Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2076310	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Surgery Center	1900 N Beauregard Street - Suite 110, Alexandria, VA	

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
D0000	An announced CLIA recertification survey was conducted at Skin Cancer Surgery Center on May 18, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour, review of the policy and procedure manual, and an interview, the laboratory failed to follow their written policy to label all histopathology staining reagents for fifteen (15) of fifteen (15) containers in the slide preparation area on 5/18 /18. Findings include: 1. During a tour of the laboratory on 5/18/18 at approximately 11:00 AM, the inspector noted twelve (12) stain reagent containers being utilized to prepare Hematoxylin and Eosin (H & E) MOHS slides. Twelve (12) of the twelve (12) reagent containers were not labeled. The inspector noted three (3) bulk containers with staining reagents were also unlabeled and inquired pertaining to the identification of the reagents. The Histotechnologist stated "I get the staining reagents from another office lab. I do not have the reagent lot numbers or expiration dates onsite." 2. Review of the policy and procedure manual revealed a Materials Reagents policy that stated "All reagents are to be labeled with reagent name, expiration date/discard date, and storage requirements". Review of the policy and procedure manual revealed a Quality Assurance (QA) policy that stated "Discard reagents that are unlabeled or those whose expiration date has passed". 3. In an interview with the laboratory coordinator at

	approximately 1 PM, it was confirmed that the laboratory did not follow their written Materials Reagent and QA policies for labeling of the histopathology reagents.
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 a tour, review of the policy and procedure manual, and an interview, the laboratory failed to include in their written procedure the steps for Hematoxylin and Eosin (H & E) staining used in patient MOHS testing. Findings include: 1. During a tour of the laboratory on 5/18/18 at approximately 11:00 AM, the inspector noted twelve (12) unlabeled stain containers being utilized to prepare H & E MOHS slides. The inspector noted that there were no staining protocols posted in the lab for the manual staining process related to the unlabeled containers. 2. Review of the policy and procedure manual revealed that the policies did not include protocols for the preparation of the stained slides. The inspector requested to review the protocols. No documentation was available for review. 3. In an interview with the laboratory coordinator at approximately 1 PM, it was confirmed that the laboratory failed to include in their written procedure the steps for H & E staining used in patient MOHS testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies, and interviews, the laboratory failed to label the in use Hematoxylin and Eosin (H & E) reagents, at total of fifteen (15)

	containers, with appropriate identification on the date of the inspection, 5/18/18. Findings include: 1. During a laboratory tour at approximately 11:00 AM on 5/18/18, it was noted that the twelve (12) H & E staining containers and the three (3) bulk reagent containers in use were not labeled with name, lot number, open date or an expiration date. The inspector asked the Histotechnologist for the lot numbers and expiration dates of the reagents in use. The documentation was not available. 2. Review of the Materials Reagents policy revealed the statement: "All reagents are to be labeled with reagent name, expiration date/discard date, and storage requirements". Review of the Quality Assurance (QA) policy revealed the statement: "Discard reagents that are unlabeled or those whose expiration date has passed". 3. During an interview with the laboratory coordinator at approximately 1 PM, it was confirmed that, on the date of the survey, the laboratory failed to label fifteen (15) of fifteen (15) H & E staining reagents with the required identification of reagent name, expiration date, and storage requirements.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, policies and procedures, and an interview, the laboratory director failed to establish a procedure to document initial and semi-annual competency evaluations for one (1) of four (4) testing personnel in calendar year 2017 and up to the survey on 5/18/18. Findings include: 1. Review of the CMS 209 revealed four (4) testing personnel. (See attached personnel code sheet.) 2. Review of the laboratory personnel files revealed no initial or semi-annual competency assessment documentation for Testing Personnel D. The inspector requested the documentation. No records were available for review. The laboratory coordinator stated that Testing Personnel D had started working in the lab in October or November of 2017. 3. Review of the policies and procedures revealed that the personnel assessment policy did not state testing personnel evaluations must be documented two (2) times in the first year of employment and annually thereafter. 4. In an interview with the laboratory coordinator at approximately 1 PM on 5/18/18, it was confirmed that the laboratory director failed to set up a procedure to document initial and semi-annual competency evaluations for Testing Personnel D in calendar year 2017 and up the survey on 5/18/18.