

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0180681	(X3) Date Survey Completed 06/20/2019
Name of Provider or Supplier Forefront Dermatology, Sc	Street Address, City, State 419 West Pittsburgh Street, Greensburg, PA	
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
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 review of Laboratory procedure manuals and interview with the Regional Clinical Manager and the Nursing Manager, the laboratory failed to follow and establish a complete competency assessment procedure to assess the competency of testing personnel (TP) who performed Potassium Hydroxide (KOH), scabies testing and consultants in 2018 to the day of survey. Findings Include: 1. The Personnel Competency Testing Policy states, "Laboratory compliance requires training /competency to be completed initially, 6 months after the start date and annually thereafter". 2. On the day of survey, 06/20/2019, review of personnel records revealed, the laboratory failed to provide a complete written policy on how to assess the competency of consultants from 2018 to 06/20/2019. 3. 6 of 7 TP competencies for KOH and scabies were performed 1/20/2018, but were not performed annually in 2019. 4. The laboratory could not provide competency assessment assessed in 2018 and 2019 for: - 3 of 4 clinical consultants. - 3 of 4 technical consultants. - 1 of 2 technical supervisors. - 1 of 2 general supervisors. 5. The Regional Clinical Manager and the Nursing Manager confirmed the findings above on 06/20/2019 around 1:15 pm.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on review peer review records and interview with the Regional Clinical Manager and the Nursing Manager, the laboratory failed to perform at least twice annually the accuracy of Potassium Hydroxide (KOH) and scabies microscopic examination for 2 of 5 testing personnel (TP) in 2018. Findings Include: 1. On the day of survey, 06/20/2019, review of KOH and scabies peer review records revealed, the laboratory did not perform at least twice annually the accuracy of KOH and scabies microscopic examination for 2 of 5 TP in 2018. 2. The Regional Clinical Manager and the Nursing Manager confirmed the finding above on 06/20/2019 around 1:30 pm.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and interview with the Regional Clinical Manager and the Nursing Manager, the laboratory failed to establish a quality assurance policy for Potassium Hydroxide (KOH), scabies and histopathology microscopic examinations performed from 10/18/2017 to the date of survey. Findings Include: 1. On the day of survey, 06/20/2019, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs for KOH, scabies and histopathology microscopic examinations performed from 10/18/2017 to 06/20/2019. 2. The Regional Clinical Manager and the Nursing Manager confirmed the findings above on 06/20/2019 around 1:55.