Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1065992	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Healthstat, Inc Clinic	755 Roanoke Street - Suite 2d, Christiansburg, VA	

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	An announced CLIA complaint survey, VA00041712, was conducted at HealthStat Inc, Clinic on June 13, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirement. Specific deficiencies cited are as follows:
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: A. Based on a review of the laboratory's policy and procedures, testing log sheets, package inserts and an interview with the nurse practioner, the laboratory failed to follow manufacturer's instructions for quality control when performing urine dipstick testing. Findings include: 1. Review of the laboratory's policy and procedures revealed a policy, "Policy #12.00, Date: 09/01/2015, Pertains to: All Health and Wellness Centers" which states: "Meet CLIA (Clinical Laboratory Improvement Act) requirements or are provided by provided contract services from a certified lab in accordance with CLIA and maintain CLIA Waiver requirements." Review of the laboratory's policy and procedures revealed a policy, "2. CLIA Testing Documentation & Control Testing" which states: "2. Onsite Clinician (or appropriate trained designee) will perform all CLIA tests according to the manufacturer instructions. These instructions are located inside each CLIA waived test kit. 3. Onsite Clinician (or appropriately trained designee) will conduct 'Quality Control Test' at the following intervals: Upon opening a new test, Clinician preference if applicable. 4. Onsite Clinician (or appropriately trained designee) will complete the 'CLIA Quality Control Log' each time a Quality Control Test is performed. This log is located in the front pocket of the provider manual." 2. Review of package insert for the Consult

	Diagnostics 10SG Urine Reagent Strips 10 Parameter identified that the manufacturer states for quality control: "Test commercially available quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips." 3. Review of the laboratory's patient testing log sheets identified a log sheet, "URINALYSIS CLIA Waived Test Log URINALYSIS". Review of the log sheet identified documentation of one urinalysis performed on 11/8/16 and one urinalysis performed on 11/9/16 with no documentation of quality controls on the log sheet. No other documentation of urinalysis tests was provided. 4. During an interview with the nurse practioner on 6/13/18 at approximately 11:10 AM, the nurse practioner (NP) stated she/he began working at the clinic on May 17, 2018 and that she/he had performed one urine test since May 17, 2018. The NP did not remember the date of performing the urine dip test nor was there written documentation of performing the test. The nurse practioner stated, "I did not run quality control." B. Based on a review of the laboratory's policy and procedures, testing log sheets, package inserts and an interview with the nurse practioner, the laboratory failed to follow manufacturer's instructions for quality control when performing Strep A testing and the Urine Human Chorionic Gonadotropin (hCG) testing. Findings include: 1. Review of the laboratory's policy and procedures revealed a policy, "Policy #12.00, Date: 09/01 /2015, Pertains to: All Health and Wellness Centers" which states "Meet CLIA (Clinical Laboratory Improvement Act) requirements or are provided by provided contract services from a certified lab in accordance with CLIA and maintain CLIA Waiver requirements." Review of the laboratory's policy and procedures revealed a policy, "2. CLIA Testing Documentation & Control Testing" which states: "2. Onsite Clinician (or appropriate trained designee) will perform all CLIA tests according to the manufacturer instructions. These instructions are located inside each CLIA waived test kit. 3. Onsite Clinician (or appropriately trained designee) will conduct 'Quality Control Test' at the following intervals: Upon opening a new test, Clinician preference if applicable. 4. Onsite Clinician (or appropriately trained designee) will complete the 'CLIA Quality Control Log' each time a Quality Control Test is performed. This log is located in the front pocket of the provider manual." 2. Review of package insert for the "Consult Diagnostics Strep A Tests Dipsticks" revealed that the manufacturer states for quality control "It is recommended a positive and negative external control be run once per kit and as deemed necessary by your internal laboratory procedures ." 3. Review of the laboratory's patient log sheets identified a log sheet, "RAPID STREP CLIA Waived Test Log RAPID STREP". Review of the log sheet identified documentation of a test performed on 2/8/17 with no documentation of quality controls on the log sheet. No other documentation of strep tests performed was provided. 4. Review of package insert for the "Consult Diagnostics Urine hCG Tests Cassettes" revealed that the manufacturer states for quality control: "It is recommended that a hCG control (containing a 20 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance with each new lot, each new shipment, monthly as a check on storage, each new untrained operator and as otherwise required by your lab internal quality system procedures." 5. Review of the laboratory's patient log sheets revealed a log sheet, "Urine HCG CLIA Waived Test Log Urine HCG". Review of the log sheet identified no documentation of Urine hCG quality control or testing being performed. No other documentation of Urine hCG was provided. 6. An interview with the nurse practioner on 6/13/18 at approximately 11:10 AM confirmed the laboratory had not followed manufacturer's recommendations for quality control failing to perform a positive and negative external control once per kit and as deemed necessary by internal laboratory procedures for the above-specified test kits.