

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1094071	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Carolina Dermatology & Endocrinology, Pa	Street Address, City, State 244 Medspring Drive, Clayton, 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
D0000	
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 proficiency testing (PT) procedure, review of 2019, 2020 and 2021 verification of accuracy records and interview with lab assistant 9/22/21, the laboratory failed to verify the accuracy of the Potassium Hydroxide (KOH)/Wet Prep test at least twice a year as required. Findings: Review of laboratory procedure "KOH Proficiency Testing" revealed "Verification of accuracy must be done at least two times a year..." Review of 2019 verification of accuracy records revealed no documentation for the participation in a system to verify the accuracy of KOH/ wet prep at least twice a year as required. Interview with lab assistant at approximately 12: 20 p.m. confirmed the laboratory failed to verify the accuracy of KOH/ wet prep at least twice in 2019.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020 and 2021 hematoxylin and eosin (H&E) quality</p>

control (QC) records and patient logs 9/22/21, the laboratory failed to document QC as required before reporting patient test results. Approximately 27 patients were tested when QC was not documented. Findings: Review of 2019 H&E QC records revealed QC was not documented 1/17/19 and 1/24/19. Review of patient logs revealed that six patients were tested 1/17/19, and one patient was tested 1/24/19. Review of 2020 H&E QC records revealed QC was not documented 7/23/20. Review of patient logs revealed five patients were tested 7/23/20. Review of 2021 H&E QC records revealed QC was not documented 1/14/21, 1/21/21 and 2/11/21. Review of patient logs revealed that four patients were tested 1/14/21, five patients were tested 1/21/21, and six patients were tested 2/11/21.

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 January 2019 and June 2019 "Monthly Quality Assurance Checklist" 9/22/21, the quality assessment (QA) program failed to identify H&E QC was not documented as required before patient testing and failed to identify a verification of accuracy for KOH/Wet Prep was not performed as required in 2019. Findings: Review of the laboratory's "Monthly Quality Assurance Checklist" for January 2019 and June 2019 revealed "Our QUALITY CONTROL POLICIES were followed:...All quality control/calibrations were performed and within acceptable limits.". The checklists are marked with a yes (Y), and failed to identify when H&E QC was not documented. See D5481. Review of the laboratory's "Monthly Quality Assurance Checklist" for January 2019 and June 2019 revealed "Our PROFICIENCY TESTING POLICIES were followed:...All proficiency test results were evaluated. Proficiency test failures were investigated and remedial action was taken." The checklists are marked with a Y, and failed to identify a twice annual verification of accuracy for KOH/Wet Prep was not performed as required in 2019. See D5217.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with lab assistant 9/22/2021, the Laboratory Director (LD) failed to ensure TP #4 had documented training for the performance of KOH/Wet Prep testing and reporting prior to performing patient testing. Findings: Review of personnel records revealed TP #4 was hired 11/15/19. Personnel records for TP #4 revealed no documentation of training for the performance and reporting of KOH/Wet Prep testing. Interview with lab assistant at approximately 1:15 p.m. confirmed the laboratory did not have documentation of KOH

/Wet Prep training for TP #4, she stated TP #4 has been working under the LD for the last year. She also confirmed TP #4 was hired on 11/15/19.

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 personnel records, the Technical Supervisor (laboratory director) failed to evaluate competency of TP #1, TP #2, and TP #3 for KOH/Wet Prep in 2019 and failed to perform a semi-annual competency evaluation in 2020 for TP #4 who was hired on November 15, 2019. Findings: Review of personnel records revealed no documentation of competency evaluations for TP #1, TP #2, and TP #3 for KOH/Wet Prep in 2019. Review of personnel records revealed no documentation of a semi-annual evaluations for TP #4 in 2020 for KOH/Wet Prep who was hired on November 15, 2019.