

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1060558	(X3) Date Survey Completed 05/30/2018
Name of Provider or Supplier Aop Pa DbA Center For Cancer & Blood Disorders	Street Address, City, State 19735 Germantown Road Ste 255, Germantown, 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
D6022	<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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control (QC) and quality assurance (QA) records and interview with the technical consultant, the laboratory director did not ensure that the QA program clearly identified QC and QA review of the Germantown laboratory. Findings: 1. The QC records included three levels of QC results for three different analyzers. According to the technical consultant two of the analyzers are located at another office. Each set of results are identified with the letter "A", "B" and "C." According to the technical consultant the QC results with the abbreviation "C" are for the Germantown office that was being surveyed. 2. The QA procedure states that the laboratory will perform a comparison between the three analyzers located in the two different laboratories twice a year. Review of the comparison records showed that the comparison was performed twice in 2016 and once in 2017. The records included only the raw data with no evaluation of the acceptability of the results. The procedure did not define parameters for the acceptability between the three analyzers and remedial actions to be taken when the parameters were not met. 3. During the survey on 05/30/2018 at 2:30 PM the technical consultant confirmed that the abbreviations "A", "B" and "C" were not identified in the procedure manual; the procedure did not identify</p>

acceptable parameters for the comparison and remedial actions to be taken when the comparison was unacceptable; and the raw data for the comparisons had not been evaluated.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the technical consultant, the testing person did not follow the laboratory's procedures for documenting their initials on the proficiency testing (PT) instrument printout in the same manner as the patients. Findings: 1. According to the laboratory's procedure manual the instrument printouts with PT results are to be initialed in the same manner as the patient printouts. 2. The PT records for 2016 through 2017 (6 events) were reviewed. The instrument printouts from the first event of 2016 and the first event of 2017 did not include the initials of the person who performed the PT test. 3. During the exit interview at 12:30 PM the technical consultant confirmed that PT instrument printouts did not include the initials of the person who performed the testing.