

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0940726	<b>(X3) Date Survey Completed</b>  10/04/2021
<b>Name of Provider or Supplier</b>  Shapiro And Borenstein Dermatology Llp D/B/A	<b>Street Address, City, State</b>  11030 Rca Center Dr Ste 3015, Palm Beach Gardens, 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>	<p>An announced recertification survey was conducted on 10/4/21 at Shapiro and Borenstein Dermatology LLP dba Gardens Dermatology and Cosmetic Surgery Center, a clinical laboratory in Palm Beach Gardens, Florida. Shapiro and Borenstein Dermatology LLP dba Gardens Dermatology and Cosmetic Surgery Center is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiencies:</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #B, the Laboratory Director failed to ensure that the laboratory had a competency procedure that was all inclusive and failed to perform competency evaluations on 8 (Testing Personnel (TP) #C - #D, and TP # F - #K) out of 10 ( TP #A - #D and #F - #K) Testing Personnel for 2 (2020 - 2021) out of 2 years(2020 - 2021). The findings included: Record review of the laboratory's policy and procedure revealed a procedure titled 'Evaluation of Technologist/Technician/Laboratory Staff Competency' which stated, "All histology technologists and technicians are evaluated for their skills in the handling of specimens, embedding, cutting permanent sections, safety procedures, quality control, special stains, and routine staining". This procedure did not include histopathology slide interpretation testing or identification of fungi (mycology subspecialty), scabies</p>

(parasitology subspecialty), and the Tzanck (for chicken pox or herpes) (virology subspecialty) testing. Review of 4 Testing Personnel records (TP# C-#D, #F, and #G) revealed that the hematoxylin and eosin, and Periodoci Acid Schiff (histopathology subspecialty) high complexity competency evaluations had not been completed for 2 (2020 - 2021) out 2 years (2020 - 2021). Record review of 4 Testing Personnel records ( TP #H - #K) revealed that the fungi (mycology subspecialty), scabies (parasitology subspecialty), and the Tzanck (for chicken pox or herpes) (virology subspecialty) moderate complexity competency evaluations had not been completed for 2 out of 2 years reviewed (2020-2021). Interview on 10/4/19 at 3:10 p.m., Testing Personnel #B stated she talked to Testing Personnel #D who stated they thought the semi - annual performance verification was the competency evaluation.