

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0944420	(X3) Date Survey Completed 07/27/2023
Name of Provider or Supplier Oncology & Hematology Specialists Pa	Street Address, City, State 100 Madison Avenue Suite C3402, Morristown, NJ	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with Testing Personnel (TP), the laboratory failed to follow all procedures for Calibration Verification from 8/25/22 to the date of the survey. The findings include: 1. The procedure "Calibration Verification" stated "calibration verification/ linearity of analytical reportable range will be monitored by participating in CAP linearity proficiency test." 2. There was no documented evidence the above mentioned procedure was followed. 3. The TP #2 listed on the CMS-209 form confirmed on 7/27/23 at 11:00 am that the PM was not followed.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Beckman Coulter Interlaboratory Quality Assurance Program (IQAP) Reports and interview with the Testing Personnel (TP), the laboratory failed to take corrective action when the Coefficient of Variation Interval (CVI) was outside acceptable limits for Hematology tests performed on the Beckman Coulter Act Diff 2 analyzer from 9/15/22 to the date of survey. The findings include:
 1. The IQAP Report on 9/15/22 stated "Please review your CVI for the following parameter(s). Refer to your IQAP manual for trouble shooting suggestions." a) Abnormal Low lot 068000 for Mean Corpuscular Volume (MCV) b) Normal lot 0780000 for MCV c) Abnormal High lot 088000 for MCV 2. The IQAP Report on 6/30/22 stated "Please review your CVI for the following parameter(s). Refer to your IQAP manual for trouble shooting suggestions." a) Abnormal Low lot 067500 Hemoglobin (Hgb) b) Abnormal High lot 077500 Hgb 3. There was no evidence corrective action was taken on the above mentioned IQAP reports. 4. The TP #4 listed on CMS-209 form confirmed on 7/27/23 at 11:55 am corrective action was not taken.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Personnel Records (PR), Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to delegate competency evaluation to a qualified person for the performance of Hematology CA for calendar years 2021 and 2022. The finding includes: 1. CA was performed by TP #3 listed on the CMS form 209 who does not have a bachelors degree which did not meet the qualifications found in 493.1409, 493.1415, and 493.1421 2. The TP #4 listed on the CMS form 209 confirmed on 7/27/23 at 10:30 am that the LD did not delegate the evaluation of competency to a qualified person.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM), Quality Assurance (QA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the QA program was maintained from January 2022 to June 2023 .
The findings include: 1. There was no documented evidence of review of the Laboratory Information System (LIS) Audit records from January 2022 to December 2022. 2. There was no documented evidence who performed the LIS Audit from January 2022 to June 2023. a) The LIS Audit documents mentioned above where not signed in the designated area. 3. The TP #2 listed on the CMS-209 form confirmed on 7/27/23 at 11:00am the LD failed to ensure the QA program was maintained.