

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2023046	(X3) Date Survey Completed 11/01/2019
Name of Provider or Supplier Pathologist Bio-Medical Laboratories, Pllc	Street Address, City, State 3600 Gaston Ave, Wadley Tower, Suite 261, Dallas, TX	
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	<p>The Director of Operations Support and Consult Coordinator were at the entrance conference conducted 11/01/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Director of Operations Support and Consult Coordinator on 11/01/2019. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiency cited was discussed. The process for submitting the corrections was explained.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, competency assessments, delegation of duties documents, and in interview with staff, the laboratory director failed to specify, in writing, the delegated duties of the cytology general supervisor to include performing competency assessments on testing personnel. Findings included: 1. Review of the CMS 209 form included one cytology general supervisor (CT-GS1), who was also a testing person, and four other cytology technologists. 2. Review of competency assessments for the four cytology technologists revealed the CT-GS1 performed and documented the evaluations in 2018 and 2019. 3. Review of written delegation of duties documents did not include the laboratory director delegating to the CT-GS1 to</p>

perform and document competency assessment for the other cytology technologists. 4. During an interview on 11/01/2019 at 11:00 am, the Director of Operations Support confirmed the laboratory director did not specify, in writing, the delegated duties of the cytology general supervisor to include performing competency assessments on testing personnel. Word Key: CMS - Centers for Medicare and Medicaid Services