

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2078111	(X3) Date Survey Completed 11/21/2019
Name of Provider or Supplier Broward Dermatology Llc	Street Address, City, State 14932 Pines Blvd, Pembroke Pines, 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 was conducted on November 21, 2019. Broward Dermatology LLC clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain from 11/21/17 to 11/21/19. Findings: The laboratory uses the "Daily Quality Control Report" to record the acceptability of the H&E stain. Review of the QC form showed that for the columns under Staining, labeled S (Superior) A (Acceptable) and U (Unacceptable), there was nothing recorded in the columns for each day patients slides were examined in 2019. The Daily Quality Control Reports for 2017 and 2018 were not available for review. During an interview on 11/21/19 at 10:03 AM, the Laboratory Director acknowledged that the acceptability of the H&E stain was not recorded, and that the previous years quality control reports were sent back to the laboratory where the technical component was performed</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification,</p>

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's final report failed to list the location where the technical component was performed for 2 (#2 and 3) out of 4 patient reports examined. Findings: Review of the Histopathology final report for patient #2 and #3, showed that the name and address of location where the technical component was performed was not listed. The final reports for patient #2 and #3 were completed in 2019. The final reports for patient #1 and #4 were completed in 2018. During an interview on 11/21/19 at 10:27 AM, the Laboratory Director acknowledged that Histopathology final report did not have the name and address where the technical component was performed for patient reports completed in 2019.