

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0935360	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Edward M Kramer Md, Inc	Street Address, City, State 27995 Greenfield Dr Ste C, Laguna Niguel, 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
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records and documentation, and an interview with laboratory personnel (LP) on 9/16/2020 between 10 am and 11:30 am, it was determined that there was no histotechnician competency procedure or annual checklist. Findings include: 1. On 9/16/2020, an inspection was conducted between 10 am and 11:30 am. 2. During a review of the laboratory procedure documentation, there was no procedure or checklist to support the annual requirement for histotechnician competency for MOHS procedures. The LP was made aware of this deficiency. 3. According to the CMS 116 report, the laboratory performs 2,554 MOHS tests per year.</p>