

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2168311	<b>(X3) Date Survey Completed</b>  06/02/2021
<b>Name of Provider or Supplier</b>  App-Pbp Llc	<b>Street Address, City, State</b>  1500 N Dixie Hwy Ste 308, West Palm Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at APP - PBP LLC on 06/02/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 with the Laboratory Director, the facility failed to ensure Histopathology Hematoxylin and Eosin (H&amp;E), special stain, and immunohistochemical (IHC) quality control (QC) stains were documented for two out of two years (10/30/19 to 06/02/21). Findings included: Record review of the procedure manual revealed a procedure titled "Unipath Florida Technical Workflow." The procedure stated "PBP will provide Unipath Florida with the Pathologist Histology Quality Evaluation Form so that the slides received can be evaluated and rated in reference to uniformity and thickness, staining with regard to nuclear detail, and general clarity." Record review of Histopathology forms revealed the laboratory did have a copy of the "Pathologist's Histology Quality Evaluation Form" and Quality Control had not been for H&amp;E, special, and IHC stains for two out of two years ( 10/30/19 to 06/02/21). Record review of the "Quality Control Staining" revealed that the H&amp;E QC had not been documented from 09/20/19 to 12/9/20. Interview on 06/02/21 at 02:10 pm, the Laboratory Director stated she was not aware that Peer Review was not sufficient for quality control and did not know she needed to document quality control in a report or a log.</p>