

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0901525	(X3) Date Survey Completed 06/29/2021
Name of Provider or Supplier Planned Parenthood Of Minnesota/Sd	Street Address, City, State 6511 W 41st Street, Sioux Falls, SD	
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	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 6/29/21. The Planned Parenthood of Minnesota/SD laboratory was found not in compliance with the following requirement: D6018
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure proficiency testing (PT) results had been reviewed, evaluated, and those activities documented for five of seven PT events reviewed (American Proficiency Institute [API] 2019 Immunology/Immunochemistry second and third and 2020 Immunology/Immunochemistry first, second and third events). Findings include: 1. Review of the API 2019 Immunology/Immunochemistry second and third PT events revealed: * The performance and corrective action documentation was absent. * There had been no other documentation that results had been reviewed or evaluated. Review of the API 2020 Immunology/Immunochemistry first, second and third PT events revealed: * The performance and corrective action documentation was absent. * There had been no other documentation that results had been reviewed or evaluated. Review of laboratory's Appendix D, Laboratory Directors Responsibilities policy reviewed and implemented February 2020 revealed: *"All proficiency testing performance reports received are reviewed by the appropriate staff and Lab Director to evaluate the</p>

laboratory's performance and to identify any problems that require corrective action; and an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory." Review of laboratory's Appendix G, Proficiency Testing Instructions policy reviewed and implemented February 2020 revealed: *" Laboratory Director, Technical Consultant, Senior Director of Quality and Clinical Development and clinic staff will review API's test scores and results of proficiency testing upon receipt." Interview on 6/29/21 at 1:30 p. m. with laboratory staff A revealed she was unaware of the performance and corrective action documentation form. The laboratory director was unavailable for interview at the time of the survey.