Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409577	09/20/2022
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record review and an interview with the testing personnel (TP) #1, the laboratory failed to establish procedures and perform annual competency assessment for the position of technical consultant listed on the CLIA CMS-209 Personnel Report form. Findings: 1. A record review of the CMS-209 Personnel Report Form revealed one out of one technical consultant listed failed to have competency assessment performed for 2021 and 2022 2. A record review of the laboratory's procedure manual revealed the laboratory failed to have a policy or procedure to assess the technical consultant position. 3. An interview on September 20, 2022, at 11:30 AM, confirmed the laboratory failed to establish a policy or procedure and perform competency for the positions of technical consultant listed on the CMS-209 Personnel Report form.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP) #1, the laboratory failed to perform external quality controls (QC) for Syphilis Health Check at the frequency required by the manufacture's instruction from February 1, 2022, through April 6, 2022. Findings: 1. Review of Diagnostics Direct, LLC product insert for Syphilis Health Check revealed external controls (positive and negative) should be tested with each new lot, new shipment, each new operator, monthly as a continued check on storage conditions and whenever problems are identified. 2. Review of procedure, "Section III: Laboratory Logbooks and Records" revealed, "F. Quality Control test and results will be performed and documented per the manufacturer's instructions. The results will be entered into the Laboratory Control logs." 3. A review of Syphilis Laboratory Control logs revealed: Great Falls location lacked external QC for April, June, and August of 2022 Missoula location lacked external QC for May and August of 2022. Helena location lacked external QC for March, May, June, and August of 2022. 4. Interview with TP#1 on September 20, 2022, at 2:30 PM, confirmed the laboratory failed to routinely perform external QC for the Syphilis test per manufacturer's instructions.