

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1002797	(X3) Date Survey Completed 03/01/2019
Name of Provider or Supplier Primary Health Physicians, PLLC	Street Address, City, State 3821 W Springcreek Pkwy, Plano, TX	
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
D0000	Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 155 reports, American Proficiency Institute (API) proficiency testing (PT) records, and staff interview, the laboratory failed to attain a score of at least 80 percent for White Blood Cell Differential PT for 1 of 3 testing events in 2017 (Hematology/Coagulation -2nd Event). Findings included: 1. Review of CMS 155 Primary Health Physicians (45D1002797) report for White Blood Cell Differential PT scores 2nd testing event in 2017 revealed unsatisfactory scores: Cell I. D. or WBC DIFF 33% 2. Review of API PT "Comparative Evaluation" record for 2017 Hematology/Coagulation -2nd Event included PT samples HEM-06, HEM-07, HEM-08, HEM09 and HEM-10. The PT samples were analyzed on the Beckman Coulter AcT Diff 2 hematology analyzer for White Blood Cell Differential</p>

(Granulocytes, Lymphocytes, and Monocytes/Mids). The unsatisfactory scores were as follows: Granulocytes Score: (0/5) 0% Lymphocytes Score: (5/5) 100% Monocytes /Mids Score: 0/5 0% OVERALL White Blood Cell Differential Score 33% The laboratory did not attain a score of at least 80 for White Blood Cell Differential for API Hematology/Coagulation -2nd Event. 3. The above findings were confirmed by Technical Consultant #2 in an interview on 03/01/2019 at 1015 hours in laboratory office.