Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2151774	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Woseth Dermatology, Pc	4040 West Daybreak Pkwy, Ste 200, South Jordan, UT	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing (PT) record review and interview with staff, the laboratory failed to handle PT testing samples in the same manner as patient samples for 1 of 1 testing events reviewed (1st event of 2019). Finding include: 1. The laboratory enrolled in PT for potassium hydroxide (KOH) wet mount preparations and mycology cultures. 2. Laboratory PT records for event 1 of 2019 document 4 laboratory personnel performed KOH testing before the results were submitted to API for grading on 02/25/2019. 3. The laboratory manager stated on 05 /01/2019 at approximately 2:30 p.m., KOH tests were reviewed by a technical consultant (TC) before submitting results to API. 4. The laboratory manager stated on 0/01/2019 at approximately 2:30 p.m. that patient KOH testing was routinely performed by only 1 test person and that patient results were not routinely reviewed by a TC before reporting.
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 procedure manual review, direct observation, lack of documentation, and interview with staff, the procedure manual failed to include the control procedure used to ensure 1 of 2 reagents used in fungal wet mount testing (Chlorizole Black E) was checked for intended reactivity with each lot number and shipment of reagent, and the step by step procedure for interpreting fungal culture results. The laboratory began testing in 10/2018 and performs 2 tests (wet mounts for fungal elements, and fungal cultures). Findings include: 1. The procedure manual included a reference for using Chlorizole Black E to identify fungal elements in dermatology samples. 2. The surveyor observed a bottle of Chlorizole Black E with other laboratory reagents. 3. The laboratory lacked documentation Chlorizole Black E had been checked for intended reactivity. 4. The laboratory manager confirmed on 05/01/2019 at approximately 3:00 p.m., some of the testing personnel use Chlorizole Black E when performing wet mount testing to identify fungal elements. 5. The laboratory procedure manual failed to include how frequently fungal cultures were to be checked for growth and how long the culture needed to be checked for growth before reporting a negative result.