

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0682212	<b>(X3) Date Survey Completed</b>  03/08/2022
<b>Name of Provider or Supplier</b>  Allied Physicians Group Pllc	<b>Street Address, City, State</b>  1101 Stewart Avenue, Suite 306, Garden City, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: D5411 Based on the review of the manufacturer package insert of HemoCue Glucose 201, the laboratory failed to perform the control requirement required. The HemoCue Glucose 201 system must be verified on the day of testing using 2 levels of controls, required by HemoCue. Finding: 1.The laboratory performed controls only once per week according to Quality Control documentation. 2.The technical consultant and general supervisor confirmed in an interview on 3/8/2022 about 11am.</p>
<b>D6021</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: D6021 Based on the review of monthly Quality Assurance (QA) review and confirmed on an interview with technical consultant, the laboratory director failed to</p>

ensure the laboratory's QA program was maintained for all phase of laboratory testing. Refer to D5411

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:  
D6042 Based on the reviewed of HemoCue Glucose 201 manufacturer package insert and Quality Control log, the technical consultant failed to follow and maintain a quality control program. Confirmed on the interview with technical consultant and general supervisor the laboratory failed to follow manufacturer requirement. Refer to D5411