

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0976513	(X3) Date Survey Completed 07/09/2021
Name of Provider or Supplier Skincare Physicians	Street Address, City, State 1244 Boylston Street, Chestnut Hill, 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 Skincare Physicians laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Histotechnologist on 7/9/21, the laboratory failed to document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar years 2019, 2020, and 2021 on 7/9/21. The review revealed that attestation statements provided by API were not signed by the analyst and laboratory director (LD) for the following events: Microbiology KOH Preparations: 2019 Event 2 2020 Events 2 & 3 2021 Event 1 The Histotechnologist confirmed in an interview on 7/9/21 at 10:30 AM that not all attestation statements were signed by the analyst and LD. .</p>
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview with the Histotechnologist, the laboratory director (LD) failed to ensure documentation of proficiency testing (PT) review as evidenced by the following: The surveyor reviewed PT records for calendar years 2019, 2020, and 2021 on 7/9/2021. The review revealed that the LD failed to ensure PT reports received from American Proficiency Institute (API) were reviewed by the appropriate staff for the following testing events: Microbiology KOH Preparation: 2021 Event 1 2020 Events 1 & 2 The Histotechnologist confirmed through interview on 7/9/21 at 10:30 AM that the PT reports from API were not reviewed by the LD or appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.