Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D2168961	04/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Northern New England	90 Washington St, Barre, VT	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's (lab) two new procedures for three new Microbiology analytes did not have a dated signature from the lab director (LD) before putting into use in January 2022 and January 2023. Findings include: 1. Review on 4/20/2023 of the lab's procedure for Mycoplasma (M.) genitalium revealed it was not signed by the LD. 2. Review on 4/20/2023 of the lab's procedure for Herpes Simplex Virus (HSV) 1 and HSV 2 revealed it was not signed by the LD. 3. Interview with the Technical Supervisor (TS) on 4/20/2023 at approximately 9:30 a.m. confirmed the above procedures had not been signed by the LD. The TS revealed that the lab began patient testing for M. genitalium in January 2022, and began patient testing for HSV 1 and HSV 2 in January 2023. 4. The lab performs 160 M. genitalium tests annually and a combined 680 HSV 1 and HSV 2 tests since January 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to approve verification studies for 3 new Microbiology tests before patient testing in 2022 and 2023. Findings include: 1. Review on 4/20/2023 of the laboratory's (lab) verification of performance specifications for Mycoplasma (M.) genitalium and Herpes Simplex Virus (HSV) 1 and HSV 2 revealed the lab performed verification studies in November of 2021. The verification studies did not have the LD's dated signature indicated acceptance or approval of the verification studies. 2. Interview on 4 /20/2023 at approximately 9:30 a.m. with the Technical Supervisor (TS) confirmed the LD had not signed the verification procedures for M. genitalium and HSV 1 and HSV 2. The TS revealed the lab begin patient testing for M. genitalium in January 2022 and patient testing for HSV 1 and HSV 2 began in January 2023. 3. The lab performs 160 M. genitalium tests annually and a combined 680 HSV 1 and HSV 2 tests since January 2023.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to date and sign Microbiology proficiency testing (PT) evaluation forms in 2021 and 2022. Findings include: 1. Review on 4/20/2023 of American Proficiency Institute (API) PT results from 2021, 2022, and 2023 revealed the evaluation forms had not been signed and dated for review by the LD or designee for 2021 Microbiology - 1st Event, and 2022 Microbiology - 1st, 2nd, and 3rd Events. 2. Interview on 4/20/2023 at 10:10 a.m. with the LD confirmed the above finding.