

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0674625	(X3) Date Survey Completed 10/19/2018
Name of Provider or Supplier Integrated Dermatology Of Bountiful	Street Address, City, State 1222 West Legacy Crossing Boulevard, Suite 200, Centerville, UT	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and confirmation by the office manager, the laboratory director failed to sign and date the laboratory histopathology Mohs surgery procedure manual as approved. Findings include: 1. The laboratory procedure manual describing the process for processing, labeling, specimen preparation, and slide staining, reviewing and reporting specimens obtained by Mohs micrographic surgical procedures failed to include the signature and date the director approved the procedures. 2. In an interview with the practice manager on 10/19/2018 at approximately 11:45 A.M. the manager confirmed the director had not approved all procedures through the presence of a signature and date.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and confirmation by staff, the laboratory director failed to ensure the laboratory established a quality assurance plan designed to monitor the general laboratory, pre-analytic, analytic and post</p>

analytic portions of histopathology laboratory testing for approximately 6 months of testing reviewed from April 2018 to October 2018. The laboratory performed testing approximately one day per month, testing approximately 6 patients per day. Findings include: 1. Procedure manual review failed to include a quality assessment plan or plans the laboratory used to establish the activities and frequency of performance to monitor the laboratory testing quality assurance for general laboratory areas (ex. twice annual testing accuracy of diagnosis, competency evaluations, confidentiality process check); pre-analytic, (test orders, collection, labeling, transportation, storage and processing); analytic, (recording gross analysis, map recording and location of tumor persistence); and post analytic, (ex. test report completion, pass word protection security for electronic signature. 2. In an interview with the practice manager on 10/19 /2018 at approximately 12:30 P.M. the manager stated he was unaware of a quality assurance plan that monitored the entire testing process.