Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0159812	05/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Allied Physicians Group Pllc	636 Wantagh Avenue, Levittown, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Control (QC) records and interview with the laboratory director and the testing person, the laboratory failed to follow the manufacturer's instructions for performing external positive and negative controls with each new lot of Henry Schein One Step urine pregnancy kit. FINDINGS: 1. On 5/9/2018 at approximately 3:00 PM the laboratory director and the testing person confirmed surveyor's findings that there were no records of external positive and negative controls for the for Henry Schein One Step uhCG, lot number HCG6110056 expiration date 9/30/18 from January 2017 through the survey date. 2. Approximately 22 patient specimens were tested and reported for uhCG during the above time frame.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory's temperature documentation and interview with the laboratory director and the testing person, the laboratory failed to follow the manufacturer's temperature requirement for the laboratory testing. FINDINGS: 1. The laboratory performs throat culture. The manufacturer of the throat culture media used for testing and the laboratory's temperature policy require that the incubator temperature to be in the range of 35-37 degree Celsius. On May 9, 2018 at approximately 3:00 PM the laboratory director and the testing person confirmed surveyor's findings that the incubator temperature was out of range, when patient samples were incubated for throat culture for 22 days from January 2, 2017 through April 4, 2018. 2. Approximately 60 patient samples were tested and reported for throat culture during this time frame.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology quality control (QC) records and an interview with the testing person and the laboratory director, the laboratory failed to ensure that hematology QC test results were within acceptable range prior to testing patient specimens. FINDINGS: On May 9, 2018 at approximately 3:00 PM, the testing person and the laboratory director confirmed surveyor's findings that the testing personnel failed to take and document corrective action for out of range Monocytes and Granulocytes for level high QC which was out of range for 25 consecutive days from 6/1/17 through 8/2/17 prior to patient testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the hematology QC records and an interview with the testing person and the laboratory director, the laboratory failed to perform and document corrective action when QC results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Refer to: D5481
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and interview with the testing person and the laboratory director, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. maintained the laboratory's QC program for hematology and bacteriology; refer to D6020; 2. maintained the laboratory's QA program for hematology; refer to D6021; 3. perform and document the annual competency evaluation for the 2 out of 6 laboratory's testing personnel; refer to D6054.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of QC records and confirmed in an interview with the laboratory director and the testing person at the time of this survey, the laboratory director failed to ensure that the QC program for hematology and bacteriology testing was maintained to assure the quality of laboratory services. Refer to: D1001, D5413, D5481, D5783
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's review of the Quality Assessment (QA) review records and confirmed during an onsite survey interview with the laboratory director and the testing person, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed twice a year, as required by their QA policy, in calendar year 2017.
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 laboratory director and the testing person, the laboratory director, acting as the technical consultant, failed to ensure that competency assessment was performed for 2 out of 6 testing personnel in calendar years 2016 and 2017.