

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0683984	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Gifford Medical Center	Street Address, City, State 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
D5309	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to ensure the collection time is transcribed accurately for 3 of 3 test requisitions reviewed from 2025. Findings include: 1. Review on 3/26/2025 of 3 paper test requisitions for specimens revealed 3 of 3 collection times documented on the test requisitions had been entered incorrectly by lab personnel during order entry and receipt into the lab information system. Patient #1's collection date and time on the test requisition was 3/20/25 at 10:30 a.m. and had been entered by the lab as 3/20/25 at 12:27 p.m.; Patient #2's collection date and time on the test requisition was 3/25/25 at 06:15 a.m. and had been entered by the lab as 3/25/25 at 07:44 a.m.; and Patient #3's collection date and time on the test requisition was 3/25/25 at 07:00 a.m. and had been entered by the lab as 3/25/25 at 07:46 a.m. 2. Interview on 3/26/2025 at 9:20 a.m. with the Technical Supervisor confirmed the correct collection times listed above had been entered by lab personnel incorrectly.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using</p>

the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory (lab) failed to develop an individualized quality control plan (IQCP) to bacteriology, mycology, parasitology and virology conduct control testing less frequent than 2 levels each day of patient testing in 2024 and 2025. Findings include: 1. Review on 3/25/2025 of verification of performance specifications revealed new test systems 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) was both completed in August 2024. 2. Interview on 3/25/2025 at 2:10 p.m. with the Technical Supervisor revealed control testing was performed for each new lot or shipment and monthly and the lab did not develop an IQCP for the CT/NG and MVP for alternative control test frequency. 3. Review on 3/26/2025 of control records for CT/NG and MVP confirmed control testing had been performed for each new lot or shipment and every month. 4. Review on 3/26/2025 of the lab's test list revealed the test volumes for analytes in CT/NG and MVP are 1,100 and 1,500 respectively.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) 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 Supervisors failed to ensure competency assessments were performed semiannually in the first year for 3 of 3 new testing personnel in 2023 and 2024. Findings include: 1. Review on 3/25/2025 of personnel form CMS-209 revealed 6 new testing personnel performing high complexity testing. 2. Review on 3/25/2025 of personnel records for revealed 3 (TP1, TP2, TP3) of the 6 new testing personnel had performed testing for at least 1 year. Review of the competency assessments for these 3 testing personnel revealed the following: TP1 started in April 2023 and had no documentation of any competency assessments in 2023 and 2024; TP2 was employed from August 2023 to December 2024 and had 1 competency assessment done in December 2024; TP3 started 11/6/2023 and had no semi annual competency assessment. 3. Interview on 3/25/2025 at 11:10 a.m. with the Technical Consultants confirmed the above findings.