

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2001260	(X3) Date Survey Completed 05/31/2018
Name of Provider or Supplier Healthstat On-Site Clinic - Reo	Street Address, City, State 5505 Airport Blvd, Boulder, CO	
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 a review of the operator's manual and staff interview, the laboratory failed to follow the manufacturer's instructions for the LifeScan OneTouch Ultra Glucose Meter. Approximately 10 patient specimens are tested annually. Findings include: a. The manufacturer requires the testing of the control solution once a week, whenever a new bottle of test strips is first opened, whenever the meter is dropped, and whenever it is suspected that the meter or test strips are not working properly. b. No documentation existed to show that the laboratory had tested the control solution once a week. c. The manufacturer requires that the control solution, meter, and test strips be at room temperature (68to 77F/20to 25C) before testing. d. No documentation existed to show that the laboratory had monitored and documented the room temperature each day of testing. e. The manufacturer requires a testing environment of 10 to 90% relative humidity. f. No documentation existed to show that the laboratory had monitored and documented the ambient humidity of the testing environment each day of testing. g. The laboratory director stated she was unaware of these regulatory requirements, and confirmed she had not been following the manufacturer's instructions for the weekly testing of the control solution, and for ensuring the environmental conditions of the testing environment as required by the manufacturer and federal CLIA regulation.</p>