Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1089084	08/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Physicians Lld D/B/A	9325 Glades Rd Ste 207, Boca Raton, 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 recertification survey conducted on 8-06-20, found that Skin Care Physicians LLC D/B/A clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 staff Interview, the laboratory failed to perform peer-review proficiency testing twice a year for Scabies a subspecialty of parasitology from 2018 to 2019. Findings Include: A review of KOH Log sheet revealed the laboratory was performing scabies testing on 4 out 4 patients from 8/21/18 to 11/19/19. A review of the proficiency testing log showed no documentation of scabies peer review testing twice a year for 2018 and 2019. During an interview on 8-6-2020 at 11:54 am, the office manager confirmed that scabies peer review proficiency was not perform twice annually for 2018 and 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on record review and Staff interview, the laboratory failed to have a quality assurance policy and review for Scabies a subspecialty of parasitology . Findings Include: A review of KOH Log sheet revealed the laboratory was performing scabies testing on 4 out 4 patients from 8/21/18 to 11/19/19. A review of Quality Assurance Policy revealed no documentation of a written policy or review for scabies testing. During an interview on 8-6-2020 at 11:54 am, the office manager confirmed there was no quality assurance policy for Scabies and was not listed as a test preformed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to create a step by step guide for how to preform Scabies testing a subspecialty of parasitology in the procedure manual. Findings Include: A review of the procedure manual revealed no documentation of step by step guide on how to preform scabies testing. During an interview on 8-6-2020 at 11:54am, the office manager confirmed there was no step by step guide for scabies testing in procedure manual.
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 staff interview, the laboratory failed to make sure 2 bottles of mineral oil that expired on October 2017 were not in current use. Findings Include: An observation of a patient room revealed a cabinet that held two mineral oil bottles that expired October 2017 for scabies testing in use. A review of KOH Log sheet revealed the laboratory was performing scabies testing on 4 out 4 patients from 8/21/18 to 11/19/19. During an interview on 8-6-2020 at 11:54am, the

	office manager and office nursing staff confirmed that two mineral oil bottles expired on October 2017 were in use for scabies testing. Based on record review and Staff interview, the laboratory failed to have a quality assurance policy and review for Scabies a subspecialty of parasitology that was performed but not documented in their CMS -116.