

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0933016	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Advanced Medical Care Center	Street Address, City, State 22 Madison Avenue, Paramus, 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 the Office Manager (OM), the laboratory failed to follow the procedure for "Performance Check for CLA-1 Luminator" used in Immunology tests for the calendar year 2019. The findings include: 1. The PM stated "The CLA-1 Electronic Controller (EC) be run a minimum of three times in succession every six months in addition to being run once with each day of use". 2. The laboratory test patients on the CLA-1 analyzer twice a year. 3 Testing was performed in May of 2019 and October of 2019. 4. There was no documented evidence that the EC was run a minimum of three times in succession in October of 2019. 5. The OM confirmed 11/13/19 at 1:30 pm that the laboratory did not follow the PM.</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 Office Manager (OM), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 12/4/17 to the date of the survey. The OM confirmed on 11/13/19 at 1:30 pm that a CA procedure was not established. Note: This deficiency was previously cited on 12/4/17. The Plan of Corrections stated "A Competency assessment will be established. The lab director and lab TP will follow this competency assessment".