

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0935092	(X3) Date Survey Completed 02/17/2022
Name of Provider or Supplier Gem State Dermatology	Street Address, City, State 388 E Parkcenter Blvd, Boise, ID	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Academy of Family Physicians (AAFP) and an interview with the clinic manager on 2/17/2022, the laboratory failed to document and retain PT result forms and attestation forms for 2021. The findings include: 1. A review of PT records from AAFP for the three events in 2021 identified that the laboratory failed to document and retain the reported results for potassium hydroxide (KOH) testing for all 2021 events. 2. A review of PT records from AAFP for the three events in 2021 identified that the laboratory failed to retain the signed attestation forms for all 2021 events. 3. An interview with the clinic manager on 2/17/2022 at 10:15 am confirmed the above findings. 4. The laboratory reports performing 117 KOH tests annually.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records from American Academy of Family Physicians (AAFP) and an interview with the clinic manager on 2/17/2022, the laboratory director failed to review PT results for 2021. The findings include: 1. A review of PT records from AAFP for the three events in 2021 identified that the laboratory director failed to review and evaluate the results for potassium hydroxide (KOH) testing for all 2021 events. 2. An interview with the clinic manager on 2/17/2022 at 10:15 confirmed that the laboratory director failed to review and evaluate the graded KOH PT results for all three events in 2021. 3. The laboratory reports performing 117 KOH tests annually.