

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0972210	(X3) Date Survey Completed 01/28/2020
Name of Provider or Supplier Rsb Dermatology Inc	Street Address, City, State 1500 E Hillsboro Blvd Ste 204, Deerfield Beach, 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	A recertification survey conducted on 01-28-2020, found RSB Dermatology Inc clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure a two-year record retention for potassium hydroxide preparation (KOH) and Scabies quality assessment (QA) records for 2018 and 2019. Findings Include: A review of the KOH quality assessment record displayed that KOH QA forms were missing for 2018 and 2019. A review of the Scabies quality assessment record revealed the Scabies QA forms were missing for 2018. During an interview on 1- 28-2020 at 11:30 am, The laboratory director and office manager confirmed that the records were missing from KOH QA records for the period of 2018-2019.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform potassium hydroxide preparation (KOH) proficiency testing (PT) twice annually for 2018 and</p>

2019. Findings Include: A review of Peer-Review Proficiency Testing record revealed that KOH PT was not preformed twice annually for 2018 and 2019. During an interview on 1-28-2020 at 11:30 am, the laboratory director confirmed that the KOH PT was not performed twice annually for 2018 and 2019.

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 interview, the laboratory failed to create step by step performance procedures for potassium hydroxide preparation (KOH) and Scabies in the procedure manual. Findings Include: A review of procedure manual record revealed the KOH and Scabies procedures were missing from the procedure manual. During an interview on 1-28-2020 at 11:30 am, the laboratory director and office manager confirmed that KOH and Scabies step by step procedures were missing from procedure manual.