Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2075170	**(X3) Date Survey Completed** 05/14/2018
Name of Provider or Supplier Healthstat Onsite Clinic/City Of Round Rock	**Street Address, City, State** 901 Round Rock Ave Suite 300-B, Round Rock, 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	TX00285495 An unannounced on-site complaint inspection was conducted on Monday, May 14, 2018. The complaint was unsubstantiated. The laboratory is in compliance with the Conditions of Participation for laboratories with a Certificate of Waiver located in the CLIA regulations at 42 CFR part 493. A deficiency is cited at D1001.
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 surveyor observations, TrueTrack glucometer instructions for use, and interview with facility personnel, the laboratory failed to follow the manufacturer's instructions for 3 of 3 expired testing supplies identified on May 14, 2018. The findings included: 1. Based on surveyor observations at 12:23 hours on 5/14/2018 in the laboratory, the following Henry Schein Safety Lancets used to collect specimens for the TrueTrack Glucose meter were observed in the cabinet above the sink: Manufacturer: Henry Schein Safety Lancets - 28G 200 per box Penetration Depth - 1.5 millimeters Ref 900-4433 Lot: S25H94H5 Expiration: 2017-06 Elapsed expiration: 318 days (45.43 weeks) The last day glucose testing was performed was 11 /14/2017 according to the "log book". The lancets would have been expired for 137 days as of 11/14/2017. 2. Based on surveyor observation at 12:31 hours on 5/14/2018 in the laboratory, the following expired TRUEcontrol was observed to be stored in the horizontal position in the TrueTrack glucometer device case: Control: Nipro Diagnostics TRUEcontrol Lot: 5L1D55 Expiration date: 2018-02-28 Elapsed time of expiration: 75 days (10.71 total week) The bottle did not have an open date written on the bottle. The TRUEcontrol Glucose Control Instructions for use (M5BIO03 Rev.20)

	states the following: "Storage and Handling: Control must be stored upright, tightly sealed, at Room Temperature (36 - 85 degrees Fahrenheit). DO NOT REFRIGERATE OR FREEZE. Write date first opened on bottle. Discard bottle after Expiration Date (EXP) printed on bottle label or 3 months after date written on bottle. Discard any bottle that appears to be cracked or leaking." 3. Based on surveyor observations at 13: 30 hours on 5/14/2018 in the laboratory, the following TrueTrack Glucose Meter Test Strip vial was observed in the TrueTrack glucometer device case: Code: 5061 Lot: RT5061 Expiration: 2019-06-14 The TrueTrack Quality Assurance and Quality Control Reference Guide for Multi-Patient Use Facilities (2011, A9NPD21, Rev. 21. A9H01-90) states the following on page 32: "Check dates on Test Strip vial label. Do not use Test Strips 120 days past written opened date or after EXP date printed on Test Strip vial label." The Test Strip vial did not have a written open date on the vial and could not be verified to be open less than 120 days. The last day glucose testing was performed was 11/14/2017 according to the "log book". 4. In an interview at 14: 32 hours on 5/14/2018 in the laboratory, during the exit summation, the Family Nurse Practitioner (Doctorate of Nursing Practice, Registered Nurse, Family Nurse Practitioner) acknowledged the supplies had exceeded the expiration date and were available for testing and stated the laboratory did not perform blood glucose level testing very often.