

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0993254	(X3) Date Survey Completed 12/02/2022
Name of Provider or Supplier Auerbach Hematology Oncology Assoc Pc	Street Address, City, State 5233 King Avenue, #308, Baltimore, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with testing personnel (TP), the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 12/02/2022 at 1:45 PM, TP #4 confirmed that the eye wash station was not located in the room where laboratory testing is performed.</p>
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 hematology instrument maintenance record review and interview with testing personnel (TP), the laboratory did not ensure that maintenance was performed on the hematology analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Medonic M-Series hematology analyzer to perform CBC (complete blood cell count) analysis. The instrument manual recommends that the laboratory</p>

perform a cleaning procedure every 6 months which takes 1 hour and 15 minutes. 2. A review of monthly hematology analyzer maintenance records from January 2021 to November 2022 showed that 6 month instrument cleaning was documented 1 time out of 21 months on 07/30/2021. 3. During an interview on 12/02/2022 at 1:45 PM, TP #4 confirmed that 6-month hematology analyzer maintenance was not documented.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on procedure manual and quality control (QC) record review and interview with testing personnel (TP), the laboratory did not ensure that all corrective actions are documented when hematology QC is unacceptable. Findings: 1. QC record review showed that the laboratory has a form called the "Medonic M-Series Quality Control Corrective Action Log" which states that, "Any out of parameter controls MUST be documented below." 2. A review of hematology QC monthly summary records from February 2021 and August 2022 showed that on 02/02/2021 the "low" level of control (lot # 2201121) was out of range for white blood cells. The control was re-run and was within the laboratory's acceptable range; 3. On 02/15/2021 the "normal" level of control (lot # 2201122) was out of range for platelets. The control was re-run and was within the laboratory's acceptable range; 4. On 08/11/2022 and 08/15/2022 the "low" level of control (lot # 2220401) was out of range for platelets. The control was re-run and was within the laboratory's acceptable range. 5. Review of "Medonic M-Series Quality Control Corrective Action Logs" for February 2021 and August 2022 show that the laboratory did not document corrective actions taken when hematology QC was outside the laboratory's range of acceptability. A comment was written on the forms by TP #4 which states, "All corrective actions for QC were resolved. Follow ups were made with CDS as needed." 6. Review of "Medonic M-Series Quality Control Corrective Action Logs" for February 2021 through August 2022 show that no corrective actions were logged for 19 of 19 months. 7. During an interview on 12/02/2022 at 1:45 PM, TP #4 confirmed that correctives action had not been documented when hematology QC was out of range.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on procedure manual, quality control (QC), and quality assurance (QA) record review and interview with testing personnel (TP), the laboratory director (LD) failed

to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The procedure, "Duties and Responsibilities of Key Operators" lists 1 of the LD's duties as "Discuss and sign monthly lab review." 2. A review of "Laboratory Director Monthly Review" forms from January through November 2022 showed that the LD did not sign the review form for 11 of 11 months. 3. During an interview at 12:30 PM on the day of the survey, TP #4 stated that they fill out the form and sign under "Key Operator" but that the LD does not look at the monthly review forms. TP #4 stated that if something important goes wrong in the lab, that they contact the LD, however there was no documentation of communication between TP #4 and the LD available at the time of the survey. 4. During an interview at 1:15 PM, TP #4 stated that although they print out the Levey-Jennings hematology QC reports monthly, the reports are not being reviewed by anyone in the laboratory to identify shifts and trends in the QC. 5. Procedure manual review also showed that the laboratory did not have a written QA procedure or an established QA program. This was confirmed by TP #4 on 12/02/2022 at 12:30 PM.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on competency assessment record review, and interview with testing personnel (TP), the laboratory director (LD) failed to ensure that the policies for monitoring the laboratory staff included the evaluation of the technical consultant (TC). Findings: 1. A review of competency assessment records from 2020 through 2022 showed that the documentation did not include an annual evaluation of the TC for the duties they perform as TC. 2. During an interview on 12/02/2022 at 12:50 PM, TP #4 confirmed that an annual competency assessment for the TC was not available.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's standard operating procedure manual (SOPM) and interview with testing personnel (TP), the laboratory director (LD) failed to specify in writing, the responsibilities and duties of each person engaged in the performance of

the pre-analytic, analytic, and post-analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results.

Findings: 1. The procedure "Duties and Responsibilities of Key Operators" in the laboratory's approved SOPM listed 5 duties for the LD including, "Sign off on proficiency testing," "Perform the cell identification," "Discuss and sign monthly lab review," "Aware of all changes in the lab," and "Reviews Stain Wright Log" as well as a list of duties for "Key Operators." 2. The procedure did not include a complete list of duties and responsibilities for the LD, clinical consultant, technical specialist, general supervisor, or TP. 3. During an interview on 12/02/2022 at 1:45 PM, TP #4 confirmed that the laboratory's approved SOPM did not include a written list of duties and responsibilities for the above listed personnel.