Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0700824	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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 (lab) written procedures and interview with staff, the lab written procedures for histology did not include instructions for the frequency to change staining reagents and did not include interpretation of quality control record entries made to evaluate the quality and acceptability of the stained tissue for histology. Findings: 1. MOHS micrographic surgery is performed. Tissue from the patient is precisely removed, processed onto a microscope slide, stained and examined for cancer; 2. The laboratory exposes the slides to a series of reagents in order to stain

	the tissue for microscopic examination. The histotechnician stated that the staining reagents are poured fresh each day of surgery and at the end of the day the reagents are discarded. The written procedures were reviewed and did not include instructions to use fresh reagents each day MOHS surgery is performed; 3. The stain quality control is reported on two separate worksheets: the "Control Slide Log" and the "Quality Control Log Daily Worksheet". When staff initial the records (on each day of surgery) they are documenting the acceptability of the stain characteristics on the stained tissue and the acceptability of the processing of the stained tissue. Staff initial the two records to document these observations. The written procedures were reviewed and did not define the quality control observations that are made by initialing each record; and 4. This was confirmed during interview with the lab director and histotechnician on the day of survey.