Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2010704	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Derm One Pllc	551 Airport Road, Bluefield, WV	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of Proficiency testing/ Quality Assurance records and interview with Office Manager (OM) and the histotechnician, there was no evidence of evaluation of the peer comparison slide activities. Findings include: 1. The laboratory did not have documentation demonstrating the laboratory director evaluated the peer comparison slides for 2017 and 2018.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and chemical inventory record review, the laboratory was not properly labeling and documenting histopathology chemicals. Findings include: 1. During a tour of the laboratory on 8/15/2018, it was observed that chemicals were not labeled with receipt and open dates. 2. The laboratory had a chemical inventory logbook that was discontinued on 6/8/2018. The forms had headings that included: date received, chemical name, lot number, expiration date, and tech initials. 3. On 8/15 /18 at approximately 2:45PM, the histopathology technician stated that he knew

	chemicals should be labeled properly but with busy schedules this was something that was overlooked. He recognized from other histopathology positions that labeling reagents is routine laboratory practice
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with Histotechnician and Office Manager (OM) , the laboratory was not evaluating histopathology case peer reviews by the appropriate staff. Findings include: 1. Comparison of slide review cases with a certified histopathologist (SkinPath Solutions) were used as proficiency testing for the laboratory. Records of the slides selected for review were maintained. The SkinPath diagnostic finding reports were returned to the lab with a diagnosis. But, there was no documentation to support the findings were compared and assessed. 2. There was no documentation of review by the director throughout 2017 and 2018. 3. On 8/15/18 at approximately 2:30PM, the Office Manager described a process where the OM selected the slides for review and sent them to SkinPath. When the diagnostic findings were returned from SkinPath she compared the results for the Director.