

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0719349	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Lisa D Zack Md Pa	Street Address, City, State 801 Anchor Rode Dr Ste 100, Naples, FL	
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	An announced recertification survey was conducted on 11/16/22 at Lisa D Zack MD PA, a clinical laboratory in Naples, Florida. Lisa D Zack MD PA., is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is description of the Standard-level deficiency.
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 record review, and interview with the Certified Dermatologic Tech, the laboratory director failed to have a personnel competency procedure to evaluate staff competency of those performing high complexity histopathology testing (slide interpretation) for two of two years reviewed (2021-2022). The findings included: Review of the CMS 209 Laboratory Personnel Report signed by the laboratory director and dated 11/16/22 revealed Personnel #A was the Laboratory Director, the Clinical Consultant, Technical Consultant, Technical Supervisor, General Supervisor, and high complexity Testing Personnel. Testing Personnel #B performed high complexity testing. Review of employee files revealed that Personnel #B had documentation for two out of two years (2021 - 2022) that was titled "Mohs Technical Competency". On 11/16/22 at 03:10 PM with the Certified Dermatologic Tech stated she was told to use the "Mohs Technical Competency" for Testing Personnel #B but Testing Personnel #B did not perform the technical component of histopathology testing. Testing Personnel #B performed histopathology slide interpretation. She was</p>

not told the competency form for Testing Personnel #B needed to be specific to Testing Personnel #B job duties. She also confirmed the laboratory did not have a competency procedure for histopathology testing personnel.