

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0216684	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Lutherville Hematology And Oncology Services	Street Address, City, State 1734 York Rd, Lutherville, 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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) plan and interview with the technical consultant, the laboratory director did not provide a written QA of the testing program for the laboratory staff on a periodic basis. Findings: 1. Section G. of the QA plan states the following- "1. The POCT Consultant will provide a written quality assessment of the testing program for the Laboratory Medical Director and Lutherville Hematology Oncology staff on a periodic basis. The assessment will be discussed with the laboratory staff and documented. 2. The Laboratory Medical Director, POCT Consultant, and Lutherville Hematology Oncology Administrative Director will meet periodically to discuss the effectiveness of current testing systems, complaints and concerns, and opportunities for improvement." 2. Review of the laboratory records for 2017 and 2018 showed that there were no written QA testing programs and no documented periodic meetings to discuss QA. 3. During the survey on 01/16/2019 at 11:00 AM the technical consultant confirmed that there were no documented QA programs and discussions for 2017 and 2018 showing that the laboratory had reviewed and discussed the effectiveness of current testing systems, complaints and concerns, and opportunities for improvement.</p>
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p>

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and interview with the technical consultant, the laboratory did not ensure that remedial actions were documented when there were deviations for the established performance specifications. Findings: 1. Review of the corrective action logs for 2017 and 2018 showed that when there were quality control (QC) failures the testing personnel did not document the corrective actions that were performed to correct the failure. The technical consultant would review the monthly QC results to verify that corrective actions were taken but the testing personnel did not document the steps taken to correct each of the failures. 2. During the survey on 01/16/2019 at 11:00 AM the technical consultant confirmed that there were no documented corrective actions for QC failures for 2017 and 2018.