

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0935915	(X3) Date Survey Completed 01/27/2020
Name of Provider or Supplier Dermatology & Skin Surgery Center	Street Address, City, State 7070 E Drive N, Battle Creek, MI	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory manager, the laboratory failed to verify the accuracy of potassium hydroxide (KOH) and Scabies preparations for 2 (January 2018 to January 2020) of 2 years. Findings include: 1. A record review revealed the laboratory had a lack of documentation of KOH and Scabies testing verification of accuracy performed twice annually for 2018 and 2019. 2. An interview on 1/23/2020 at 11:23 am with the laboratory manager confirmed the laboratory did not have verification of accuracy performance documentation for KOH and Scabies testing available.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory manager, the Technical Consultant failed to evaluate the competency of testing personnel performing</p>

potassium hydroxide (KOH) and Scabies preparations for 15 (Testing Personnel #1-#15) of 16 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's established "Personnel Competency Policy /Procedure" revealed a section stating, "The Director is responsible for ensuring that the testing personnel have completed proper training and that the training is documented and reviewed by him/her. The Director may delegate this responsibility to the Technical Consultant (moderately complex labs) or the Technical Supervisor (highly complex labs) if they are qualified." 2. A record review of testing personnel competency assessments for KOH and Scabies testing revealed testing personnel competencies assessed by an office personnel who was not listed on the CMS-209 form as the Laboratory Director or a Technical Consultant for the following dates: a. Annual competencies performed on 9/11/2018 and 4/12/2019 for Testing Personnel #1-10 and #12-15. b. Initial competency performed on 11/4/2019 for Testing Personnel #11. 3. An interview on 1/23/2020 at 9:54 am with the laboratory manager confirmed the office personnel assessing testing personnel competencies was not qualified as a Technical Consultant.