

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0894379	(X3) Date Survey Completed 10/20/2022
Name of Provider or Supplier Potomac Family Planning Center	Street Address, City, State 966 Hungerford Drive #24, Rockville, MD	
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
D6021	<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: Based on standard operating procedure manual (SOPM), quality control (QC) and quality assurance (QA) record review and interview with the laboratory staff, the laboratory director (LD) failed to follow the established QA program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The procedure, "Quality Control Review and Approval" states, "On a monthly basis, the Laboratory Director/Technical Consultant will review all quality control documentation performed by the testing personnel. Upon review, the Laboratory Director/Technical Consultant will sign off and date the quality control review form designated for this purpose." 2. A review of "Rh Control Logs" from January through September, 2022 showed that the LD signed a "quality control review form" which states, "I have reviewed and approved the Rh Control log for (month reviewed)" for January through June, 2022. 3. There were no "quality control review forms" present at the time of the survey for July through September, 2022. 4. During an interview on 10/20/2022 at 12:30 PM the laboratory staff confirmed that the LD did not ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>