Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0656150	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Skin Pathology Services Inc	2660 E Market St, Warren, OH	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to enroll in a proficiency testing (PT) program for gram stain testing. Findings Include: 1. The laboratory failed to enroll in a gram stain proficiency testing (PT) program. (Refer to D2001)
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the

	laboratory failed to enroll in a gram stain proficiency testing (PT) program. Findings Include: 1. Review of the laboratory's test menu, provided on the date of the inspection, revealed the laboratory performed and reported an annual average of 24 gram stain testing procedures on patient tissue biopsy specimens. 2. Review of the laboratory's "Gram Stain, Lillies's" policy and procedure, provided on the date of the inspection, found instructions for the histologic/cytologic tissue gram stain procedure and the following expected results: "Gram negative - red Nuclei, etc. - red Gram positive - intense blue-black" 3. The Surveyor requested the laboratory's 2016, 2017 and 2018 gram stain PT documentation from the LM. The LM confirmed the laboratory was not enrolled in a gram stain PT program and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10 /02/2018 at 10:35 AM.
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 record review and interviews with the Laboratory Manager (LM) and tissue processor, the laboratory failed to define criteria consistent with the manufacturer's instructions and document humidity conditions for reliable tissue biopsy procedures and test result reporting. Findings Include: 1. Review of the laboratory's policies and procedures did not find any instructions to monitor and document humidity conditions consistent with manufacturer's operating specifications. 2. Review of the Tissue-Tek VIP Vacuum Infiltration Processor E150/E300 Series manufacturer's operating humidity conditions revealed the following: "The ambient operating humidity range is 0% to 85% relative humidity." %; percent 3. The Surveyor requested the laboratory's policy and procedure of the humidity criteria consistent with the manufacturer's instructions and the 2016, 2017 and 2018 humidity documentation from the LM and tissue processor. The LM and tissue processor confirmed the laboratory had not established humidity criteria consistent with the manufacturer's instructions, did not monitor and document humidity in 2016, 2017, and 2018, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 10/02/2018 at 10:35 AM.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the Technical Supervisor (TS) failed to evaluate and document the competency of Testing Personnel (TP) #2 responsible for high complexity tissue biopsy gross testing procedures at least annually after the first year. Findings Include: 1. Review of the laboratory's "Histology Laboratory Competency Performance" policy and procedure, provided on the date of the inspection, revealed "Once a year, the Laboratory Director observes each employee from the beginning to the end of their duties..." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 09/12/2018, revealed two individuals listed as TP who had tested patient specimens for at least one year and responsible for highly complex Histopathology testing procedures. 3. Review of the laboratory's 2016, 2017 and 2018 annual competency assessment documentation, provided on the date of the inspection, revealed TP#2 did not have a tissue biopsy grossing competency assessment conducted in 2017 and 2018. 4. The Surveyor requested the laboratory's 2017 and 2018 competency assessment documentation for TP#2 from the LM. The LM confirmed the laboratory did not assess the competency of TP#2 in 2017 and 2018, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 10/02/2018 at 10:40 AM.