

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0240587	(X3) Date Survey Completed 05/10/2022
Name of Provider or Supplier Southern Dermatology	Street Address, City, State 4201 Lake Boone Trail, Suite 200, Raleigh, 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy/procedure, lack of documentation and interview with HT (Histotech) 5/10/22, the laboratory failed to verify the accuracy of the KOH (Potassium Hydroxide)/Wet Prep testing and the Tzanck stain at least twice annually since June of 2019, approximately 3 years in which verification of accuracy was not performed. Findings: Review of laboratory policies and procedures revealed no documentation of a specific procedure for the verification of accuracy of the KOH /Wet Prep testing and the Tzanck stain. For example: Laboratory procedure "Quality Assessment Program" states "3. Ongoing Assessment:...The programs and methods used for Proficiency Testing and results of this testing will be evaluated by the Laboratory Director or an appropriate, designated staff member annually.". There was no documentation in the laboratory procedure manual of "programs and methods used for Proficiency Testing". Review of laboratory records revealed no documentation of a twice annual verification of accuracy for the KOH/Wet Prep testing and the Tzanck stain. Interview with HT at approximately 11:15 a.m. confirmed the laboratory had no procedures for the verification of accuracy for the KOH and Tzanck testing. She also confirmed the laboratory had no documentation of a twice annual verification of accuracy for the KOH and Tzanck testing.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,</p>

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 procedures, and interview with HT 5/10/22, the laboratory procedure for Mohs testing is not complete and/or current. 1. The laboratory procedures for quality control of Mohs testing fail to state how quality control of the Hematoxylin and eosin (H&E) stain is performed and documented. Findings: Review of laboratory procedure "Quality Control Program" revealed "Documentation of QC: Since each slide serves as its own QC, separate documentation of QC is not maintained, except for Histopathology - Mohs Surgery slides, where QC Slide is created in the first slide of the case; this is outlined more fully in the "Histopathology - Mohs Surgery Policy/Procedure.". Review of laboratory procedure "Histopathology - Mohs Surgery Policy/Procedure" revealed "Quality Control Procedures....Since there do not seem to be any suitable, commercially available control materials for this procedure, each patient specimen is tested in duplicate.". During interview at 11:00 a.m. the HT stated the first slide of the day is reviewed by the surgeon after staining and is recorded on the "Cryostat Maintenance Record" by case number and a number indicating which practioner reviewed the quality of the slide. 2. Review of laboratory procedure "Histopathology - Mohs Surgery Policy/Procedure" revealed the procedure failed to include the practioner's method for mapping and inking (grossing) the Mohs surgical specimen. Findings: Review of laboratory procedure manual revealed no documentation of the practioner's method for mapping and inking (grossing) Mohs surgical specimens. Interview with HT at approximately 11:00 a.m. confirmed the Mohs procedure and the procedure manual failed to include the practioner's method for mapping and inking (grossing) Mohs surgical specimens.

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 review of laboratory policies and procedures, review of 2019, 2020, 2021 and 2022 cryostat maintenance logs and interview with HT 5/10/22, the laboratory failed to perform and/or document all required weekly and/or yearly maintenance of the cryostat 2 of 6 months reviewed in 2019, 3 of 12 months reviewed in 2021, and 3 of 4 months reviewed in 2022. Findings: Review of laboratory policy "Quality Control Program" revealed " 5. Maintenance and Function Checks: Equipment will be maintained according to the protocols included in this manual, and in all cases consistent with manufacturer's recommendations. Such maintenance will be documented in the related log forms.". Review of laboratory procedure "Equipment Quality Control - Cryostat Use Protocol" and "Cryostat Maintenance Record" logs revealed daily, weekly, monthly and yearly maintenance tasks. For example: Daily - Check calibration thermometer, Weekly - reagents changed weekly, Monthly - Clean Air Filter and Change H&E monthly, Yearly - Preventive maintenance. Review of 2019 "Cryostat Maintenance Record" logs revealed weekly maintenance was not documented 2 of 4 weeks in November of 2019 and monthly maintenance was not documented in October of 2019. Review of 2021 "Cryostat Maintenance Record" logs revealed weekly maintenance was not documented 1 of 4 weeks in May of 2021, 1 of 5 weeks in June of 2021, and 3 of 4 weeks in October of 2021. The 2021 logs also revealed no documentation of yearly preventive maintenance. Review of 2022 "Cryostat Maintenance Record" logs revealed daily temperatures were not recorded 11 of 15 days in January of 2022, weekly maintenance was not documented 1 of 3 weeks in February of 2022 and monthly maintenance was not documented in April of 2022. Interview with HT at approximately 11:15 a.m. confirmed the maintenance was not documented as required. She stated she does it automatically and must have forgot to document it.

D5779

CORRECTIVE ACTIONS
 CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
 Based on surveyor observation, review of laboratory policy, review of laboratory records, and interview with histotechnician (HT) 5/10/22, the laboratory failed to follow established corrective action policy when the cryostat analyzer was not functioning properly. Findings: Surveyor observed three cryostat analyzers in the histopathology laboratory, a Leica cryostat #002078, a Leica CM 1510 S and a QS12 Avantik. Interview with HT at approximately 10:30 a.m. revealed the laboratory was currently using the Leica CM 1510 S cryostat. The HT stated the laboratory had three cryostats due to the laboratory having problems with the cryostat holding set temperatures and they had obtained a loner, the Avantik, to use as a backup when the cryostat was sent out for service. Review of laboratory policy "Protocol for Dealing with a Nonfunctioning Cryostat" revealed "If the unit does not work, the patients who have been scheduled for surgery on that day will be called immediately and surgery canceled and rescheduled. If the patient is already here, and if the case has already started, the case will be completed using the standard excision technique or referred to another facility for completion of Mohs case, or completed at a later date after repairs are made to the cryostat, or a replacement unit is installed. The service contract

	<p>company will then be called for repair. Patients will not be scheduled for Mohs surgery until the unit is functioning properly. Complete a Request for Corrective Action to document actions taken." . Review of laboratory records revealed the laboratory failed to complete the "Request For Corrective Action" form to document the corrective actions taken when the cryostat was not functioning properly as per laboratory policy. Interview with HT at approximately 10:45 a.m. confirmed the laboratory failed to complete a "Request For Corrective Action" form as per laboratory policy.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records and interviews with HT 5/10/22, the laboratory director (LD) failed to provide overall management and direction of the laboratory. Findings: 1. The LD failed to ensure verification of accuracy was performed as required for KOH/Wet Prep and Tzanck testing. See D6086. 2. The LD failed to ensure quality assessment (QA) programs were maintained as established. See D6094. 3. The LD failed to ensure policies were established for monitoring competency of technical supervisors (TS's) and general supervisors (GS's). And failed to perform competencies of 3 of 3 TS and 3 of 3 GS. See D6103. 4. The LD failed to specify in writing the duties and responsibilities of each testing personnel (TP), TS and GS. See D6107. 5. The LD failed to evaluate the competency of 5 of 6 TP at least annually for approximately 3-4 years. See D6120.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy/procedure, lack of documentation and interview with HT 5/10/22, the LD failed to ensure verification of accuracy was performed for the KOH/Wet Prep testing and the Tzanck stain testing at least twice annually since June of 2019, approximately 3 years in which verification of accuracy was not performed. Findings: See D5217.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory policy/procedure, review of 2019, 2020, 2021 and 2022 laboratory records, surveyor observation, and interviews with HT 5/10/22, the LD failed to ensure quality assessment (QA) programs were maintained to assure the quality of laboratory services. Findings: 1. Review of laboratory "Quality Assessment Program" revealed "The programs and methods used for Proficiency Testing and the results of this testing will be evaluated by the Laboratory Director or an appropriate, designated staff member annually." Review of laboratory procedures revealed the laboratory had no documentation of "programs and methods" to verify the accuracy of the KOH/Wet Prep testing and the Tzanck stain. Laboratory records revealed the laboratory failed to perform a verification of accuracy for the KOH/Wet Prep testing and the Tzanck stain since June of 2019. See D5217. 2. Review of laboratory "Quality Assessment Program" revealed "All Quality Control (QC) records such as log sheets that have not been reviewed previously will be reviewed by the Laboratory Director or an appropriate designated staff member annually.". Findings: Review of laboratory records revealed no documentation of annual review of "Cryostat Maintenance Record" which includes cryostat maintenance and H&E daily QC documentation. Maintenance of the cryostat was not performed and/or documented as required. See D5433. Interview with HT at approximately 11:15 a.m. confirmed the laboratory did not perform annual review of QC and maintenance log sheets. 3. Review of laboratory "Quality Assessment Program" revealed "A review of every Request for Corrective Action will be performed by the Laboratory Director or an appropriate, designated staff member...This review will include evaluation of the corrective actions taken...". Findings: Review of laboratory records revealed the laboratory failed to complete a "Request for Corrective Action". See D5779. 4. Review of laboratory "Quality Assessment Program" revealed "The competency of Testing Personnel and all staff members will be evaluated and documented after initial training and as part of their annual review by the Laboratory Director or an appropriate, designated staff member to ensure that all laboratory staff maintain their competency in testing and laboratory management functions.". Laboratory records revealed competency assessments of testing personnel and of staff performing "laboratory management functions" (TS and GS) were not performed annually as required. See D6103 and D6120.

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 review of laboratory policies, review of laboratory records and review of submitted CMS (Centers for Medicare & Medicaid Services) Form 209 (CMS-209) the LD failed to ensure policies and procedures were established for the monitoring of personnel who perform duties as Technical Supervisor (TS) and General Supervisor (GS) and failed to ensure competency assessments were performed for the duties and responsibilities of each TS and GS. 1. The LD failed to ensure policies were established for the monitoring of personnel who perform duties as TS and GS. Findings: Review of CMS Form 209, "LABORATORY PERSONNEL REPORT

(CLIA)" revealed the laboratory has 4 personnel that serve as technical supervisors (TS) and 4 that serve as general supervisors (GS). The LD also serves as one of the TS and GS on the CMS-209. Review of laboratory records revealed no documentation the LD specified in writing the duties and responsibilities of each TS and GS listed on the CMS-209. See D6107. Review of laboratory policies revealed no policy or procedure for the monitoring of duties and responsibilities of personnel who are listed on the CMS-209 as TS and GS. 2. The LD failed to ensure competency assessments were performed for the duties and responsibilities of 3 of 3 TS and 3 of 3 GS personnel. Review of laboratory procedure "Quality Assessment Program" states "The competency of...all staff members will be evaluated and documented after initial training and as part of their annual review by the Laboratory Director or an appropriate, designated staff member to ensure that all laboratory staff maintain their competency in ...laboratory management functions....laboratories performing Moderate and High Complexity testing require semiannual performance assessments during the first year and annual assessments thereafter. Personnel evaluations will include review and suitable revision of Authorized Duties Forms.". Review of laboratory records revealed no documentation of competency assessments for 3 of 3 TS and 3 of 3 GS.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, review of laboratory records and review of submitted CMS-209 5/10/22, the LD failed to specify in writing the duties and responsibilities of each TS, each GS and each Testing Personnel (TP). Findings: Review of CMS Form 209, "LABORATORY PERSONNEL REPORT (CLIA)" revealed the laboratory has 4 personnel that serve as TS and 4 that serve as GS. The LD also serves as one of the TS and GS on the CMS-209. The CMS-209 also lists 6 of 6 personnel as TP. Review of laboratory policy "Quality Assessment Program" revealed "Personnel evaluations will include review and suitable revision of Authorized Duties Form." Review of laboratory records revealed no documentation the LD specified in writing the duties and responsibilities of each TS, GS and TP listed as personnel on the CMS-209. The records also revealed no documentation of an "Authorized Duties Form".

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly,

accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, review of laboratory records and interview with HT 5/10/22, the technical supervisor (laboratory director) failed to evaluate the competency of all testing personnel since 2019, a period of approximately 3 to 4 years in which competency assessments were not performed on 5 of 6 TP. Findings: Review of laboratory procedure "Quality Assessment Program" states "The competency of Testing Personnel and all staff members will be evaluated and documented after initial training and as part of their annual review by the Laboratory Director or an appropriate, designated staff member to ensure that all laboratory staff maintain their competency in testing and laboratory management functions....laboratories performing Moderate and High Complexity testing require semiannual performance assessments during the first year and annual assessments thereafter. Personnel evaluations will include review and suitable revision of Authorized Duties Forms.". Review of laboratory records revealed documentation of one competency assessment, TP #2, for "KOH Wet Prep Tzank Gram Stain Scabies" performed on 5/4/19. There were no competency assessment for TP #2 in 2020, 2021 and 2022. Review of laboratory records revealed no competency assessments for TP#3, TP#4, TP#5 and TP#6 in 2019, 2020, 2021 and 2022.