

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0972210	(X3) Date Survey Completed 08/20/2025
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	An announced CLIA recertification survey was conducted at RSB DERMATOLOGY INC from 08/14/2025 to 08/20/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for frozen sections for two out of six testing dates in two months (July and August) reviewed in 2025. Based on record review and staff interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for pathology sections for nine out of nine months (April, May, June, July, August, September, October, November and December) reviewed in 2024 and for 2025 41 out of 52 testing dates from January to August 2025. Findings included: 1-Review of the procedure manual signed by the Laboratory Director (LD) on 01/08/2025, revealed that on policy "Quality Control Testing" stated: "You must maintain records of daily control of patient's specimen testing. These records must be on hand for a minimum of two years. Completed forms are maintained in laboratory QA log filed by month." 2-The laboratory used the "MOHS DAILY QC WORKSHEET" to record the acceptability of the daily H&E stain for the frozen section testing. Review of the MOHS DAILY QC WORKSHEET log for July and August 2025 revealed that on 07/23/ 2025 and 08/06/2025, there was no record of H&E QC slide approval. 3-Review of pathology section "H&E Quality</p>

Control" log from 04/2025 to 12/2024, the laboratory failed to have documentation of the acceptability of the H&E quality control slide. Review of "HEMATOXYLIN & EOSIN STAINING QUALITY CONTROL WORKSHEET" for year 2025, revealed that the laboratory failed to have documentation of acceptability of the daily QC slide for the following dates: 01/08/2025, 01/13/2025, 01/16/2025, 01/27/2025, 02/03/2025, 02/05/2025, 02/11/2025, 02/17/2025, 02/19/2025, 02/24/2025, 02/26/2025, 03/05/2025, 03/10/2025, 03/12/2025, 03/17/2025, 03/19/2025, 03/24/2025, 03/26/2025, 04/07/2025, 04/09/2025, 04/14/2025, 04/16/2025, 04/21/2025, 04/23/2025, 04/28/2025, 05/05/2025, 05/07/2025, 05/12/2025, 05/14/2025, 05/19/2025, 05/21/2025, 05/26/2025, 05/28/2025, 06/04/2025, 06/09/2025, 06/30/2025, 07/09/2025, 07/14/2025, 07/16/2025, 07/21/2025, 07/23/2025, 07/28/2025, 07/30/2025, 08/06/2025 and 08/11/2025. 4-Based on review of Form CMS-116 signed by the LD on 08/14/2025, revealed that the annual test volume was 2,500 tests performed. 5-During an interview on 08/14/2025 at 03:00 PM the Office Consultant confirmed that the TP failed to document the acceptability of the Daily QC slide for H& E Stain for the days and months of reference listed above.

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.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory Quality Assessment (QA) failed to identify and correct that the laboratory failed to have documentation of the approval of the daily Quality Control (QC) slide Hematoxylin and Eosin (H&E) stain from April 2024 to August 2025. Based on record review the QA failed to identify and correct that the laboratory failed to document the daily log for Hematoxylin and Eosin Maintenance log and temperature records for the Pathology section during one out of seven months in 2025 (January, February, March, April, May, June, July and August). Findings included: 1-Review of daily QC slide for H&E stain from April 2024 to August 2025, revealed that the laboratory failed to have documentation of the approval. Refer to D5473. 2-Review of procedure manual signed by the Laboratory Director (LD) on 01/08/2025, revealed that the policy "QUALITY ASSURANCE FORM" stated that the QA form will be used to monitor the ongoing and overall quality. The form will document the overall quality of the total testing process and if problems have been identified." The laboratory listed the monitored parameters, Daily: H&E Quality Control, Functions verifications: Microscope, Fume Hood, Eye Wash, Embedding Center, Refrigerator, Humidity, Room temperature, Hematoxylin & Eosin Maintenance Log, QC Logs: Microtome, Oven and water bath. 3-Review of maintenance records for 2024 and 2025, revealed that for May 2025 the laboratory had 8 testing dates and failed to document the Hematoxylin & Eosin staining Maintenance Log, Path daily Quality Control. Function Verification 1 (included Oven temperature, Waterbath temperature, Embedding Center temperature, room temperature, room humidity) and Daily Quality Control. Function Verification 2 (included Coverslipper, Eyewash, Fume Hood, Microscope and Microtome). 4-Review of "PATHOLOGY MONTHLY QUALITY ASSURANCE CHECKLIST" for May 2025 signed by the LD on 05/28/2025, revealed that the laboratory failed to identify and correct the lack of documentation. 5-During an interview on 08/14/2025 at 03:30 PM, the laboratory consultant representative confirmed that the QA plan failed to

ensure that the laboratory documented the approval of daily QC slide for H&E stain for the period reviewed and failed to correct the missing documentation for May 2025.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the LD failed to ensure the laboratory documented the approval of the daily Quality control slide for Hematoxylin & Eosin (H&E) stain since April 2024. (Refer D5473) and failed to ensure the Quality Assurance detected and corrected the missing documentation for daily quality control for pathology in May 2025. (Refer to 5793)