

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2032981	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Dermatologic Surgery Center Of	Street Address, City, State 1133 Medina Road, Suite 100, Medina, OH	
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 record review and an interview with the Clinical Manager , the laboratory failed to follow their written policies and procedures for initial training and 6 month competency assessment for one out of two Testing Personnel (TP) performing high complexity histopathology grossing procedures. This deficient practice had the potential to affect all patients tested at this laboratory. Findings include: 1. Review of the laboratory's 'Quality Assessment' policy and procedure found the following statement: "The competence of testing personnel and all staff members will be evaluated and documented every year by the laboratory director to ensure that all laboratory staff maintains their competency in testing and laboratory management functions. Proper training will be provided to correct any deficiencies found. CLIA regulations for laboratories performing moderate to high complexity testing require semi-annual assessments thereafter. Personnel evaluations will include review and suitable revision of the authorized duties form." 2. Review of the laboratory's competency assessment documentation found the following annual competency assessments for TP #1: 12-26-18 12-23-19 3. An interview with TP #1 and the Clinical Manager, on 9/29/20 at 10:14 am, found that TP #1 began performing high complexity histopathology grossing 8/1/19. 4. The surveyor requested evidence of initial training prior to patient testing and 6 month competency assessment for TP #1 to perform high complexity histopathology grossing procedures. 5. An interview with TP #1 and the Clinical Manager, on 9/29/20 at 10:17 am, confirmed that the initial</p>

training prior to patient testing and 6 month competency assessment for TP #1 to perform high complexity histopathology grossing procedures were not performed; thus, the documents could not be produced.