessment QC studies and did not obtain in-house QC data that demonstrates a single lot number of CT/NG and MVP test cartridges were tested for 31 days to support the QCP to perform QC monthly.