| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2052328 | 01/24/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pathologists Bio-Medical Laboratories, Pllc | 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 |
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| **D5625** | CYTOLOGY<br>CFR(s): 493.1274(c)(3)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, documents and interview it was determined that the laboratory failed to establish written policies and procedures for a program for the identification and review of prior negative gynecologic specimens for each patient with a current High Grade Squamous intraepithelial Lesion (HSIL) or malignant neoplasm. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe a process for the search and review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, or malignant neoplasm reported by the laboratory. 2. During an interview at 11:00 AM on January 23, 2018, the Cytology Supervisor employed at Facility B stated that the review of previous negative gynecologic cases from current HSIL cases was performed at Facility B and there was no procedure for the review program. |
| **D5629** | CYTOLOGY<br>CFR(s): 493.1274(c)(5)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and |

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| | procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures, records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required statistics in 2016 and 2017. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure for an annual statistical laboratory evaluation of six required statistics. 2. The Survey Team requested and the laboratory failed to provide an annual statistical evaluation from 2016 or 2017 for the six required statistics. 3. During an interview at 11:15 AM on January 23, 2018, the Cytology Supervisor from Facility B confirmed that there were no written policies and procedures for documenting and evaluating annual statistics. |
| **D5655** | CYTOLOGY<br>CFR(s): 493.1274(e)(4)<br><br>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory cytology specimens or slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that cytology specimens or slide preparations were identified and reported as unsatisfactory. 2. During an interview at 11:20 AM on January 23, 2018, the Cytology Supervisor from Facility B confirmed that there were no written policies and procedures for identifying cytology specimens or slide preparations as unsatisfactory. |
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