

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2014725	(X3) Date Survey Completed 05/27/2021
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 6807 Knightdale Boulevard, Suite C, Knightdale, 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
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: Based on review of laboratory procedure manual and interview with Regional Manager and Histology Technican (HT) 5/27/21, the laboratory procedures for potassium hydroxide (KOH) and Ectoparasite testing are incomplete and/or incorrect and the laboratory failed to have a procedure for the Tzanck stain. 1. The laboratory procedure "KOH Examination and QC" failed to include what elements are to be reported. Findings: Review of laboratory procedure "KOH Examination and QC" revealed "...Documentation: 1. The orders and results of the KOH prep are documented in the patient's electronic medical record and a positive or negative test</p>

result is recorded,...". The procedure fails to include what elements are to be recorded as positive or negative. For example; ringworm or yeast. 2. The laboratory procedure "Ectoparasite Examination" failed to include what elements are reported and refers to documentation of a KOH prep versus an Ectoparasite examination. Findings: The laboratory procedure "Ectoparasite Examination" revealed "...Documentation: 1. The orders and results of the KOH prep are documented in the patient's electronic medical record and a positive or negative test result is recorded,...". The procedure fails to indicate documentation is for Ectoparasite examination and the procedure fails to include what elements are to be recorded as positive or negative. For example; scabies or lice. 3. The procedure manual failed to include a procedure for the Tzanck stain. Review of procedure manual revealed no documentation of a procedure for Tzanck stain. Interview with HT at approximately 12:00 p.m. confirmed the procedures for KOH and Ectoparasite exam failed to include what elements are to be recorded. She stated that their old procedures included this information but she was told to use the new procedure manual from the new owners. She also confirmed the new procedure manual failed to include a procedure for Tzanck stain. Interview with Regional Manager at approximately 2:00 p.m. confirmed the procedure for KOH and Ectoparasite exam failed to include what elements are to be recorded as positive or negative. He stated that the EMR has the elements and the testing personnel would chose negative or positive for each one. He also confirmed the procedure manual failed to include a procedure for Tzanck stain.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with HT 5/27/21, the laboratory failed to document quality control of the Tzanck stain each day of use. Review of laboratory records revealed the laboratory performed the Tzanck stain approximately 7 times from 2019 until time of survey 5/27/21. The records failed to reveal documentation of quality control for the Tzanck stain. Interview with HT at approximately 2:00 p.m. confirmed the laboratory had not documented quality control of the Tzanck stain.

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 laboratory personnel records, review of laboratory procedure manual

and interview with Regional Manager and HT, the laboratory director (LD) failed to ensure prior to testing patient specimens that 2 of 2 testing personnel (TP) had documented training for the performance of KOH, ectoparasite examination and Tzanck testing. And the LD failed to ensure that training for 3 of 3 TP was documented for the new electronic medical record (EMR) EMA, installed in May of 2019. Findings: 1. The LD failed to ensure prior to testing patient specimens that TP #2 and TP #3 had documented training for the performance of KOH, ectoparasite and Tzanck testing. Findings: Review of laboratory personnel records revealed no documentation of training for the performance of KOH, ectoparasite and Tzanck testing. Review of laboratory procedure "KOH Examination and QC" revealed "... Accuracy 1. Verification of accuracy of the KOH prep is completed with each Provider Performed Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collecting and reading each test." The procedure fails to state how training or initial competency is assessed. Review of laboratory procedure "Ectoparasite Examination" revealed "...Accuracy 1. Verification of accuracy of the KOH prep is completed with each Provider Performed Microscopy (PPM). Each physician and mid-level provider uses clinical correlation, along with collecting and reading each test. 2. Initial competency is assessed using an internal pictorial quiz. Twice yearly, quality assurance via peer review will be completed and maintained in Quality Control Logbook." Review of laboratory procedure "Subject: Personnel Competency Testing" revealed "Procedure...Initial training indicating that the testing personnel have demonstrated testing, read the procedure manual, perform quality control, recognize test failures, and follow reporting procedures must be documented...The director is responsible for ensuring that the testing personnel have completed proper training and that the training documented and reviewed by him /her." Review of laboratory procedure manual revealed no procedure for Tzanck testing. See D5403. Review of laboratory personnel records for TP #2 and TP #3 revealed no documentation of training or initial competency for KOH, ectoparasite and Tzanck testing. Interview with Histology technician at approximately 11:00 a.m. confirmed there was no documentation of training for the KOH, ectoparasite and Tzanck testing for TP #2 and TP #3. 2. The LD failed to ensure training was documented for TP#1 (LD), TP #2, and TP #3 for the new EMR EMA installed in May of 2019. Review of laboratory procedure "Subject: Personnel Competency Testing" revealed "Procedure...Initial training indicating...and follow reporting procedures must be documented...The director is responsible for ensuring that the testing personnel have completed proper training and that the training is documented and reviewed by him/her." Review of laboratory personnel records revealed no documentation of training for the EMR EMA for TP#1 (LD), TP #2, and TP #3. Interview with Regional Manager at approximately 11:00 a.m. confirmed there was no documentation of training for TP#1 (LD), TP #2, and TP #3 for the new EMR EMA. He stated that all personnel were trained for all test reporting, including the Mohs reporting, but they did not have documentation of the training.