

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2142357	(X3) Date Survey Completed 04/09/2018
Name of Provider or Supplier Dermatology Clinic DbA Valley View Dermatology	Street Address, City, State 5900 Inland Shores Way N Suite 202, Keizer, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based upon review of temperature records and discussion with staff, the laboratory failed to establish a written temperature plan and normal ranges for the refrigerator and room temperature. Findings include: 1. When reviewing the log book used to document refrigerator temperature, there was no temperature range for acceptable temperatures indicated in the log. 2. When asked to provide documentation of procedures for corrective action for temperature outliers, none could be provided. 3. The CONSULT HcG test the lab uses specifies a temperature range of 2-30 degrees Celcius. The lab routinely stores it at room temperature but currently no one monitors room temperature, nor is there a normal range established for room temperature to ensure it is not stored above 30 degrees.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
Based upon physical inspection of the 10% potassium hydroxide (KOH) and urine pregnancy test kit (HCG) and discussion with staff, it was noted that expired product was being used for patient testing. Findings include: 1. Upon inspection of the two (2) bottles of 10% KOH stored next to the microscope, used in making skin scraping wet mounts, it was found that both of these were expired. One in December of 2015 and the second in February of 2017. 2. Upon inspection of the test kit used for urine HCG testing, it was discovered that the test kit in use was expired as of March 31, 2018.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based upon review of procedures and discussion with staff, the laboratory has failed to write and follow a Quality Assurance (QA) plan for this laboratory. Findings include: 1. Upon request to review the laboratory's written QA plan, one could not be produced. 2. Upon discussion with staff, staff confirmed there was no QA plan established for this laboratory.