Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2135751	04/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Rush Dermatology Patient Services	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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manuals and patients' test records and interview, the procedure manual did not include the following when applicable to the test procedure: *Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. *Control procedures *Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability *The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. *Description of the course of action to take if a test system becomes inoperable. Findings: 1. Records show that the laboratory had 3 seperate lob books. When the surveyor asked why there was so many log books, testing personnel told her that the other log books were for specimen send out. However, there were no written procedures that described the step- by - step process for processing patients' specimens. 2. There were no written procedures that described the expected results for Quality Control of the Hematoxylin and Eosin (H&E) stains. 3. There were no written procedures that described corrective actions to implement if Quality Control of H&E stain should fail. 4. There were no written procedures that described the laboratory's process for entering patients' test results into patients' Electronic Medical Records. Review of 3 patients' test reports revealed that the laboratory did not document the Mohs Accession Numbers when it reported results for Mohs for 3 of 3 patients' test reports reviewed. 5. There were no written procedures that described the step-by- step course of action to take if a test system becomes inoperable. 6. During survey date 04 /16/18, the Histologist confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation, review, and interview; the laboratory failed to establish a maintenance protocol for its laboratory instrumentation. Findings: 1. During the walk through of the laboratory, the surveyor observed the following laboratory equipment in the laboratory. a. Microscope b. Microtome c. Stainer d. Fume Hood e. Biological Safety Cabinet 2. Review of manufacturer's product information books for the laboratory's Microscope and Fume Hood revealed that there was no maintenance protocol included in the information books for either the Microscope or Fume Hood. 3. Review of laboratory procedures manuals revealed that there were no procedures that describes a maintenance protocol for the laboratory's Microscope and Fume Hood. 4. During survey date 04/16/18, the Histologist confirmed the surveyor's findings..
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based review of the laboratory's procedures manuals, patients' testing logs, Mohs Maps, patients' test reports and interview; the test reports did not indicate the following: *Specimen source, when appropriate. Findings: 1. There were no procedures that instruct personnel on entering patient's test results into the patients' records. 2. Review of patients' testing logs revealed that the following information is documented on the testing log: a. Patient Name b. MRN c. Case # d. Specimen Site e. Diagnosis f. stages 3. Review of patients' Mohs Maps revealed that Mohs Map titled, "Mohs Intake," consists of two pages. One page was used for drawing the orientation of patient's tissue specimens and the other for documenting observations and results of Mohs. The following information was documented: b. Patient Name c. DOB d. MRN e. Tumor/Site f. Biopsy # g. Specimen #/ Mohs Accession # 4. During survey date 04 /16/18, the surveyor requested 3 patients' final reports for review. Review of the patients' final reports revealed that the laboratory failed to record/document Mohs Accession # when it reported the final results in the patients' electronic medical record for 3 of 3 patients test reports reviewed. Further investigation revealed that the laboratory entered the Biopsy # that was recorded on the pathology report instead of the Mohs Accession #. The surveyor noted that this laboratory was not the laboratory that performed and generated the results on the pathology report. 3. During survey date 04/16/18, the Histoloist confirmed the surveyor's findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review and interview; the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the post analytic systems as specified in 493.1291. Findings: 1. Review of the laboratory's procedures manuals revealed that there was no instructions that described the laboratory's process for reviewing the final reports for patients test results. 2. Review of 3 patients' test records revealed that the Mohs Accession # was not included in the final reports of patient testing for 3 of 3 patients' test records reviewed. 3. During survey date 04/16/18, the Histologist confirmed the surveyor's finings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by: Based on review and interview; the laboratory director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and

	correct problems identified in the post analytic systems as specified in 493.1291. Findings: 1. Review of the laboratory's procedures manuals revealed that the laboratory's written Quality Assurance (QA) Program did not include a description of how it assesses and corrects problems during the reporting of results. There wasn't even a written procedure that describes the laboratory's instructions for entering patients' results into the Electronic Medical Record. 2. There was no documentation to show that QA of the EMR was even monitored. The laboratory's QA consisted of only a Case QA, which included the following information: a. Stain b. Case/Slide# c. Diagnosis d. Tumor Present e. Comment 3. During survey date 04/16/18, the Histologist confirmed the surveyor's findings.