

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0950710	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Bel Air Oncology Center	Street Address, City, State 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of maintenance records and interview with the technical consultant (TC), the laboratory did not maintain all records when service was performed on the hematology analyzer. Findings: 1. The laboratory did not have written documentation of analyzer problems nor the completed service reports technicians completed when on site. 2. The hematology analyzer was serviced during the month of March 2018 for issues with the motor. The manufacturer analyzer technician replaced the motor during this time. The laboratory did not maintain a copy of the written service report. 3. The hematology analyzer was serviced during the month of March 2018 for issues with the lamp. The analyzer consultant replaced the bulb during this time. The laboratory did not maintain a copy of the written service report. 4. The TC confirmed that all maintenance records were not available.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory records and interview with the technical consultant (TC), the laboratory did not ensure that analytic processes were maintained for the overall quality of laboratory testing. Findings: 1. The lab name on federal licensure is "Bel Air Oncology Center". 2. During the time of the survey the laboratory had five different names documented on laboratory records and identification of the name error was not discovered and corrected to ensure the overall quality of laboraotry testing. 3. The name of the lab printed on five patient final reports was "MedStar Oncology Center at Belair". 4. The name of the lab printed on calibration records from June 12, 2019 was "Medstar Georgetown Cancer Institute. 5. The name of the lab printed on proficiency testing records for the years 2018 and 2019 was "Franklin Square Oncology Center" 6. The name of the lab printed on quality control records from the year 2018 was "Medstar Oncology Center at Belair" 7. The name of the lab printed on calibration and verification documents from June 2018 was "Medstar Belair Oncology" 8. The TC stated that she was not aware that the lab had that many names on various lab documents throughout the lab.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the patient final report and interview with the technical consultant (TC), the laboratory did not ensure that the name of the lab where testing was performed printed on the final report. Findings: 1. The lab name on federal licensure is "Bel Air Oncology Center". 2. The name of the lab printed on five patient final reports was "MedStar Oncology Center at Belair". 3. The TC stated that she was not aware that the name on patient final reports were different than the name of the license.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on review of maintenance records and interview with the technical consultant (TC), the TC failed to ensure that all maintenance records were available when service was performed on the hematology analyzer. Findings: Refer to D5429