Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2142357	10/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Clinic Dba Valley View Dermatology	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based upon review of records and interview with staff, the laboratory failed to document bi-annual verification of competency for providers who perform dermatological procedures on patients in this location. Findings include: 1. The Mohs surgeon on staff at this laboratory had only one documented record of bi-annual verification or peer review in the past year, dated 09/23/2019 though he has been performing Mohs surgery at this location since 09/2018. 2. The Physician's Assistant (PA) at this site performs potassium hydroxide (KOH) mounts on a routine basis. No written documentation of bi-annual verification was able to be produced during survey 10/14/2019 for 2018 or 2019. 3. No written documentation of bi-annual verification or peer review for twwo (2) providers that perform histopathology slide interpretation could be produced during survey. 4. Staff members interviewed during survey 10/14/2019 at approximately 2 pm confirmed there were no written proficiency records on file other than the one mentioned above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual for this laboratory and discussion with staff, the laboratory failed to have a written procedure for the process of collecting and processing dermatologic biopsy specimens. Findings include: 1. There was no Standard Operating Procedure (SOP) for the collection, processing and interpretation of biopsy specimens collected at this laboratory.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient Histopathology test reports, the laboratory failed to ensure the name and address of the laboratory performing slide interpretation for Histopathology was clearly indicated. Findings include: 1. Upon review of the final Histopathology slide interpretation report for this laboratory, name and address of this location was absent. 2. Staff confirmed during interview on 10/14/2019 at approximately 1 p.m. that the name and address of this laboratory did not appear on the final patient report.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based upon review of records and interview with staff, the Laboratory Director (LD) failed to fill the responsibilities of the LD. Findings include: 1. See citations D5217, D5401 and D6094.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based upon review of records and discussion with staff, the Laboratory Director (LD) failed to ensure that a Quality Assessment (QA) program was put into place after the

	last survey. Findings include: 1. During the survey on 04/09/2018, it was noted that no QA program had been established for this laboratory by the LD. 2. This deficient practice was cited after the above survey. 3. During the survey on 10/14/2019, when requested, no documentation of an established QA program could be produced. This is a repeat deficiency. 4. Interview with staff during the 10/14/2019 at approximately 2: 30 p.m. confirmed that no QA program had been instituted since the last survey.