Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2153803	(X3) Date Survey Completed 06/05/2024
Name of Provider or Supplier St Petersburg Dermatology	**Street Address, City, State** 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 on-site announced CLIA recertification survey was conducted at St. Petersburg Dermatology on 06/05/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Nursing Manager, the laboratory failed to ensure 5 of 5 bottles of Mineral Oil and 4 of 4 bottles of Chlorazol Black were properly labeled with the name of the reagent, lot number, expiration date, and date in use. Findings included: During a tour of the laboratory on 06/05/2024 at 11:50 am, five bottles containing a clear liquid were observed. One bottle was labeled "Mineral", one had a blank label, and three contained no labels. Four bottles containing a dark liquid were also observed. Two of the bottles were labeled "KOH", one was labeled "Chlorazol Black E KOH", and one contained no label. During the observation on 06/05/2024 at 11:50 a.m., the Nursing Manager confirmed the Mineral Oil used for Scabies testing and Chlorazol bottles used for Fungi testing were not labeled properly. Record review of the laboratory's policy titled Quality Assurance for Routine Stains showed "All reagents and supplies used in the lab will be documented upon opening and put in use. This will consist of open date, lot number, and expiration date." Photographic evidence was obtained.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Nursing Manager and Testing Personnel #C, the laboratory failed to ensure the Chlorazol Black that was used for mycology (Fungi) testing was not expired prior to performing seven patient tests from 08/18/23 to 03/06/24. Findings included: On 06/05/24 at 11:30 a.m., observation of the Chlorazol Black container revealed the Lot number was 1120 and the expiration date was 04/30/2023. A review of the patient testing log revealed seven patients were tested for Fungi using the expired solution (8/18/23, 11/29/23, 12/6/23, 12/12/23, 12/15/23, 02/07/24, and 03/06/2024). On 06/05/2024 at 11:30 AM, the Nursing Manager stated she had pulled the original container of Chlorazol Black from the shelf but not the aliquoted bottles in the examination rooms. On 06/05/2024 at 11: 55 AM, Testing Personnel #C stated he did not know that the aliquoted bottles of Chlorazol Black were expired. Photographic evidence was obtained.