Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521826	07/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Great Nw, Hawai'I,	2112 E Franklin Rd, Meridian, ID	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure record review and testing person interview, the laboratory failed to follow their written procedure for microscopic examination of urine sediment. Findings: 1. Review of the Health Center Manual procedures revealed the following: Urine Tests, page 4, stated to spin urine at 1800-2100 RPM. 2. Review of the centrifuge calibration records revealed that the centrifuge was set at 3250 rpm and calibrated to 3362 rpm on 03/2020. 3. Interview with the testing person on 07/30/2020 at 11:30 AM confirmed the above findings.
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 of available timers in the laboratory and an interview with the testing person, the laboratory failed to calibrate available timers in use. Findings: 1. Observation at the Boise location on 07/29/2020 at 12:30 PM revealed that 2 of 4 timers did not have documentation of calibration and on the back of the timers stated for household use only. 2. Observation at the Meridian location on 07/30/2020 at 11: 30 AM revealed that 1 of 1 timer did not have documentation of calibration and on the back of the timers stated for household use only. 3. A review of available laboratory records revealed no documentation of timer calibrations. 4. An interview with the technical consultant and testing person on 07/29/2020 at 12:35 PM confirmed the above findings.