

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2133984	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier Advanced Care Oncology &	Street Address, City, State 741 Northfield Ave, West Orange, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed on the Sysmex XS 1000i series analyzer with the American Proficiency Institute (API) in the 3-2018 and 2-2019 events. The findings include: 1. The laboratory received an "Unacceptable" result for % Lymphocyte on samples XE-15 in 3-2018 and XE10 in 2-2019. 2. There was no documented evidence that the laboratory investigated the failures. 3. The TP #1 listed on CMS form 209 confirmed on 9/27/19 at 1:10 pm that the laboratory did not perform and document an evaluation of unacceptable PT results.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in</p>

the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Test Personnel (TP), the laboratory failed to have all applicable procedures for Hematology Tests from 4/30/18 to the date of the survey. The finding includes: 1. The laboratory did not have a procedure for the course of action to be taken if the test system becomes inoperable. 2. The TP #1 confirmed on 9/26/19 at 1:20 pm that the PM did not have all applicable procedures.