

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D1069533	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Horizon Health Martin Medical	Street Address, City, State 109 Pugh Street, Martin, SD	
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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/8/18. The Martin Community Health Clinic laboratory was found not in compliance with the following requirement: D5437.
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Medonic hematology analyzer maintenance records, Medonic Operator's manual, test volume form, and interview with laboratory personnel A, the laboratory failed to perform and document the calibration of the hematology analyzer every 6 months of patient testing for 23 of 23 months (August 2016 through July of 2018) reviewed. Findings include: 1. Review of the Medonic maintenance records revealed no documentation of a calibration had been performed in 23 months of 23 months reviewed. Review of the Medonic Operator's manual revealed under section 7 Calibration: "It is recommended to calibrate the instrument every 6 months." Review of the test volume form revealed 818 patient samples had been tested on the hematology analyzer in 2017. Interview with laboratory personnel A on 8/8/18 at 12: 20 p.m. revealed he was not aware calibrations had not been performed.</p>