

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1071032	(X3) Date Survey Completed 06/28/2019
Name of Provider or Supplier Illinois Dermatology Institute Llc	Street Address, City, State 1550 N Northwest Hwy, Ste 300, Park Ridge, IL	
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
D6096	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</p> <p>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the laboratory director (LD), the LD failed to take and document all necessary remedial actions whenever significant deviations from the laboratory's established performance characteristics are identified in the specialty of Histopathology. Findings include: 1. The laboratory's Mohs' procedures manual and case quality assurance (QA) results were reviewed. 2. The laboratory's Mohs QA procedure states the following: "One case in 20 will be reviewed by a qualified Board Certified Dermatopathologist. Each case will be reviewed for accuracy and completeness." 3. Review of 9 cases revealed the following: * The Dermatopathologist did not agree with the presence of Tumor for 7 out of 9 cases reviewed on 02/05/2019. * The LD failed to take and document any actions needed in response to the result discrepancies created from the Dermatopathologist's interpretations. * The LD failed to access and correct, if applicable, the possible patient affect for the cases where disagreements of result interpretations were made for 7 out of 7 patients. 4. The manual failed to include a policy and procedure for investigating and resolving the QA review result discrepancies. 5. On 03/19/2019 at 1:00 PM, the LD confirmed the above findings.</p>