Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0989114	09/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Allied Physicians Group Pllc	100 Manetto Hill Road Ste 302, Plainview, 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) 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 review of waived test manufacturer's instructions, lack of urine analysis (UA) Quality Control (QC) records, as well as interview with the Technical Consultant (TC), the laboratory failed to comply with manufacturers' instructions for performing the test. FINDINGS: 1. There was no documentation of QC performance for Siemens Multistix 10 SG reagent test strip bottles from 2023 through the survey date. 2. This is contrary to Siemens Multistix 10 SG manufacturer's instructions which indicated QC must be performed when opening a new bottle. 3. The TC confirmed the findings September 23, 2025, at approximately 11:30 A.M.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Testing (API) PT (Proficiency Testing) records as well as interview with the Technical Consultant (TC), the laboratory failed to document attestation to the routine integration of the samples into the patient workload using the laboratory's routine methods. FINDINGS: 1. There was no

	documentation of API testing personnel attestation for the following PT events: a. 2024 Throat Culture First Event. b. 2024 Throat Culture Second Event. c. 2024 Throat Culture Third Event. 2. The TC confirmed the findings September 23, 2025, at approximately 11:00 A.M.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of competency and training documentation, Standard Operating Procedures (SOPs), as well as interview with the TC, the laboratory failed to comply with written policies and procedures to assess employee and, if applicable, consultant competency. perform competency and training documents for technical consultant (TC) #2. FINDINGS: 1. There was no documentation of TC #2 competency and training performance and assessment. 2. The current, approved SOPs did not include instructions for performing such activity. 3. It was noted that TC #2 was responsible for Proficiency Testing (PT) review and corrective action performance for unsatisfactory PT scores. 4. The TC confirmed the findings September 23, 2025, at approximately 10:30 A.M.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of SOPs, API PT summary reports, lack of corrective action records, as well as interview with the TC, the laboratory failed to perform and document plan of correction for all PT scores less than 100%. FINDINGS: 1. There was no documentation of plan of correction performance for the following API PT scores: a. Erythrocyte Count Test Analyte: 2024 Second Event = 80%. b. Mean Corpuscular Hemoglobin (MCH) Test Analyte: 2024 Second Event = 80%. c. Mean Corpuscular Hemoglobin Concentration (MCHC) Test Analyte: 2024 Second Event = 80%. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on September 23, 2025, at approximately 11:00 A.M.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by:

	Based on review of SOPs, Quality Assurance (QA) records, as well as interview with the TC, the laboratory failed to perform and document general laboratory systems quality assessment including a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. FINDINGS: 1. There was no documentation of TC #2 PT review from 2024 through the survey date. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TC confirmed the findings on September 23, 2025, at approximately 10:30 A.M.
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of SOPs as well as interview with the TC, the laboratory failed to have ongoing mechanism to ensure the accuracy of manual entries by personnel into the Laboratory Information System (LIS) to ensure the information was transcribed or entered accurately. FINDINGS: 1. The current, approved SOPs did not include instructions for validation of patient test results entered into the Athena Electronic Medical Records (EMR). 2. The TC confirmed the findings on September 23, 2025, at approximately 10:00 A.M.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of SOPs as well as interview with the TC, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to routinely perform a review of systems for accurate transfer of information and correct problems identified in the preanalytic systems. FINDINGS: 1. The current, approved SOPs did not include instructions for performing such activity. 2. The TC confirmed the findings on September 23, 2025, at approximately 10:00 A.M.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of humidity records, SOPs, lack of corrective action records as well as interview with the TC, the laboratory failed to perform and document corrective action for test systems that did not meet the laboratory's established performance specifications. FINDINGS: 1. Documented humidity of the "Sick Lab" and "Well Lab" deviated from the specified range of 20% - 80% for the following: a. Sick Lab: i. January 2024, four total days. ii. February 2024, five total days. iii. January 2025, thirteen total days. iv. February 2025, ten total days. b. Well Lab: i. January 2024, three total days. ii. February 2024, two total days. iii. January 2025, thirteen total days. iv. February 2025, nine total days. 2. There was no documentation of corrective action performance for the respective out-of-range humidity. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TC confirmed the findings on September 23, 2025, at approximately 10:00 A.M.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of SOPs, lack of Quality Assessment (QA) records, as well as interview with the TC, the Laboratory Director (LD) and TC failed to ensure compliance with established QC and QA programs to assure the quality of laboratory services provided and to identify failures in quality as they occur. FINDINGS: 1. There was no documentation of QA performance for calendar years 2023 and 2024. 2. This is contrary to instructions included in the current, approved SOPs. 3. The TC confirmed the findings on September 23, 2025, at approximately 10:00 A.M.