

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 45D2052327</p>	<p>(X3) Date Survey Completed 01/29/2021</p>
<p>Name of Provider or Supplier Pathologists Bio-Medical Laboratories, Pllc</p>	<p>Street Address, City, State 1600 West College St - 1st Floor #185, Grapevine, TX</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>Laboratory representatives were present at the entrance conference conducted 01/29 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 01/29 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.</p>
<p>D2007</p>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologist (CAP) testing records, laboratory's CMS 209 form, and staff interview, the laboratory failed to ensure that patient samples were analyzed with the laboratory's regular patient workload by personnel who routinely in the laboratory for 3 of 3 events in 2019 (Event HER2-B, Event PM2-A, PM2-B) 4 of 4 events in 2020 (Event HER2-A, Event HER2-B, Event PM2-A, Event PM2-B). Findings: 1. Review of laboratory policy titled "CAP Proficiency Testing" stated: "C. CAP PT Survey Documentation and Reporting ... 4. The pathologist and Laboratory Director complete the Attestation Statement in accordance to policy a. The pathologist who interpreted the survey signs their name in the Testing Personnel section b. The Laboratory Director or Designee signs their name in the Director (or Designee) section" 2. Review of the College of American Pathologist (CAP) testing records revealed Testing Person-1 (TP-1) tested</p>

the following events: 2019 Histopathology specialty HER2 Immunohistochemistry Event HER2-B Note there was no attestation form available for Event HER2-A ER/PgR Immunohistochemistry Tissue Microarray Event PM2-B 2020 Histopathology specialty HER2 Immunohistochemistry Event HER2-A & Event HER2-B ER/PgR Immunohistochemistry Tissue Microarray Event PM2-A & Event PM2-B Review of the College of American Pathologist (CAP) testing records revealed Testing Person-2 (TP-2) tested the following events: 2019 Histopathology ER/PgR Immunohistochemistry Tissue Microarray Event PM2-A 3. Review of the laboratory's CMS 209 form revealed four Testing Persons (TP-1, TP-2, TP-3, TP-4) were listed as performing high complexity testing (histopathology). Testing Person-1 (TP-1) Hire date: 07/15/2016 Testing Person-2 (TP-2) Hire date: 09/01/2001 Testing Person-3 (TP-3) Hire date: 07/01/2000 Testing Person-4 (TP-4) Hire date: 10/20/2020 Based on these hire dates TP-2 should have participated in proficiency testing in 2020 and TP-3 should have participated in proficiency testing in 2019 and 2020. Note: TP-4 was hired after proficiency testing dates had been completed in 2020. 3. During an interview on 01/29/2021 at 09:50 am, the Safety, Quality & Compliance Manager confirmed the above findings.