Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0685509	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatologists Of Southwest Ohio	100 W Third Avenue, Suite 250, Columbus, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interviews with the Compliance Officer (CO) and Manager (M), the laboratory failed to blindly verify the accuracy of the Mohs tissue biopsy slide interpretation procedures performed. This deficient practice had the potential to affect all patients tested under the subspecialty of histopathology. Findings Include: 1. Review of the laboratory's "Peer Review" policy and procedure provided on the date of the inspection approved via signature and date by the Laboratory Director on 09/10/2019 found the following statement: "...The histology technician will retrieve a blind MOHs case from the a previous month and prepare all necessary components for review. Copy current MOHS map report that shows clear margins. Blank MOHS map with only patient information Case slides" 2. Review of one out of three of the 2018 "Mohs Microscopic Surgery Operative Map" and one out of three 2019 "Mohs Microscopic Surgery Operative Map" which was sent with each case for peer review revealed that the original diagnosis and tissue map was included. 3. The CO and M confirmed the laboratory did not perform blind peer reviews for Mohs slide interpretations. The interviews occurred on 03/12/2019 at 3:15 PM.
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 record review and an interview with the manager, the laboratory failed to ensure Testing Personnel (TP) met the high complexity TP qualification requirements for inking and grossing procedures. This deficient practice had the potential to affect

	all patients tested under the subspecialty of histopathology. Findings Include: 1. Review of the laboratory's CMS-209 form, approved and signed by the Laboratory Director on 09/26/2019, found TP#5 listed and certified by the Laboratory Director to perform high complexity test procedures. 2. Review of 2018 and 2019 annual competency assessment documents approved by the Laboratory Director via signature and date for TP#5 titled "Yearly Competency Evaluation for Histology Technician" found the following statement: "...Receive, log (in the MOHS logbook), and process, bisect when necessary, relax cut, ink and map" 3. Review of education documentation revealed TP#5 possessed a high school diploma from May 1981 which does not meet the minimum TP qualifications for high complexity testing procedures listed on the 2018 and 2019 annual competency assessments. 4. The manager confirmed TP#5 was performing high complexity grossing procedures. The interview occurred 09/11/2019 at 2:00 PM.