Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409577	05/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Montana	1500 Cannon Street, Helena, MT	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review, product inserts, and interview with testing personnel TP #4, the laboratory failed to follow the manufacturer's instructions to perform external quality controls at the frequency required by Syphilis Health Check from May 21, 2022, to May 23, 2024, for four out of four testing locations. Findings: 1. A review of quality control records for syphilis testing revealed laboratory staff failed to perform and document the external positive and negative QC monthly per the Syphilis Health Check product insert for four out of four testing locations from May 21, 2022, to May 23, 2024. 2. Based on the test volume sheet, 1713 syphilis patient tests were performed from May 2023 to May 2024 (12 months). 3. An interview with TP #4 on May 23, 2024 at 11:30 AM, confirmed laboratory staff were not performing external QC monthly per the Syphilis Health Check product insert from May 21, 2022, to May 23, 2024.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

	baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, product inserts, procedure manual, and interview with the Clinical Operations Coordinator (not listed on the CMS 209 form), the laboratory failed to establish and follow a procedure for performing function checks on each piece of equipment, including timers involved in patient testing, from May 21, 2022, to May 23, 2024. Findings: 1. Observed timers in the laboratory on May 21, 2024, at 11:00 AM at the Billings, MT location and on May 23, 2024, at 10:45 AM at the Helena, MT location. 2. A review of product inserts for EldonCard RhD, Syphilis Health Check, Alere hCG Cassette, and OraQuick Advance Rapid HIV-1/2 Antibody Test revealed testing steps with time constraints. 3. A review of maintenance documentation revealed the laboratory failed to perform and document function checks for their timers. 4. A review of laboratory procedures revealed the laboratory failed to establish a procedure that defines the function checks on each piece of equipment, including timers that are peripherally involved in patient testing. 5. An interview with the Clinical Operations Coordinator (not listed on the CMS 209 form) on May 21, 2024, at 11:40 AM confirmed the laboratory failed to perform function checks on their timers from May 21, 2022, to May 23, 2024.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of laboratory policies and an interview with the testing personnel (TP) #4, the laboratory director failed to ensure that an approved policy manual was available to all personnel responsible for any aspect of the testing process from May 21, 2022, to May 23, 2024. Findings: 1. No policy manual signed by the laboratory director listed on the CMS-209 form was available for review at the Helena location on May 23, 2024. 2. An interview with TP #4 on May 23, 2024, at 11:35 AM confirmed the lack of an onsite policy manual approved by the laboratory director from May 21, 2022, to May 13, 2024.