

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0080097	(X3) Date Survey Completed 08/04/2023
Name of Provider or Supplier South Shore Skin Center	Street Address, City, State One Scobee Circle, Plymouth, MA	
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 CLIA recertification survey was conducted for the South Shore Skin Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on personnel competency record review and interview with the National Director of Laboratory Operations (NDLO) on 8/4/2023, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year the individual tested patient specimens in the subspecialty of Mycology. Findings include: 1. On 8/4/2023, the surveyor asked for the 2022 personnel competency records for review. The review revealed that annual competency evaluations were not documented at least annually for seven (7) out of ten (10) Testing Personnel (TP) performing potassium hydroxide (KOH) preps in 2022. 2. The NDLO confirmed in an interview on 8/4/2023 at 9:30 AM that the TC failed to document annual competency evaluations for seven (7) out of ten (10) TP's in 2022. The NDLO stated the 2022 competency records were misplaced. 3. The laboratory performs 18 mycology (KOH Preps) tests annually in the subspecialty of Mycology.</p>