

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D1029529	(X3) Date Survey Completed 06/06/2023
Name of Provider or Supplier Speare Primary Care	Street Address, City, State 103 Boulder Point, Plymouth, NH	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation, and staff interview, the laboratory failed to perform general chemistry quality control testing according to manufacturer's instructions in 2021, 2022 and 2023. Findings include: 1. Review on 6/5/2023 of the operator's guide for the DCA Vantage instrument revealed instruction on page 87 to perform control testing at intervals determined by the laboratory, for each new shipment of reagents, for each new lot number of reagents, each time a calibration card is scanned, whenever the laboratory questions the test results, and for training new operators. 2. Observation on 6/5/2023 at 10:00 a.m. of the laboratory revealed 2 DCA Vantage instruments and 2 lots of hemoglobin A1c test reagent cartridges (lot 0588 expires 4/30/2025 received on 5/9/2023, and lot 0593 expires 5/31/2025 received on 5/18/2023). Lot 0588 was opened and in use with 1 opened box (2 of 10 test cartridges remained) and 2 unopened boxes. There were 4 unopened boxes of lot 0593. 3. Review on 6/5/2023 of control logs for hemoglobin A1c, performed on the DCA Vantage, revealed the laboratory performed control testing using 2 of 2 DCA Vantage instruments on 4/2/21, 7/14/21, 10/13/21, 1/19/22, 4/27/22, 7/27/22, and 11/1/22. Further review of the control log revealed the controls were to be performed quarterly. There was no control testing for the first quarter of 2023 and no control testing specific for new cartridge lots or calibration observed above. 4. Interview on 6/5/2023 at 10:00 a.m. with the office manager confirmed the above findings. The office manager revealed the laboratory's policy was to perform control testing quarterly and confirmed that control testing had not been performed for each new lot or shipment or after the calibration cards were scanned.</p>