

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1062915	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Medderm Associates, Inc	Street Address, City, State 3965 5th Ave, Ste 200, San Diego, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation of testing personnel competency assessment records, a review of patient records, and interviews with the laboratory director (LD), office manager (OM), and histology technician (HT) on August 8, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish a written policy and procedure to assess the testing personnel competency for the years 2022, 2023, and 2024. Findings include: 1. Based on the lack of policy and procedure and competency assessment records, the laboratory failed to establish an approved written policy and procedure for competency assessment of the HT for the subspecialty of Histopathology. 2. Based on an interview with the OM at approximately 11:30 a.m. on August 8, 2024, it was determined that it was the practice of the laboratory to use the training program from Cryoembedder to train any new HT hired, but no record of training or competency evaluation had been documented since 2017. 3. Based on the review of patient records, the laboratory failed to provide documentation of training and competency assessment for the HT performing Histopathology sample processing, operating the cryostat, creating slides, staining, and labeling at the laboratory for the years 2022, 2023, and 2024. 4. This deficient practice was affirmed by interviews with the LD, OM and HT on August 8, 2024, at approximately 11:30 a.m. 5. According to the laboratory's testing declaration submitted at the time of the survey, the laboratory performed 250 Mohs tests for the subspecialty of Histopathology annually, for which the competencies of the HTs were not performed.</p>

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on the laboratory personnel interview and testing personnel competency and competency policies and procedures record review on August 8, 2024, the laboratory director is herein cited for failure to ensure that policies and procedures were established for monitoring individuals who conduct analytical and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209