

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2200334	<b>(X3) Date Survey Completed</b> 03/23/2021
<b>Name of Provider or Supplier</b> Sylvan Dermatology Llc	<b>Street Address, City, State</b> 32 Parking Plaza, Suite 300, Ardmore, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 laboratory (LD), the laboratory failed to establish a competency assessment procedure to assess 1 of 2 testing personnel (TP) and 1 of 1 consultant/supervisor competency in 2021. Findings include: 1. On the day of survey, 03/23/2021, the LD could not provide a competency assessment procedure to assess the competency for 1 of 2 TP and 1 of 1 consultant/supervisor competency in 2021. 2. The LD confirmed the findings above on 03/23/2021 around 9:10 am.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and interview with laboratory director (LD), the laboratory failed to document QC procedures each day of patient testing for 6 of 6 patient specimens examined for Potassium hydroxide (KOH) microscopic</p>

examinations from 1/5/2021 to 03/20/2021. Findings Include: 1. On the day of survey, 03/23/2021, the LD was unable to provide QC records performed each day of patient testing for 6 of 6 KOH microscopic examination performed from 1/5/2021 to 03/20/2021. 2. One patient was examined for KOH microscopic examinations on each of the follow days: 01/05/2021, 02/05/2021, 02/12/2021, 02/26/2021, 03/12/2021 and 03/20/2021. 3. The LD confirmed the findings above on 03/23/2021 around 9:20 am.