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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>51D0993670    | <b>(X3) Date Survey Completed</b><br>10/26/2022 |
| <b>Name of Provider or Supplier</b><br>Pineview Gynecology   | <b>Street Address, City, State</b><br>1322 Pineview Drive, Morgantown, WV |   |
| 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>  |
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| <b>D0000</b>              | An announced, on site, routine recertification survey was conducted at Pineview Gynecology on October 26, 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.   |
| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on written policies and procedures (P&amp;P), record review, lack of documentation, and interview the laboratory failed to follow the established process to assess employee competency for all 6 required criteria in 2021 for 3 of 4 laboratory testing personnel. Findings: 1. Review of P&amp;P identified an established process for assessing the elements of competency of laboratory testing personnel for the BD Affirm test system. 2. Review of TP competency records for 2021 identified a competency assessment of criteria (6) Problem solving skills for 4 of 4 TP. 3. Review of TP competency records for 2021 revealed no documented competencies of the other 5 required criteria for 3 of 4 TP; 1) Direct observation of routine patient testing 2) Monitoring the recording and reporting of test results 3) Review of test results, worksheets, QC records, PT records, maintenance records 4) Direct observation of instrument maintenance 5) Assessment of test performance with external blind testing or external PT 4. An interview with the laboratory manager, 10/26/22 at approximately 8:00 AM, confirmed the findings.</p> |