

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0686080	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Allied Physicians Group Plc	Street Address, City, State 124 Main Street, Suite 1, Huntington, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory competency records and confirmed in an interview with one of two technical consults and the office manager/testing person at the time of the survey, the laboratory failed to follow their written laboratory policies and procedures to assess the competency of the two technical consultants in calendar year 2017.</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 the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.</p>

(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 the surveyor's review of the laboratory's policy/procedure manual and interview with the office manager/testing person and one of two technical consultants, the laboratory failed to have a policy/procedure manual that is up to date and accurate. Findings: The current policy/procedure manual still lists the previous consulting organization, Med Tech Consulting, as their current consulting organization. The laboratory discontinued affiliation with Med Tech Consulting in 2016.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of competency assessment records and confirmed in an interview with the office manager/testing person and one of two technical consultants at the time of the survey, the director, acting as the technical consultant, failed to ensure that competency assessment for the hired two technical consultants was performed in calendar year 2017. Refer to D5209