

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 47D0090944	<b>(X3) Date Survey Completed</b> 10/08/2025
<b>Name of Provider or Supplier</b> Grace Cottage Hospital	<b>Street Address, City, State</b> 185 Grafton Rd, Townshend, VT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) personnel failed to follow the lab's D-Dimer quality control (QC) procedure for 2 out of 12 months reviewed in 2024 and 2025. Findings include: 1. Review on 10/8/2025 of the lab's D-Dimer individualized quality control plan (lab procedure reference 5.0111, last revised 4/28/2025) revealed instruction to perform QC testing using 2 levels of control material for each new lot and every 30 days. 2. Review on 10/8/2025 of D-Dimer control records from October 2024 through September 2025 revealed 30 day QC testing due in December 2024 and August 2025 had not been performed. QC had been performed for cartridge lot T14965 on 11/9/2024 and was due 12/9/2024 but no additional QC was performed for this lot number; QC was performed on a new lot, T15174, on 1/3/2025. QC was performed for cartridge lot T15689 on 7/29/2025 and was due 8/29/2025 but was not performed until 9/6/2025. 3. Review on 10/8/2025 of patient test records revealed 10 patient D-Dimer tests performed using cartridge lot T14965 had been reported between 12/9/2025 and 1/3/2025; and 4 patient D-Dimer tests performed using cartridge lot T15689 had been performed between 8/29/2025 and 9/6/2025. 4. Interview on 10/8/2025 at 11:30 a.m. with the Hematology Technical Supervisor confirmed the above findings and revealed the QC for D-Dimer testing had not been monitored to ensure QC was performed with the frequency instructed in the procedure.</p>
<b>D5439</b>	<b>CALIBRATION AND CALIBRATION VERIFICATION</b>

CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory (lab) failed to perform calibration verification using at least a minimal value near the lower limit of the lab's reportable range, a midpoint value, and a maximum value and every 6 months for Vitamin B12 and Vitamin D in 2025. Findings include: 1. Review on 10/7/2025 of calibration verification records for vitamin B12 and vitamin D revealed calibration verification performed failed to include 3 levels; 1 near the lower limit and 1 near the upper limit of the lab's reportable range and a 3rd level in-between. Calibration verification for vitamin B12 performed in January 2025 included 2 levels above the reportable range and 1 below the reportable range, no level in the middle. Calibration verification for vitamin B12 was performed again 10 months later in October 2025 and included only 1 level above and 1 level below the lab's reportable range, no third level was run in the middle of the range. Vitamin D's calibration verification in January 2025 included 5 samples but the lowest value (level 1) failed to meet acceptable criteria resulting in the lowest value verified well above the lab's lower limit of the reportable range; no follow up was conducted to address the failed performance for level 1. Calibration verification for vitamin D was performed again in June 2025; this included only 1 patient sample run as a blind sample with a reference lab. 2. Interview on 10/7/2025 at 1:15 p.m. with the Chemistry Technical Consultant confirmed the above findings and revealed the lab did not have acceptable criteria for performance using blind patient specimens.