Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1102438	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Healthstat On-Site Clinic	**Street Address, City, State** 4651 Charlotte Park Drive, Suite 100, Charlotte, NC	

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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on observation and staff interviews on 6/7/18 at 1:45 p.m., the laboratory failed to follow the manufacturer's instructions for the performance of waived testing. The laboratory: 1. The laboratory did not have any manufacturer's package inserts (PI) for the test performed. 2. The laboratory did not follow the manufacturer's storage and handling instructions because they did not have the manufacturer's PI. 3 The laborator did not use proper expiration date for the storage method. Findings: a. The surveyor observed at 2:45 p.m. in the One Touch Ultra Glucose storage pouch, one bottle of expired Level Control 1 control, Lot No.: 4070302, and Expiration Date: 03/2018. 4. The laborataory was not following the manufacturer's instructions for establishing quality control (QC) procedures as instructed in the PI. The laboratory did not have the manufacturer's PI for the tests performed. 5. The laboratory did not have a written policy ot procedure to address quality control failures for either internl (procedural) or external (liquid). The laboratory did not have the manufacturer's PI. 6. The laboratory did not have a policy or procedure or instructions or the manufacturer's Operator's Manual for the One Touch Ultra Glucose analyzer that explained the devices error codes that could be displayed during instrument daily startup. The did laboratory did not have copy of the Operator's Manual on site. 7. The laboratory did not have any records of testing person training for any of the test performed.