

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2010733	(X3) Date Survey Completed 03/11/2021
Name of Provider or Supplier Skinpath Solutions	Street Address, City, State 2000 Lake Park Drive, Se, Smyrna, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 11, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency document review and laboratory manager's interview, the laboratory director (LD) failed to ensure TP annual competencies were performed by qualified staff as required. Findings include: 1. TP document review revealed annual competencies for TPs# 5 - 8 (CMS 209) were not performed by the Technical Supervisor(TS) who is also the laboratory director (LD) in 2019 and 2020. The competencies were instead performed by non-technical staff. 2. An interview with the laboratory Manager on 03/11/2021 in a conference room at approximately 1:30 p.m. confirmed the aforementioned annual competencies were not performed in 2019 and 2020 by the (TS) who is also the laboratory director.</p>