Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0927132	05/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
High Valley Dermatology	2085 Providence Way, Idaho Falls, ID	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review, policy and procedure review, and interview with the office manager, the laboratory failed to establish policies and procedures to ensure positive identification of histopathology tests. Findings include: 1. Record review of one of three Mohs test records, revealed that the laboratory failed to correct the specimen accession identification on the original Micrographic Surgery "EMF" report. The Mohs patient test log identified the slide as M23-048 performed on 05/11/2023. On 05/17/2023 the slide was relabeled as M23-288. 2. Record review of pathology notes (EMF) indicates that the pathologist reevaluated the patient specimen size and determined that the tissue sample was adequate to be prepared for a histopathology slide (E23-048). 3. Record review of the "EMF" report revealed the laboratory failed to generate a corrected "EMF" report to reflect the changed identification numbers in the final report. 4. Policy and procedure review revealed that the laboratory failed to have policies and procedures to ensure that patient specimens reflect the identification through all the phases of testing. 5. Interview with the office manager confirmed on 05/31/2023 at 03:22 PM that the laboratory does not have a policy or procedure that includes corrected reporting. 6. The laboratory reports performing 900 histopathology tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review of competency assessments and interview with the office manager, the laboratory failed to have policies and procedures to assess competency. Findings include: 1. Record review of histopathology competency assessment log "Mohs Log," revealed that the competency assessment log "Mohs log" does not indicate who was being assessed or who was the assessor. 2. Record review revealed that the laboratory failed to have policies and procedures to assess 2 of 2 testing personnel competencies. 3. Interview with office manager confirmed on 05/31/2023 at 04:20 PM confirmed that the laboratory failed to have policies and procedures to assess competency. 4. The laboratory performs approximately 900 histopathology and 50 KOH test annually.
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 on record review and interview with the office manager, the laboratory failed to verify the accuracy of histopathology testing twice annually. Findings include: 1. Record review of twice annual verification for 2 of 2 testing personnel (TP), revealed that verification of accuracy for histopathology testing was performed when TP "needed assistance" for identification. 2. Interview with the office manager on 05/31 /2023 at 004:40 PM confirmed that twice annual verification done on histopathology was not performed in accordance with CLIA regulations. 3. The laboratory reports performing approximately 900 histopathology tests annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on patient record review, lack of policy and procedure, and interview with the office manager the laboratory failed to have an ongoing mechanisms to monitor, assess, and correct problems. Findings include: 1. Record review of patient report #17123 collection date "05/11/2023 09:11" revealed 2 of 2 corrections reported on 05 /11/2023 at 05:16 PM MDT and on 05/17/2023 at 05:13 AM MDT. 2. Record review revealed no assessment performed for 2 of 2 corrections on patient report #17123. 3. Policy and procedure review revealed no mechanism was in place to monitor, assess and correct problems. 4. Interview with the office manager on 05/31/2023 at 03:22:00 PM confirmed that the laboratory does not have a policy or procedure to monitor,

	assess, and correct problems. 5. The laboratory performs approximately 950 tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on policy review and interview with the office manager the laboratory failed to have complete written procedures in place that contain all required elements for testing personnel to follow for potassium hydroxide (KOH) microscopic examination. Findings include: 1. The procedure for KOH microscopic examinations failed to include requirements for magnification required and presence of fungal elements in the microscopic examination, limitations of the procedure, reportable results (presence /absence), the laboratory's system for entering results in the patient record, a description of the course of action to take if the test system becomes inoperable and literature references. 2. Interview with office manager on 05/31/2023 at 04:40 PM confirmed that the current procedure manual in use by the laboratory did not contain all applicable elements required by federal regulation. 3. The laboratory reports approximately 50 KOH tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on record review of the Staining Quality Control (QC) log and interview with the office manager, the laboratory failed to ensure testing personnel did not use expired stains. Findings include: 1. Record review of the Staining QC log revealed that the Eosin stain was opened on 04/06/2021 (lot number 113506 expiration of 1/31 /2023). 2. Record review of Staining QC log revealed that Eosin was "changed" on 01

	/23/2023 and 01/31/2023, the laboratory failed to document Eosin lot numbers and expiration dates from 04/06/2021 to 02/16/2023. 3. Interview with the office manager on 05/31/2023 at 05:10 PM confirmed that Staining QC log does not indicate if expired Eosin stain was replaced by an unexpired Eosin stain. 4. The laboratory reports performing approximately 900 histopathology tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, document review, and interview with the office manager, the laboratory failed to perform preventative maintenance (PM) on 2 of 2 microscopes. Findings include: 1. Observation of 2 of 2 microscopes revealed that there was no annual PM performed for year(s) 2021 and 2022. 2. Document review of two of two microscopes revealed no documentation of PM performed. 2. Interview with the office manager on 05/31/2023 at 04:15 PM confirmed that the laboratory could not provide documentation that PM was performed for years 2021 and 2022.