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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D1019065              | <b>(X3) Date Survey Completed</b><br><br>01/18/2021 |
| <b>Name of Provider or Supplier</b><br><br>Forefront Dermatology, Sc DbA Advanced Dermatology                              | <b>Street Address, City, State</b><br><br>1235 Lake Pointe Pkwy Ste 200, Sugar Land, TX |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1487 D6168 Condition: Laboratories performing high complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately. |
| <b>D6029</b>              | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(11)</p> <p>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)(11) 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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory's personnel records and staff interview, it was</p>   |

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|              | <p>revealed the laboratory director failed to ensure that testing personnel had documentation of the appropriate training to perform moderate complexity testing- KOH and Scabies preparations (refer to D6066).</p>  |
| <b>D6066</b> | <p><b>TESTING PERSONNEL QUALIFICATIONS</b><br/>CFR(s): 493.1423(b)(4)(ii)</p> <p>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of site-specific training for 1 of 4 testing personnel performing moderate complexity testing- KOH and Scabies preparations. Findings include: 1. A review of the laboratory's CMS 209 form (signed by the laboratory director on 1/14/21) revealed the laboratory identified 4 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of site-specific training for testing person #5 (demonstrating that they can perform all testing operations for this laboratory) to perform moderate complexity testing- KOH and Scabies preparations. 3. An interview with testing person #2 on 1/18/21 at 2:00 p.m. in the office, after review of the records, confirmed the above findings. Key: KOH - potassium hydroxide</p>   |
| <b>D6102</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(12)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, a review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure documentation of site-specific training for 1 of 2 testing personnel performing high complexity testing- Mohs. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/14/21) revealed the the laboratory identified 2 testing personnel performing high complexity testing- Mohs. 2. A review of the laboratory's personnel records revealed testing person #7 had no documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- Mohs. 3. An interview with testing person #2 on 1/18/21 at 2:00 p.m. in the office, after review of the records, stated that testing person #7 was brought in, just one day, to do testing and that it was a last minute, emergency situation. No on-site training was done. This confirmed the above findings.</p> |
| <b>D6168</b> | <p><b>TESTING PERSONNEL</b><br/>CFR(s): 493.1487</p>  |

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 2 testing personnel to perform high complexity testing- Mohs (refer to D6171).

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent

stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 2 testing personnel to perform high complexity testing- Mohs. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/14/21) revealed the laboratory identified 2 testing personnel performing high complexity testing- Mohs. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify testing person #7 to perform high complexity testing- Mohs. 3. An interview with testing person #2 on 1/18/21 at 2:00 p.m. in the office, after review of the records, stated that testing person #7 was brought in, just one day, to do testing and that it was a last minute, emergency situation. No documentation of education was obtained. This confirmed the above findings.