

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2084448	(X3) Date Survey Completed 05/24/2018
Name of Provider or Supplier Healthstat Onsite Clinic/Western Growers- Watsonvi	Street Address, City, State 150 Carnation Dr Ste 5, Freedom, CA	
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 review of the Laboratories test menu and the manufacturers package inserts on May 24, 2018 the laboratory failed to follow manufacturers' instructions for performing controls on lots or reagents or cartridges for the tests performed. Findings Include: a. The laboratory performs HbA1c on Alere Afinion, microalbuming and urinalysis on McKesson CONSULT Urinalysis strips on Clinitek 50 analyzer, Urine HcG with test kits, fingerstick point of care glucose testing with One Touch Quinotel glucose meter and strips, Flu A&B and Rapid Strep test kits. b. The control reagent for the HbA1c Alere afinion cartridges, expired on 03-2018. 1. The laboratory had no documentation of control results for lots of cartridges recieved. 2. The laboratory had no documentation of HbA1c reagent cartridge lots or expiration dates. 3. The laboratory had no documentation of HbA1c control lots or expiration dates. c. Tru-View Urine HcG; 1. The laboratory had no documentation of control results performed for cartridge lot numbers. 2. The laboratory had no documentation of cartridge lot numbers or expiration dates. d. HemeCue Hgb & Hct; 1. The laboratory had no documentation of control results performed 2. The laboratory had no documentation of reagent lot numbers or expiration dates. e. One Ultra Touch fingerstick point of care Glucose testing; 1. The laboratory had no documentation of control results performed, 2. The laboratory had no documentation of test strip reagent lot numbers or expiration dates. f. Quidel Flu A&B test kits: 1. The laboratory had no documentation of control results performed. 2. The laboratory had no documentation of test kit lots or experiation dates. g. Quidel Quick Vue Rapid Strep Test kits: 1. The laboratory had no documentation of control results performed. 2. The laboratory had</p>

no documentation of test kit lots or expiration dates. h. Micro albumin Urine: 1. The laboratory had no documentation of control results performed. 2. The laboratory had no documentation of test kit lots or expiration dates. i .McKession Urine dipstick, Microalbumin: 1. The laboratory had no documentation of control results performed. 2. The laboratory had no documentation of reagent strip lots or expiration dates. j. Storage requirements for test kits: 1. Manufacturers instructions for storage of flu A&B test kits requires the kits to be maintained at 38 - 86 degrees Fahrenheit. The laboratory had no mechanism for observing or recording the temperatures in the storage and testing location. 2. Manufacturers instructions for the HbA1c cartridges are to be stored at room temperatures of 55-77 degrees Fahrenheit, and tested at ambient temperature of 64-86 degrees Fahrenheit. The laboratory had no mechanism for observing or recording the temperatures in the storage and testing location. k. The laboratory documents the patient identity with first initial of first name and last initial of last name on patient testing results logs. a. The patient results logs do not have the year in which the testing is performed. b. The patient testing log is not reviewed and signed off by medical personnel as stated on patient testing log. l. These deficient findings were affirmed by interview with the laboratory testing personnel and the medical provider at the Clinic on May 24th, 2018 at approximately 2:30 pm. m. The laboratory reports performing approximately 5600 waived tests annually. The testing personnel and medical provider were not able to produce a complete count for each test performed at this site at the time of survey.