

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2312042	(X3) Date Survey Completed 08/08/2025
Name of Provider or Supplier Blue Ridge Dermatology Associates	Street Address, City, State 4225 Macon Pond Rd Suite 300, Raleigh, 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
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 policies and procedures, lack of documentation and interview with histology technician (HT) 08/08/25, the laboratory failed to establish a competency assessment policy or procedure for testing personnel (TP) who perform potassium hydroxide (KOH) testing. Findings: Review of laboratory policies and procedures revealed no documentation of a procedure or policy for the competency assessment of TP who perform KOH testing. Interview with HT at approximately 11:00 a.m. confirmed the laboratory had no policy or procedure for the competency assessment of TP who perform KOH testing.</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> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, review of laboratory records, lack of documentation and interview with HT 08/08/25, the laboratory failed to verify the accuracy of the KOH testing since testing began in November of 2024. Findings: Review of laboratory policies and procedures revealed no procedure and/or policy or enrollment in proficiency testing (PT) for the verification of accuracy of the KOH</p>

testing performed. Review of laboratory records revealed no documentation of a verification of accuracy for the KOH testing performed since testing began in November of 2024. Interview with HT at approximately 11:00 a.m. confirmed the laboratory had no policy or procedure for the verifying the accuracy of the KOH testing and they also did not enroll or participate in proficiency testing for the KOH testing. They stated the laboratory previously had a Provider Performed Microscopy Procedure (PPMP) certificate and they have never performed a verification of accuracy for the KOH testing.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, review of laboratory policies/procedures and interview with HT 08/08/25, the technical consultant (TC), laboratory director (LD), failed to evaluate and perform semi-annual competency assessments on 13 of 13 testing personnel (TP) who perform KOH testing. Findings: Review of laboratory records revealed no documentation of competency assessments for 13 of 13 TP who perform KOH testing since November of 2024, a period of approximately 10 months. Review of laboratory policies/procedures revealed the laboratory failed to establish a competency assessment procedure for TP who perform KOH testing. (See D5209). Interview with HT at approximately 11:00 a.m. confirmed there were no competency assessments performed for TP who perform KOH testing. They stated the laboratory previously had a Provider Performed Microscopy Procedure (PPMP) certificate and they have never performed competency assessments for the KOH testing.