

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0967345	(X3) Date Survey Completed 02/23/2022
Name of Provider or Supplier Essentia Health Duluth Clinic	Street Address, City, State 400 East 3rd Street, Duluth, MN	
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
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to include direct observation of routine patient test performance in the annual competency evaluations for 5 of 5 testing personnel in 2020 and 2021. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery as confirmed by the Laboratory Manager (LM) during a tour of the laboratory at 1:10 p. m. on 02/23/22. 2. The Mohs Dermatology Frozen Sections procedure located in the Mohs Procedure Manual indicated tissue grossing was performed by the Histotechnician testing personnel. 3. The Training and Competency procedure did not include tissue grossing in the criteria used for Histotechnician competency assessments. 4. The 2020 and 2021 competency assessment forms reviewed for 5 of 5 Histotechnicians did not include assessment of tissue grossing competency. 5. The laboratory performed approximately 2500 Mohs cases annually as indicated in the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 3: 30 p.m. on 02/23/22, the LM confirmed the above finding.</p>