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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 51D0680137 | (X3) Date Survey Completed 05/27/2025 |
| Name of Provider or Supplier Blue Ridge Cancer Care Princeton | Street Address, City, State 660 New Hope Road, Princeton, WV | |
| 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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| D0000 | An initial certification survey was conducted at Blue Ridge Cancer Care Princeton on May 27, 2025, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below. |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on review of laboratory policies and procedures, testing personnel (TP1 and TP2) competency records, interview with the laboratory manager, and interview with the laboratory director (LD), the laboratory failed to establish a written protocol for the assessment of competency for testing personnel performing manual peripheral blood smear review. Findings: 1. Review of the policies and procedures manual "CLIA Compliance" revealed no written protocol for the competency assessment of testing personnel performing manual peripheral blood smear review. 2. Review of TP1 and TP2 2025 competency records identified competency assessments performed 2/10/2025. 3. During a phone interview with the laboratory manager, 5/27/25 at 3:00 PM, the laboratory manager agreed there was no written policy or procedure for the process of documenting competency for testing personnel performing manual peripheral blood smear review. 4. An exit interview with the LD, 5/27/2025 at 3:40 PM, confirmed the lack of written protocol for competency assessment of testing personnel.</p> |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> |

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures, lack of documentation, interview with the laboratory manager, and interview with the laboratory director (LD), the laboratory failed to include (b)(1) requirements for the labeling and storage of peripheral blood smear slides and referral of patient specimens for further testing in the written policies and procedures for the laboratory. Findings: 1. Review of the policies and procedures manual "CLIA Compliance" identified the lack of written protocols for the following: the labeling and storage of prepared peripheral blood smear slides and the referral of patient specimens that are determined to need more testing. 2. During a phone interview, 5/27/25 at 3:00 PM, the laboratory manager agreed that no policy or procedure for the labeling, storage, and referral of the patient specimens could be located. 3. An exit interview with the LD, 5/27/25 at 3:40 PM, confirmed the lack of written protocols.