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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>21D0950710       | <b>(X3) Date Survey Completed</b><br><br>02/29/2024 |
| <b>Name of Provider or Supplier</b><br><br>Bel Air Oncology Center                                                         | <b>Street Address, City, State</b><br><br>12 Medstar Blvd Suite 180, Bel Air, MD |                                                     |
| 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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| D6029              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the competency assessment of the technical consultant (TC) and interview with the TC, the laboratory director did not ensure that the competency assessment for the TC had been completed for 2022. Findings: 1. Review of the competency records for the TC showed that the worksheet for 2022 was missing. 2. During the survey on 02/29/2024 at 12:15 PM the TC confirmed that the evaluation of the TC for 2023 was not available at the time of the survey.</p> |
| D6049              | <p>TECHNICAL CONSULTANT RESPONSIBILITIES<br/>CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the quality control (QC) lot number documentation, "QC Problem</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

and Observation Chart", and interview with the technical consultant (TC), the TC did not ensure that the testing personnel (TP) were documenting the correct start dates for the QC materials and that all QC activity worksheets were maintained. Findings: 1. The QC records for April 2023 showed that the new lot of QC materials were opened on 04/14/2023 and started on 04/10/23; July 2023 showed that the new lot of QC materials were dated/opened 07/27/23 and were put into use on 07/03/23; and October 2023 showed that the new lot of QC materials was opened 10/04/23 but may have been put into use on 09/29/23. 2. According to the TC, the QC materials are good for more than three months. The QC materials are to be put into use every three months at the beginning of the month even if the expiration date is in the middle of the month. 3. The activity worksheets for documenting unacceptable QC results, "QC Problem and Observation Chart", were not available for the months of August and December 2023. 4. During the survey on 02/29/2024 at 12:15 PM the TC confirmed that the she/he was not verifying that the TP's were documenting accurate open and start dates for the QC materials and that the "QC Problem and Observation Chart" were missing for months of August and December in 2023.