

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 47D0091900	<b>(X3) Date Survey Completed</b> 08/15/2019
<b>Name of Provider or Supplier</b> Uvmhn Porter Medical Center	<b>Street Address, City, State</b> 115 Porter Dr, Middlebury, 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>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to demonstrate it can obtain performance specifications comparable to those established by the manufacturer for 2 Hematology analyzers introduced in 2018 before reporting patient results. Findings include: 1) Review on 8/14/2019 of the laboratory's method verification records for Hematology XN-L 450 analyzer and XN-1000 analyzer revealed no signature and date of approval by the laboratory director. Further review revealed the method verification procedures for the two analyzers had been performed by the manufacturer representative in April 2018. There was no documentation that the laboratory performed its own method verification of manufacturer's performance specifications prior to patient testing. These analyzers are used for complete blood cell counts with white blood cell differentials (CBC/diff). 2) Interview on 8/14/2019 at 8:45 a.m. with Staff B (General Supervisor) confirmed the above finding. Staff B revealed the laboratory has never performed their own method verification studies prior to implementing a new test system. 3) The laboratory's annual patient CBC/diff test volume is 106,252.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p>

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform a positive and negative control for Immunochemistry testing in 2017, 2018, and 2019. Findings include: 1) Review on 8/15/2019 of Immunochemistry control records from 6/13/2017 through 6/12/2019 revealed the laboratory performed control testing every day and failed to perform a negative control for Anti-A and Anti-B antisera used for determining ABO blood type. 2) Interview with Staff A (testing personnel) on 8/15/2019 at 10:45 a.m. confirmed the above findings. 3) The laboratory's annual patient test volume for ABO blood typing is 1,395.