Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1074714	11/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cary Skin Center At Pinehurst	205 Pavilion Way, Suite 200, Southern Pines, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of peer review documentation and operation manager interview 11/30/18, the laboratory failed to verify the accuracy of the Mohs histology testing at least twice a year in 2017 and 2018. The laboratory employs 4 testing personnel (TP) which perform Mohs histology testing, 2 TP began employment in January of 2018. Review of laboratory policies revealed the laboratory performs quarterly peer reviews as part of their quality assessment program to verify the accuracy of the Mohs histology testing performed. Review of laboratory policy "Quality Improvement Plan Mohs Surgery" revealed ..."3. Identify Important Aspects of Care...Mohs Surgery Peer Case Review-A retrospective peer review of selected cases conducted quarterly." Review of laboratory policy "General Information and Routine Procedure for Mohs Surgery Peer Review Cases" revealed "1. The reviewers receive case reports and slides, and complete the Peer Review Quality Assurance (QA) Report form as cases are reviewed. The concordance of clinical history and final tumor eradication are assessed and results recorded on the form....3. Upon the completion of your review, return the forms and all reviewed material to ....." Review of "Peer Review Quality Assurance (QA) Reports revealed the following: 1. Peer review documentation for TP #1 revealed no documentation of peer reviews for 2017 and 2018. 2. Peer review documentation for TP #2 revealed a peer review for the 1st quarter of 2017. There was no documentation of peer reviews for the 2nd, 3rd and 4th quarters of 2017. There was also no documentation of peer reviews for 2018. 3. Peer review documentation for TP #3, who began employment in January of 2018, revealed no documentation of peer reviews for 2018. 4. Peer review documentation for TP #4, who began employment in January of 2018, revealed no documentation of

	peer reviews for 2018. Interview with operations manager at approximately 1:00 p.m. confirmed peer reviews were used to verify the accuracy of the Mohs testing performed and peer reviews were to be performed quarterly as per laboratory policy. She also confirmed that the peer reviews were not performed in 2017 and 2018 as required.
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 laboratory procedure manual and operation manager interview 11 /30/18, the laboratory's procedure manual was not complete and current for the testing performed. The laboratory began the Melanoma Antigen Recognized by T Cells 1 immunostain (MART-1 IHC) testing procedure in July of 2018. 1. Review of laboratory procedure "MART-1 IHC Staining" revealed the procedure failed to indicate the type of quality control used, the identity of the quality control, the frequency of quality control, the criteria used to determine if quality control is acceptable and the corrective action to take if quality control results are unacceptable. 2. Review of laboratory procedure "MART-1 IHC Staining" revealed the procedure failed to include an interpretation of the testing results obtained. For example: There is no description of what is considered positive or negative for the test result. 3. Review of laboratory procedure "MART-1 IHC Staining" revealed the procedure failed to include the laboratory's system for entering the test results in the patient record. Interview with operation manager 11/30/18 confirmed the Mart-1 IHC staining procedure was incomplete. She stated it was a new procedure and they were still working on it.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on surveyor observation, review of test volumes and operation manager interview 11/30/18, the laboratory failed to discard staining reagents that had exceeded their expiration dates and were available for use. At approximately 11:15 a. m. the surveyor observed the following staining reagents had exceeded their expiration dates and were available for use: 1. Gill Hematoxylin 3, Lot # 57906, expiration date 05/18. 2. Eosin Y, Alcohlic, Lot # 60086, expiration date 07/18. 3. Gills Hematoxylin, Lot # 61896, expiration date 08/18. Review of yearly test volumes revealed approximately 2000 histopathology tests were performed annually. Test volumes indicate approximately 1,000 patients had been tested from June 2018 until time of survey, 11/30/18, using expired staining reagents. Interview with operation manager, during laboratory tour, at approximately 11:15 a.m. confirmed the staining reagents had exceeded their expiration dates. The operation manager immediately discarded the expired reagents.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with operations manager 11 /30/18, the laboratory failed to document quality control of the Melanoma Antigen Recognized by T Cells 1 Immunostain (MART-1 IHC) testing procedure. The laboratory began the MART-1 IHC testing procedure in July of 2018. Review of quality control records revealed no documentation of quality control performed for the Mart-1 IHC procedure since testing began in July of 2018, a period of approximately 6 months in which quality control was not documented. Interview with operations manager at approximately 1:00 p.m. confirmed the laboratory failed to document quality control of the Mart-1 IHC testing procedure. She stated they performed the quality control before testing each time, but they did not document it.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 of laboratory procedure manual, quality control records and operation manager interview 11/30/18, the laboratory director failed to ensure the Melanoma Antigen Recognized by T Cells 1 immunostain (MART-1 IHC) quality control program was established and maintained. 1. The laboratory director failed to ensure the quality control procedure for MART-1 IHC was complete and current (see

	D5403). 2. The laboratory director failed to ensure quality control results were documented for the MART-1 IHC immunostain (see D5601).
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 of laboratory policies, review of peer review documentation and operation manager interview 11/30/18, the laboratory director failed to ensure the laboratory's quality assessment program was maintained to assure the quality of laboratory services provided. The laboratory performs quarterly peer reviews as part of their quality assessment program. The laboratory director failed to ensure quarterly peer review were performed for 2 of 2 testing personnel in 2017 and 4 of 4 tesing personnel in 2018 (see D5217).