

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0679766	(X3) Date Survey Completed 10/23/2020
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 5505 Peachtree Dunwoody Road, Atlanta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 23, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on document review and an interview with the practice administrator, the laboratory director failed to review and evaluate Medical Laboratory Evaluation (MLE) proficiency test (PT) results as required by Clinical Laboratory Improvement Amendments. Findings include: 1. Review of MLE PT documents revealed the laboratory director failed to review and evaluate KOH Slide PT results of 2018 MLE - M3 Event, 2019 MLE-M1 Event, 2019 MLE-M2 Event and 2019 MLE-M3. 2. An interview with the practice administrator on 10/23/2020, in the break room at approximately 01:40 p.m., confirmed and verified that (MLE) PT results forms were not reviewed and signed by the laboratory director.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on document review and an interview with the practice administrator, the lab</p>

failed to document corrective action for unsuccessful Medical Laboratory Evaluation (MLE) proficiency test (PT) results as required by Clinical Laboratory Improvement Amendments. Findings include: 1. Review of MLE PT documents revealed the laboratory failed to document corrective action for failed KOH Slide (K-6) PT results of 2018 MLE - M3 Event. 2. An interview with the practice administrator on 10/23 /2020, in the break room at approximately 01:30 p.m., confirmed that there was no corrective action performed and documented for the above failed (MLE) PT results.

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 the laboratory's maintenance, Quality Assurance(QA) records and an interview with the practice administrator, the laboratory failed to ensure that Monthly (QA) reports and maintenance logs were reviewed and signed in 2019 and 2020. Findings include: 1. Maintenance and Quality Assurance report review revealed QA and maintenance logs were not reviewed and signed in 2019 and 2020 by the Technical Supervisor(TS) who is also the laboratory director. 2. An interview with the practice administrator on 10/23/ 2020, at approximately 01:40 pm, in the break room confirmed that maintenance logs and QA reports were not reviewed and signed by the (TS) who is also the laboratory director.