

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0159812	(X3) Date Survey Completed 01/19/2022
Name of Provider or Supplier Allied Physicians Group Pllc	Street Address, City, State 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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology Horiba ABX 60 analyzer Quality Control (QC) report for year 2021, confirmed in an interview with laboratory testing person and laboratory director (LD), the laboratory failed to implement and maintain the corrective action plan for out of range controls on the Horiba ABX 60 hematology analyzer. Refer to: D5481 FINDINGS: 1.The laboratory failed to implement and maintain the corrective action plan for out of range controls on the Micros 60 hematology analyzer. 2.The corrective action plan from the survey conducted on 5/9/2018 stated, "that the testing person has been instructed to inform LD when controls are out of range and not to run patient specimen." 3.The following controls were out of range for these months: Low Control MX 432 Exp 1/5/22- December -1 day ; November 11 MX428 Exp 5/5/21- March - 3 days Normal Control MX 432 Exp 1/5/22-December-1 day; November-2days MX431 Exp 11/5/21-October-4 days MX430 Exp 9/5/21-August-12 days; July-12 days MX429 Exp 7/5/21 -June-6 MX428 Exp 5/5/21 -April-4 days MX427 Exp 3/5/21- February-3 days High Control MX430 Exp 9/5/21-August-6 days; July-9 days MX429 7/5/21-May-7 days; April-6 days MX428 5/5/21-March-7 days 4. Approximately 2000 patients have been tested and results reported. 5.The laboratory testing person and laboratory director confirmed on January 19, 2022 about 3:00pm , that laboratory failed to meet the laboratory's criteria for control acceptability. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 5/9/2018</p>
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 review of standard laboratory operating procedure (SOP) manual, lack of a corrective action reports, interview with testing person and laboratory director, laboratory failed to establish a written corrective action procedure for out of range controls for Horiba ABX 60. FINDINGS: 1.The corrective action plan from the survey conducted on 5/9/2018 stated, "that the testing person has been instructed to inform LD when controls are out of range and not to run patient specimen." 2.The laboratory testing person and laboratory director confirmed on January 19, 2022 about 3:00pm , that laboratory failed to meet the laboratory's criteria for control acceptability PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 5/9/2018

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, confirmed in an interview with the testing person and laboratory director, and prior survey 5/9/18 plan of correction, laboratory director failed to provide overall management of the laboratory. The laboratory director failed to implement and maintain the: 1. laboratory's QC program was maintained, refer to D6020; 2. laboratory's Quality Assessment program was maintained, refer to D6021; PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 5/9/2018.

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 review of QC report and confirmed in an interview with laboratory testing

person and laboratory director, the laboratory director failed to ensure the QC program was established to ensure the quality of service provided by the lab. Refer to: D5481, D5783 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 5/9/2018.

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 lack of QA policy and QA documentation, confirmed in an interview with the laboratory testing person and laboratory direct at the time of this survey, the laboratory director failed to establish and maintain that the laboratory's QA program for all phases of laboratory testing. Refer to: D5481, D5783, D6000, D6020, PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON 5/9/2018.