

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2152412	(X3) Date Survey Completed 07/02/2026
Name of Provider or Supplier Mohs-Tek, Inc	Street Address, City, State 1342 Bell Ave Ste 3h, Tustin, CA	
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
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory personnel qualifications, the pathology processing log, a review of ten (10) Histopathology patient test records, and interviews with laboratory testing personnel (TP) on July 2, 2026, at approximately 11:30 am it was determined that the laboratory director failed to ensure that testing personnel who routinely performed Specimen Grossing, including specimen measurement and description, were qualified to perform high complexity testing under 493.1489. The findings included: Laboratory director failed to ensure that testing personnel satisfied the education and training requirements necessary for high complexity testing in accordance with regulation 493.1489(b). See 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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training

equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on surveyor's review of laboratory personnel qualifications, the pathology processing log, a review of ten (10) Histopathology patient test records, and interviews with laboratory testing personnel (TP) on July 2, 2026, at approximately 11:30 am, it was found that two (2) of three (3) testing personnel who regularly performed Specimen Grossing including specimen measurement and description were not qualified to perform high complexity testing under regulation 493.1489(b). The findings included: 1. The laboratory conducted high-complexity histopathology tests, including both gross (macroscopic) and microscopic examinations. Gross examination consisted of tasks such as weighing, measuring, describing color, ensuring proper orientation for diagnostic purposes, and other tissue characteristics, as well as mechanical procedures like inking and marking; these are all considered high-complexity tests. Three testing personnel were responsible for performing gross examinations: TP#2 did not meet the education requirements of 493.1443(b)(3) II(A) for conducting high complexity macroscopic examinations. TP#3 lacked laboratory training necessary to meet the requirements of 493.1443(b)(3) II(B) for conducting high complexity macroscopic examinations from 08/18/2025 to 04/23/2026. 2. On the day of the survey, Testing Personnel #1 (the laboratory owner and representative) confirmed that the laboratory did not maintain educational records for Testing Personnel #2. Testing Personnel #1 also verified that the training record for Testing Personnel #3 was approved by the Laboratory Director eight months after Testing Personnel #3 began performing tests. Testing Personnel #3 started testing on 08/18/2025, but the Laboratory Director did not sign off on the training documents until 04/23/2026. 3. The laboratory's testing declaration form, signed by the laboratory director on June 26, 2026, indicated that approximately 62,000 histopathology tests were performed annually.