Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2153803	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
St Petersburg Dermatology	1530 Dr Mlk Jr St N, Saint Petersburg, FL	

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	An announced CLIA recertification survey was conducted at St. Petersburg Dermatology on 08/16/2022 - 08/30/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager the laboratory failed to perform competency evaluations on 4 out of 4 (#A, #B, #C, #D) Laboratory Personnel. Findings Included: Review of the laboratory's policy and procedure titled "Competency and CLIA competency assessment" last signed by the Laboratory Director on 12/21/2018 revealed "Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens. After the first year, competency assessment must be performed at least annually." It also stated that "Documented competency is required for individuals Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to comply with the procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities." Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 08/30/2022 revealed Laboratory Personnel #C acted as the Technical Supervisor for Histopathology and Testing Person for High Complexity, Laboratory Personnel #A and #D performed High Complexity testing, and Laboratory Personnel #B acted as the Technical Consultant and Testing Person for Moderate Complexity. Review of

	Laboratory Personnel files revealed no evidence of completed competency evaluations. During an interview on 08/16/2022 at 2:00 PM, the Lab Manager confirmed that there were no completed competencies in the personnel files for Testing Personnel #A-#D.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager the laboratory failed to verify the accuracy of Histopathology testing at least twice a year for 2 out of 2 years (2020-2022) reviewed. Findings Included: Review of Proficiency Testing revealed no proficiency or peer reviews for Histopathology testing for 2020, 2021, or 2022. On 08 /16/2022 at 3:30 PM, the Lab Manager confirmed that the documentation to confirm that this was done could not be located.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager the laboratory failed to perform a monthly QA (quality assurance) checklist per their policy for 2 out of 2 (2020-2022) years reviewed. Findings Included: Review of the policy and procedure manual (last signed as reviewed by the Laboratory Director on 12/21/2018) stated that the laboratory would complete a monthly QA checklist. No QA checklists had been completed in 2020, 2021, and 2022. On 08/16/2022 at 3:30 PM the Lab Manager confirmed that the QA checklist had not been completed in 2020, 2021, or 2022.