

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2135751	(X3) Date Survey Completed 06/08/2018
Name of Provider or Supplier Rush Dermatology Patient Services	Street Address, City, State 610 S Maple, Suite 5500, Oak Park, 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
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 review, changes in procedures were not approved, signed, and dated by the current laboratory director. Finding: 1. Review of Plan of Correction (POC) documents received on 06/08/18 revealed that the laboratory submitted a new modified procedures manual to the survey of 04/16/18. The surveyor observed that the new procedures were not approved, signed, and dated by the laboratory director.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.</p> <p>This STANDARD is not met as evidenced by: Based on review, the laboratory failed to maintain duplicates of the original report, as well as the corrected report, when errors in the reported patient test results are detected. Findings: 1. Review of Plan of Correction (POC) documents received 06/08/18 to the survey of 04/16/18 revealed that, as the POC for D tag 5805; the laboratory modified the reports of 16 patients' test reports. The POC reads as follows: "Mohs</p>

accession numbers were added to reports on the three patients noted to be missing them during the survey. Thirteen patients were found to be previously affected and their reports have been corrected." 2. Review of patients test reports revealed that there was no documentation to indicate both the corrected results and the fact that the report is a corrected report for 16 of 16 patients' test reports