

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2058021	(X3) Date Survey Completed 05/08/2018
Name of Provider or Supplier Healthstat Onsite Clinic/Saif	Street Address, City, State 440 Church Street Suite 101, Salem, OR	
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: Base on review of Quality Assurance records, Quality Control logbooks, Temperature logs, and discussion with the staff the laboratory failed to follow manufactures package inserts for the waived test kits performed. Findings include: 1. The surveyor requested and the laboratory failed to provide the laboratory's policies and procedures and delegation of responsibilities for laboratory testing. 2. The surveyor requested and the laboratory failed to provide documentation of evaluations of laboratory testing personnel to ensure that they can perform each test correctly before they are allowed to report patient test results. There was no documentation that the laboratory personnel where given training when they were hired and when new test kits or system are introduced. 3. Review of refrigerator temperature logbook (2-8 degrees Celsius) from December 2015 to April 2018 shows 11 months have days that temperature readings of the storage refrigerator ranges from -5.0 to 1.0 degree Celsius. No documentation's of corrective taken to make sure reagents and vaccines were not compromised. 4. Storage temperature requirements for the following waived test kits, Consult Diagnostic Rapid Strep A, Consult Diagnostic Urine Pregnancy kit, Consult Diagnostic Blood Glucose -Quintet AC, Consult Diagnostic McKesson 10SG Urine test strips and Quidel Quick Vue Rapid Influenza test kits were not monitored. These test kits have storage requirements from 25 to 36 degree Celsius (Room temperature). No evidence of room temperature being recorded since 2013. 5. Review of the Quality Control records from 2013 to May 2018 shows the laboratory failed to perform and to follow manufacturer's package insert recommended external quality control requirements which are, each new lot shipment, each time new kit is open, and</p>

new or untrained operator/testing personnel. These external quality control requirements are most common to all the waived test kit the laboratory performs. The Quality Control records for each waived test kit are listed below. a. Rapid Strep A. quality control were performed on the following dates 07/2/2013, 11/6/2013, 11/25/2013, 02/14/2014, 05/14/2014, 07/07/2015 and 07/03/2017. b. Rapid Influenza quality controls were performed on the following dates 10/21/2013 and 10/17/2017. c. Urine pregnancy quality controls were performed on the following dates 07/02/2013, 11/25/2013 and 10/9/2017. d. Urinalysis dipstick quality control were performed 07/2/2013 and 09/20/2017. e. Blood glucose meter quality control were performed 07/2/2013, 11/7/2013 and 10/9/2017. f. Cholestech LDX quality control were performed 08/6/2013 and 08/20/2013. 6. There is no available package insert for the Consult Diagnostic McKesson 10 SG Urine Reagent Strip. 7. These findings were confirmed by the Testing Personnel and the Nurse Practitioner on 05/08/2018 @ 14:00.