

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1014883	(X3) Date Survey Completed 11/13/2019
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the CLIA liaison, the laboratory failed to have a electronic request for patient testing for 3 (WR070464, BD012571, and KL062741) of 14 patient charts audited. Findings include: 1. A review of patient testing logs revealed 1 patient (WR070464) received scabies testing and 2 (BD012571 and KL062741) patients received potassium hydroxide (KOH) testing. 2. A review of the 3 patient charts revealed a lack of a test request for testing as follows: a. WR070464 - scabies testing on 2/20/18 b. BD012571 - KOH testing on 2/27/19 c. KL062741- KOH testing on 5/09/19 3. An interview on 11/13/19 at 12:08 pm with the CLIA liaison confirmed an electronic test request was not available.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the CLIA liaison, the laboratory failed to</p>

maintain a record system that included the specimen receipt time into the laboratory for each Mohs' tissue specimen stage for 10 (NS17-001, NS18-085, NS18 -286, NS18 -421, NS18 - 629, NS18 - 879, NS19 - 052, NS19 - 190, NS19 - 516, and NS19 -805) of 10 Mohs' patient charts audited. Findings include: 1. Record review for 10 of 10 Mohs' cases reviewed, the laboratory failed to include the specimen receipt time into the laboratory for each Mohs' tissue specimen stage on the final Mohs' map as follows: a. NS17 - 001 - no time for level 1 b. NS18 - 085 - no time for level 1 c. NS18 - 286 - no time for level 1 d. NS18 - 421 -no time for levels 1 and 2 e. NS18 -629 - no time for levels 1 and 2 f. NS18 -879 - no time for level 1 g. NS19 -052 - no time for levels 1 and 2 h. NS19 -190 - no time for level 1 i. NS19 -516 - no time for levels 1-3 j. NS19-805 - no time for level 1 2. During the interview on 11/13/19 at 12: 23 pm, the CLIA Liaison acknowledged the final Mohs' map scanned into the patient's chart did not contain the specimen receipt times for each tissue stage.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the CLIA liaison, the laboratory failed to ensure test results were reliably transferred from the patient testing log to the patients electronic medical record (EMR) for 3 (WR070464, BD012571, and KL062741) of 14 patient charts audited. Findings include: 1. A record review of the potassium hydroxide (KOH) and scabies patient testing logs revealed the following patients had testing performed on the following dates: a. Patient WR070464 - scabies testing on 2 /20/18 b. Patient BD012571 - KOH testing on 2/27/19 c. Patient KL062741 - KOH testing on 5/09/19 2. A patient chart audit of the patients tested above revealed a lack of documentation of final test reports in the patient's EMR file. 3. During the interview on 11/13/19 at 12:08 pm, the CLIA liaison acknowledged the final test reports were not documented in the patient's EMR file.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the CLIA liaison, the laboratory failed to indicate the name and address of the laboratory location where testing was performed for 12 (December 2017 to November 2019) of 12 months. Findings include: 1. Record review for 12 of 12 months of Mohs' testing revealed the Mohs' maps that was either scanned or a photographic picture taken of the report did not provide the name and address of the laboratory performing the testing. 2. During the interview on 10/13/19 at 12:23 pm, the CLIA liaison acknowledged the Mohs' reports lacked the name and address of the testing facility.