

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2052328	(X3) Date Survey Completed 08/28/2024
Name of Provider or Supplier Pathologists Bio-Medical Laboratories, Pllc	Street Address, City, State 4708 Alliance Boulevard, Suite 870, Plano, 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	An announced survey of the laboratory was conducted on 08/28/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's gynecological cytology requisitions, laboratory's policies/procedures and staff interview, the laboratory failed to ensure for 2 of 2 Pap smears' requisitions received from January to August 2024, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy were documented. Findings included: 1. Review of the following 2 of 2 Pap smears' requisitions received from January to August 2024 revealed neither one had documentation of patient's last menstrual period, or indication of whether the</p>

patient had a previous abnormal report, treatment, or biopsy. They were: Patient's medical record number: 8590406 Date of requisition: 04/25/2024 Case/accession number: 24-NT-000374; 1110409844 Test ordered: Pap Patient's medical record number: 7835383 Date of requisition: 06/18/2024 Case/accession number: 24-NT-000519; 1112732108 Test ordered: Pap 2. Review of laboratory's policy "Gynecologic Cytology Screening and Reporting" (last reviewed by laboratory director on 06/11/2024) revealed: "Each requisition is checked to verify that all required clinical information is present. If any required information is missing, the case is submitted to the exceptions team and a request is entered in the CRM. The exceptions team is responsible for obtaining the information." 3. The laboratory was asked to provide documentation of the exceptions team obtaining the missing information, and no such documentation was available for review prior to survey exit. 4. In an interview on 08/28/2024 at 1315 hours in the office, the facility's Senior Manager of Quality, Safety and Compliance (as indicated on submitted Survey Entrance/Exit document) confirmed the findings.