Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0917694	03/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
High Valley Dermatology And	703 Rigby Lake Dr, Rigby, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and proficiency testing (PT) record review, the laboratory director failed to sign the attestation statements from the College of American Pathologists (CAP) for the human chorionic gonadotropin (hCG) analyte for 2017. Findings: 1. A CAP PT document review revealed the laboratory director failed to sign the attestation statements for the hCG analyte for 2017. 2. An interview on March 12, 2018 at 9:15 AM, with the laboratory manager, confirmed the laboratory director failed to sign the PT attestation statements for hCG testing for 2017.
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 an interview with the laboratory manager and a record review of personnel documents, the laboratory failed to follow the written procedure for assessing employee competency for the Consult Diagnostics human chorionic gonadotropin (hCG) and potassium hydroxide (KOH) tests since the last survey on April 12, 2016. Findings: 1. A record review of personnel documents for the 14 testing personnel listed on the CMS-209 Personnel Report form, revealed the laboratory failed to perform competency assessments on 14 testing personnel. 2. An interview on March 12, 2018 at 9:30 AM, with the laboratory manager, confirmed the laboratory failed to perform competency assessment on the 14 testing personnel.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and a record review, the laboratory failed to monitor and record the room temperature where the Consult Diagnostics human chorionic gonadotropin (hCG) patient samples are tested as required by the manufacturer's instructions since the last survey on April 12, 2016. Findings: 1. A record review revealed the laboratory failed to monitor and record the room temperature of the laboratory where hCG tests are performed. 2. An interview on March 12, 2018 at 10:00 AM, with the laboratory manager, confirmed the laboratory failed to monitor and record the laboratory room temperature.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and a record review, the laboratory failed to establish the quality control plan (QCP) and the quality assurance plan (QAP) for the Consult Diagnostics human chorionic gonadotropin (hCG) Individualized Quality Control Plan (IQCP) since the last survey on April 12, 2016.

	Findings: 1. A review of the IQCP for the Consult Diagnostics hCG test revealed the laboratory failed to establish the QCP and the QAP. 2. An interview on March 12, 2018 at 10:00 AM, with the laboratory manager, confirmed the laboratory failed to write the QCP and the QAP for the Consult Diagnostics hCG test.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on an interview with the laboratory technician and a record review of personnel documents, the laboratory failed to establish and follow a written procedure for assessing employee competency at least semiannually during the first year of patient testing on the Consult Diagnostics human chorionic gonadotropin (hCG) since the last survey on April 12, 2016. Findings: 1. A record review of personnel documents revealed 8 out of 14 testing personnel listed on the CMS-209 Personnel Report form, failed to have competency assessments performed at least semiannually during the first year of patient testing. 2. An interview on March 12, 2018 at 9:30 AM, with the laboratory manager, confirmed the laboratory failed to perform semiannual competency assessments on the testing personnel.