| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D2084143 | 03/26/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Piedmont Cancer Institute | 1240 Eagles Landing Parkway, Stockbridge, GA | |

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** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 26, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>A tour of the testing facility during the survey revealed that the Laboratory Director (LD) failed to assure proper storage of reagents essential for test results reporting. THE FINDINGS INCLUDE: 1. A tour of the laboratory Reagent/ Supplies Storage Room #1 confirmed that the temperature and the humidity was not monitored to assure that the reagents/ supplies were stored as indicated by the manufacturers' requirements. 2. A tour of the laboratory Reagent/ Supplies Storage Room #2 confirmed that the temperature and the humidity was not monitored to assure that the reagents/ supplies were stored as indicated by the manufacturers' requirements. 3. A tour of the laboratory Storage Room #1 and #2 confirmed the manufacturer reagent storage requirements below: a) Becton Dickinson Blood Collection Vacutainer Tubes, Becton Dickinson Urine C&S Vacutainer Tubes, and Greiner Bio-One Blood Collection Vacutainer Tubes required storage at 2C - 25C temperatures; b) Guardant |

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| | 360 CDx Specimen Collection Kits and Para Pak C&S Specimen Collection Medium required storage at 2C - 30C temperatures; c) Hemoccult Test Kits, Para Pak Zn-PVA Formalin, and Total Fix Ova & Parasite Fixative required storage at 15C - 30C temperatures; and d) Invitae Genetic Specimen Collection Kits required to storage at 18C - 25C temperatures. 4. An exit interview with Testing Personnel 2 (TP2), identified on the 2025 - CMS 209 Personnel Form, on March 26, 2025, at 3:00pm, in the back office review room, confirmed that the LD failed to assure proper storage of reagents essential for patient testing. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br>This STANDARD is not met as evidenced by:<br>A review of the 2023 - 2025 ABX Pentra 60 C+ Quality Control Records, 2023 - 2025 Quality Assurance Records and the CBC Analysis procedure confirmed that the Testing Personnel (TP) and Laboratory Director (LD) failed to follow corrective action and QC reporting procedures as documented in the procedure manual. THE FINDINGS INCLUDE: 1. A review of the QC data for the CBC Analysis Procedure confirmed that the TP did not follow the failed QC rejection and corrective action procedures as documented in Section VII: Procedural Notes, Steps (e) - (f) of the CBC Analysis SOP. 2. A review of the QA Records for the CBC Analysis Procedure confirmed that the LD did not submit QC data to the Horiba Peer Review Program as documented in Section VII: Procedural Notes, Steps (g) of the CBC Analysis SOP. 3. An exit interview with Testing Personnel 2 (TP2), identified on the 2025 - CMS 209 Personnel Form, on March 26, 2025, at 3:00pm, in the back office review room, confirmed that the LD and TP failed to follow corrective action and QC reporting procedures as documented in the procedure manual. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>A review of the 2023 - 2025 Quality Assurance (QA) Records, confirmed that the LD failed to maintain the established Quality Control (QC) and Quality Assessment (QA) Programs to identify and to prevent failures in quality. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 QA Records confirmed that the LD failed to identify, investigate, or correct the serious errors presented by the ABX Pentra 60 C+ Hematology Analyzer Serial ID # 810PCP15080 for the period of December 29, 2023 through August 20, 2024. 2. An exit interview with Testing Personnel 2 (TP2) identified on the 2025 - CMS 209 Personnel Form conducted on March 26, 2025, at 3:00pm in the back office review room confirmed that the LD failed to maintain the established Quality Control (QC) and Quality Assessment (QA) Programs to identify and to prevent failures in quality. |

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| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>A review of Personnel Records and the Quality Assurance Records confirmed that the Laboratory Director (LD) failed to assign and place in writing the delegation of the Technical Consultant (TC) duties to a qualified personnel. THE FINDINGS INCLUDE: 1. A review of the QA Records confirmed that records were reviewed by Testing Personnel #2 (TP2 on the 2025 - CMS 209 Personnel Form) with an additional documented review of activity by the LD. 2. A review of the Personnel Records confirmed that the required personnel training and competencies for Testing Personnel #1 and Testing Personnel #3 (TP1 and TP3 on the 2025 - 209 Personnel Form submitted) were performed by TP2. 3. A request for a Letter of Designation, from the Laboratory Director, stating the assignment of these duties to TP2 was not available at the time of survey. The 2025 - CMS 209 Form listed the LD as the TC. 4. An exit interview with TP2 on March 26, 2025, at 3:00pm, in the back office review room, confirmed that the LD failed to assign and to place in writing, the delegation of Technical Consultant (TC) duties to qualified personnel. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>A review of the 2023 - 2025 Quality Control (QC) Records, 2023 - 2025 Quality Assurance Records, 2023 - 2025 Temperature/ Humidity Records, 2023 - 2025 Patient Testing Records for the ABX Pentra 60 C+ Hematology Analyzer ID # 810PCP15080, and the Standard Operational Procedure (SOP) Manual confirmed that the Laboratory Director (LD) failed to provide overall management and direction to the laboratory personnel. Refer to: D5413, D5791, D6020, D6032, and D6097 |
| **D6097** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(7)<br><br>(e)(7) that patient test results are reported only when the system is functioning properly;<br><br>This STANDARD is not met as evidenced by:<br>A review of 2023 - 2025 Quality Control (QC) Records for the ABX Pentra 60 C+ Hematology Analyzer with Serial ID # 810PCP15080, confirmed that Laboratory |

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| | Director (LD) and Testing Personnel (TP) failed to assure the analyzer was functioning properly before reporting patient results. THE FINDINGS INCLUDE: 1. A review of Cumulative QC Report, printed on January 31, 2024, for the ABX Pentra 60 C+ Hematology Analyzer Serial ID # 810PCP15080 confirmed that while the QC values were not failing - erratic Coefficients of Variation were present for PLT and WBC Differential Indices indicating a possible problem with the analyzer aperture responsible for testing these indices. 2. A review of the Cumulative QC Report, printed on March 29, 2024, for this analyzer confirmed additional erratic Coefficients of Variation for PLT, WBC Indices, and RBC indices, indicating a possible problem with the aperture(s) responsible for testing RBC, PLT and WBC Differential Indices. 3. A review of additional Cumulative QC Reports, printed for Feb - June 2024, confirmed the continuation of the failed QC values. Cumulative QC Reports confirmed that a failure had developed on the April 2024 Cumulative QC Reports. 4. The Cumulative Reports for the February - June 2024 and August 2024 periods showed a minimum of twenty-five (25) days in which two (2) to three (3) QC Levels for RBC and RBC Indices. These dates included: 04/08/2024, 04/15/2024, 04/22 /2024, 04/29/2024, 05/09/2024, 05/13 - 15/ 2024, 05/17/2024, 05/20/2024, 05/28 - 31/ 2025, 06/03/2024, 06/04/2024, 06/07/2024, 06/10/2024, 06/14/2024, 06/17 - 21/ 2024, 06/24/2024, and 08/15/2024 5. A review of 2023 - 2025 Quality Control (QC) Records for the analyzer, for the period December 29, 2023 - August 20, 2024, confirmed that there was no documentation that the issue was acknowledged, investigated, or corrective actions taken. 6. On August 20, 2024, the Horiba Technical Engineer performed the required 6-Month Preventive Maintenance. Documentation of the maintenance visit shows that during this service visit the issue was reported to Horiba. 7. A review of patient testing printouts from the analyzer, for the period of December 29, 2023 - August 20, 2024, confirmed that patient testing was performed and released from the analyzer. 8. An exit interview with Testing Personnel 2 (TP2), identified on the 2025 - CMS 209 Personnel Form, on March 26, 2025, at 3:00pm, in the back office review room, confirmed that the LD and TP failed to assure the analyzer was functioning properly before reporting patient results. |