

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1014883	(X3) Date Survey Completed 05/30/2023
Name of Provider or Supplier Forefront Dermatology, S C DbA Lakeshore	Street Address, City, State 6225 Prairie Street, Norton Shores, MI	
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
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, 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.</p> <p>This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interviews, the laboratory failed to establish requirements for specimen labeling for 2 (May 2021 to May 2023) of 2 years reviewed. Findings include: 1. The surveyor observed Testing Personnel #4 enter the laboratory with a piece of tissue on a piece of gauze with no specimen labeling. Testing Personnel #4 proceeded to ink and orient the tissue on 5/30/23 at 1:26 pm. 2. A review of the laboratory's policies and procedures revealed a lack of specimen labeling policy for mohs surgery specimens. 3. An interview on 1:36 pm with the Mohs Technician confirmed the specimen had not been labeled and indicated multiple</p>

specimens may be present in the laboratory at the same time if there are more than one cases in a testing day. 4. An interview on 5/30/23 at 3:45 pm with the Clinical Supervisor confirmed the laboratory had not established a specimen labeling policy for mohs surgical specimens. B. Based on record review and interview with the Clinical Supervisor, the laboratory failed to establish a microscopic tissue evaluation procedure for its testing on mohs surgical specimens for 2 (May 2021 to May 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of a microscopic tissue evaluation procedure for its testing on mohs surgical specimens. 2. The surveyor requested the microscopic tissue evaluation procedure on 5/30/23 at 3:26 pm and it was not made available. 3. An interview on 5/30/23 at 3:45 pm with the Clinical Supervisor confirmed the laboratory had not established a microscopic tissue evaluation procedure for its testing on mohs surgical specimens.

D6121

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Clinical Supervisor, the Technical Supervisor failed to perform direct observations of patient test performance, specimen handling, processing, and testing for 1 (Testing Personnel #4) of 6 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's competency assessment records revealed Testing Personnel #4 last had their direct observations of patient test performance, specimen handling, processing, and testing assessed on 11/6/19. 2. An interview on 5/30/23 at 2:30 pm with the Clinical Supervisor revealed the laboratory had not performed direct observations of patient test performance, specimen handling, processing, and testing for Testing Personnel #4 as part of their competency assessments since 11/6/19.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Clinical Supervisor, the Technical Supervisor failed to assess the problem-solving skills for 1 (Testing Personnel #4) of 6 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's competency assessment records revealed Testing Personnel #4 last had their problem-solving skills assessed was 11/6/19. 2. An interview on 5/30/23 at 2:30 pm with the Clinical Supervisor revealed the laboratory had not assessed the problem-solving skills of Testing Personnel #4 as part of their competency assessments since 11/6/19.