Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0691538	07/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Consultants Pa	1215 Town Centre Dr Suite 200, Eagan, MN	

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
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 4 of 4 testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during the entrance interview at 10:05 a.m. on 07/12/19. 2. TP1, Testing Personnel 2, Testing Personnel 3, and Testing Personnel 4 were listed on the Laboratory Personal Report (CLIA) Form CMS-209 as high complexity testing personnel. 3. Initial training records were not found for 4 of 4 testing personnel. See D6171. 4. Semiannual competency assessment were not found for 4 of 4 testing personnel during review of laboratory personnel records. The laboratory was unable to provide a semiannual competency assessment for the testing personnel upon request. 5. In an interview at 10: 15 a.m. on 07/12/19, TP1 indicated all testing personnel began high complexity testing in August 2018 and confirmed semiannual competency evaluations had not been completed.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: . Based on review of education documents and interview with laboratory personnel, the laboratory failed to ensure personnel performing high complexity testing meet the qualification requirements of 493.1489. Findings are as follows: The laboratory failed to ensure all testing personnel met the qualification criteria to perform highly complex testing. See D6171 The performance of highly complex testing procedures by unqualified personnel constitutes Condition- level noncompliance. The laboratory performed approximately 3390 high complexity tests annually.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

	control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure 3 of 4 testing personnel met the qualification criteria required to perform high complexity testing. In addition, the laboratory failed to ensure 4 of 4 testing personnel received documented laboratory training for the high complexity testing they performed. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery under the subspecialty of Histopathology as confirmed by Testing Personnel 1 (TP1) during the entrance interview at 10:05 a.m. on 07/12/19. 2. During the entrance interview, TP1 stated she and the 3 other testing personnel (TP) prepared tissue obtained during the Mohs Micrographic surgery procedure and began performing the highly complex component of inking tissue in August 2018. 3. Training documents for 4 of 4 TP were not found during review of laboratory records. The laboratory was unable to provide training documents upon request. 4. Education credentials were not available on-site for 4 of 4 TP on date of survey. TP1 indicated she and 2 other TP had obtained Medical Assistant certificates and one TP had obtained Histotechnician certification. The laboratory was given an opportunity to provide the education credentials. 5. In an interview at 10:05 a.m., TP1 confirmed tissue inking training had not been documented for 4 of 4 TP and 3 of 4 TP did not have the required education to perform high complexity testing. 6. Education credentials received via email on 07/16/19 confirmed 3 of 4 TP did not meet the minimum educational requirements needed to perform high complexity testing. See below. TP Education 1 Certified Medical Assistant 2 Registered Medical Assistant 3 Certified Histotechnician (meets education requirements) 4 Certified Dermatology Tech