

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2010705	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Derm One Pllc	Street Address, City, State 4130 Robert C Byrd Drive, Beckley, WV	
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
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assessment records and interview with Office Manager (OM) and histotechnician (HT), the laboratory director did not ensure that test systems used for all aspects of testing were reviewed by qualified personnel. Findings: 1. Laboratory Quality Assessment Review Chart which documented quality indicators for pre-analytic, analytic and post-analytic phases of testing was available but there was no evidence found of director review for 2017 and 2018. The OM and HT could not sign this document the Technical Supervisor or Laboratory Director. . 2. Quality Chart Logging Checks were found which documented accuracy of patient test management. The checks were performed using the information from 5 patient charts, 3X per year. There was no evidence of director review of these documents for 2017 and 2018. 3. Daily H & E Stain Quality Control was documented by HT. However, there was no evidence of director review for 2017 and 2018. 4. Various temperature charts documenting room temperature, Cryostat temperature, and humidity, plus eye wash and general maintenance charts were found. However, there was no evidence of director review. 5. The OM and HT agreed that the documents were not signed as reviewed by the Laboratory Director/Technical Supervisor.</p>