Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0917694	11/05/2020
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
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on record review of proficiency testing (PT) for KOH from American College of Physicians (ACP) and an interview with the Laboratory Director on November 5, 2020, the laboratory failed to not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Findings: 1. 2020 event 1 KOH from ACP, both medical testing personnel performed testing on samples K-1 and K-2 on February 12, 2020 and both medical testing personnel signed the attestation as testing personnel. 2. 2020 event 2 KOH from ACP, both providers performed testing on samples K-3 and K-4 on May 28, 2020 and neither medical testing personnel signed the attestation as testing personnel. 3. 2020 event 3 KOH from ACP, both medical testing personnel performed testing on samples K-5 an K-6 on October 1, 2020 and both medical testing personnel signed the attestation as testing personnel. 4. An interview with the laboratory director on November 5, 2020, at 10:30 am, revealed that both medical testing personnel were performing the PT test on the same slides prior to the submission deadline for training purposes.

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 procedures and an interview with the laboratory director on November 5, 2020, the laboratory failed to have written procedure for proficiency testing (PT) that was available to, and followed by, laboratory personnel. Findings: 1. A record review of the laboratory procedures manual revealed the laboratory did not have a PT procedure for their laboratory personnel to follow. 2. An interview with the laboratory director on November 5, 2020, at 10:55 am, confirmed that the laboratory did not have a PT procedure for their laboratory personnel to follow.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) log review and an interview with the laboratory director on November 5, 2020, the laboratory, at least once a day when patient specimens are assayed, failed to perform two control materials that correlate with the specimen matrix that is being tested. Findings: 1. A record review of the QC log revealed that the laboratory was only performing urine QC on the hCG combo test. The laboratory uses hCG combo test for both serum and urine samples. They perform approximately 175 serum hCG tests per year using the hCG combo. 2. An interview with the laboratory director on November 5, 2020, at 11:55 am, confirmed that the laboratory did not perform serum QC on the hCG combo test, that they only perform urine QC on the hCG combo test.