

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0679766	(X3) Date Survey Completed 07/03/2018
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 3, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: 3,
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory document review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency. Findings include: 1. Laboratory document review revealed the laboratory failed to establish and follow written policies and procedures, using the 6-procedure requirements, to assess TP competency. 2. An interview with the office manager in the laboratory area on 7/3/18 at approximately 12:30 p.m. confirmed written policies and procedures to assess TP competency were unavailable at the time of survey</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on laboratory document review and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as required. Findings include: 1. Laboratory document review revealed the laboratory failed to establish and follow written policies and procedures to monitor, assess, and correct problems in all phases of laboratory testing. 2. An interview with the office manager in the laboratory area on July 3, 2018, at approximately 12:30 p.m. confirmed there was not a laboratory quality assessment policy and procedure available at the time of survey.

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 review of laboratory documents and staff interview, the laboratory failed to provide a policy and procedure manual (SOP) for all tests, assays, and examinations performed by the laboratory. Findings include: 1. Laboratory document review revealed the laboratory failed to provide an SOP for the following tests, assays, and examinations: Potassium Hydroxide (KOH) testing. 2. An interview with the office manager on 7/3/18 in the laboratory area at approximately 12:30 p.m. confirmed a laboratory SOP was not available at the time of survey.

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 laboratory document review and staff interview, a laboratory policy and procedure manual (SOP) was not available to include the documents required by

Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Laboratory document review revealed an SOP was not available with the following documents required by CLIA: requirements for patient preparation, specimen collection, specimen labeling, specimen processing, and criteria for specimen acceptability and rejection, normal values; step-by-step performance of the Potassium Hydroxide (KOH) procedure including interpretation of results; and the laboratory's system for entering results in the patient record and reporting patient results. 2. An interview with the office manager on 7/3/18 in the laboratory area at approximately 12:30 p.m. confirmed the aforementioned documents were unavailable at the time of survey.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on laboratory document review and staff interview, the laboratory director (LD) failed to specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. Laboratory document review revealed the LD failed to establish in writing the duties and responsibilities of each individual engaged in the performance of all phases of laboratory testing. 2. An interview with the office manager on 7/3/18 in the laboratory area at approximately 12:30 p.m. confirmed the LD has not specified in writing the duties and responsibilities of each individual engaged in the performance of all phases of laboratory testing.