

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2030276	(X3) Date Survey Completed 09/12/2019
Name of Provider or Supplier Advanced Care Oncology &	Street Address, City, State 385 Morris Ave, Springfield, 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
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that all PT results received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for Hematology testing performed with the American Proficiency Institute (API) in event 1-2019. The TP #4 listed on CMS form 209 confirmed on 9/12/19 at 10:10 am that the API PT results were not reviewed.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) 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</p>

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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements for Hematology tests from 11/14/17 to the date of the survey. The TP #4 listed on CMS form 209 confirmed on 9/12/19 at 10:30 am that a CA procedure was not established.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities for four out of four TP engaged in the performance of Hematology testing from 11/14/17 to the date of survey. The TP #4 listed on CMS form 209 confirmed on 9/12/19 at 11:15 am that the LD did not specify the duties and responsibilities of TP.