

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2094173	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Healthstate Onsite Clinic/Hsm Arlington	Street Address, City, State 605 109th Street, Arlington, TX	
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	TX00285496 An on-site complaint investigation was conducted on June 12, 2018. The complaint was substantiated.
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 surveyor observations, review of the Consult Diagnostics Quintet AC blood glucose monitoring system operator's manual, and interview with facility personnel, the laboratory failed to perform quality control each time a vial of test strips was opened for 1 of 1 vials available for patient use on June 12, 2018. The findings included: 1. Based on surveyor observations at 13:43 hours on June 12, 2018, the surveyor observed the following glucometer and test strips available for patient testing: Glucometer: Consult Diagnostics Quintet AC blood glucose monitoring system Test strips: Lot: 211691323, Expiration: 2018 - 09- 03 2. Based on review of the Consult Diagnostics Quintet AC blood glucose monitoring system operator's manual (Reorder No. 5055), under the section About Quality, states the following: "What is a Quality Control Test? To ensure proper monitoring function, it is necessary to perform a quality control test. When Should a Quality Control Test be Performed? Before executing a blood glucose test with the meter for the first time. When opening and using a new vial of test strips. When the meter is dropped or splashed with liquids. Whenever the test results are not consistent with symptoms. Whenever checking if the system is working properly. Whenever practicing testing and checking correct procedure." 3. In an interview at 14:03 hours on June 12, 2018 in the laboratory, when asked if the laboratory had performed quality control when opening and using a new vial of test strips (Lot: 211691323, Expiration: 2018 - 09- 03), the</p>

Testing Person stated she had not performed quality control on the vial that was currently available for patient testing. When asked if the laboratory had performed any patient testing with the new vial of test strips, Testing Person stated that only one (1) patient had been tested for a glucose level since that test strip vial had been opened.