

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0935092	(X3) Date Survey Completed 08/03/2020
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
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 record review and interview with the laboratory medical assistant the laboratory failed to document the accuracy of potassium hydroxide (KOH) and scabies microscopic examination at least twice annually. Findings: 1. A record review revealed the laboratory failed to document the accuracy of KOH and scabies microscopic examination, at least semiannually, for the detection of fungal elements and scabies since the last survey on February 27, 2018. 2. An interview on August 3, 2020 at 2:00 PM with the laboratory medical assistant, confirmed the laboratory failed to document the accuracy of KOH and scabies microscopic examination.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedures, observation and interview with the laboratory medical assistant the laboratory failed to follow their written procedure for KOH testing. Findings: 1. In the laboratory's written procedure for KOH examination, page one, it states to use 20% KOH 2. Observation of reagents in the laboratory revealed that there</p>

was only 10% KOH, lot 9218 expiration 08/06/2021, available for use at the time of the survey. 3. An interview on August 3, 2020 at 3:00 PM, with the laboratory medical assistant, confirmed that the concentration of KOH that was being used by the laboratory for KOH examination was 10% and that was the only concentration of KOH at the facility.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and interview with the laboratory medical assistant, the technical consultant failed to evaluate the testing personnel for their competency to perform scabies microscopic examination. Findings: 1. A record review revealed the laboratory failed to document the competency of scabies microscopic examination, for four out of four providers. 2. An interview on August 3, 2020 at 2:30 PM, with the laboratory medical assistant, confirmed that the laboratory director and 3 physician assistants perform scabies microscopic examination and that they had no documentation of competency.