Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2162777	03/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mohs Lab Center For Dermatology &	5030 Tennyson Parkway Suite 200, Plano, TX	

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
D0000	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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 review of the laboratory's test menu, review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the professional component of H&E and PAS stained histology slides in 2022. The findings include: 1. A review of the laboratory's test menu revealed the laboratory performed H&E and PAS stains for histology specimens. 2. A review of the laboratory's records from 2022 revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for the professional (reading) portion of the interpretation of the stained slides. 3. The laboratory was asked to provide documentation of performing twice annual accuracy assessments for H&E and PAS stain reading in 2022. No documentation was provided. 4. An interview with the laboratory supervisor on 03/23 /2023 at 1355 hours in the break room revealed the laboratory did not include the reading portion as part of its twice annual accuracy assessments. This confirmed the findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessments from 2022 and 2023 and staff interview, it was revealed the laboratory failed to have documentation of a qualified technical supervisor or general supervisor of performing 6 of 6 competency assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022 and 2023 revealed 6 of 6 competency assessments were performed by someone other than the technical supervisor or general supervisor. 2. The personnel who performed the competency assessments did not qualify as a technical supervisor or general supervisor. 3. An interview with the laboratory supervisor on 03/23/2023 at 1240 hours in the break room - after his review of the records- confirmed the findings.
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 review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments twice within the first year for 1 of 2 testing personnel who required them. The findings include: 1. A review of the laboratory's personnel records revealed 2 testing personnel required twice annual competency assessments within the first year of testing in the records reviewed. They were (as listed on Form CMS 209): Testing personnel number 1 (start date: 10/2021) Testing personnel number 2 2. A review of the personnel records for testing personnel number 1 revealed competency assessments were performed at the following times: October 2021 January 2023 3. The laboratory was asked to provide documentation of a second competency assessment being performed by October 2022. No documentation was provided. 4. A interview with the laboratory supervisor on 03/23/2023 at 1240 hours in the break room - after his review of the records- confirmed the findings.
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 review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing annual competencies for 1 of 1 personnel. The findings include: 1. A review of the laboratory's personnel records revealed testing personnel number 3's (as listed on Form CMS 209) starting date was March 2012. 2. Further review of the laboratory's personnel records for testing personnel number 3 revealed annual competency assessments were performed: June 2021 January 2023 3. The laboratory was asked to provide documentation of an annual competency assessment performed in 2022 for testing personnel number 3. No documentation was provided. 4. An interview with the laboratory supervisor on 03/23/2023 at 1240 hours in the break room - after his review of the records- confirmed the findings.
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 the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 7 testing personnel (refer to D6171).
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 7 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 7 testing personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify testing personnel number 6 to perform high complexity testing. The review of the personnel records revealed testing personnel number 6 had a General Education Development (GED) certificate as the highest level of education achieved. 3. The laboratory was asked to provide additional education records to qualify testing personnel number 6. No documentation was provided. 4. An interview with the laboratory supervisor on 03/23/2023 at 1240 hours in the break room - after his review of the records- confirmed the findings.