Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383718	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Ames Health Center	2530 Chamberlain St, Ames, IA	

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 review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116 form), the laboratory procedure manual, and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 07/12/2023, the laboratory director failed to approve, sign and date all laboratory procedures. The findings include: 1. The Iowa State Agency received a CLIA Application for Certification (CMS-116 form) on 07/29 /2022 requesting a change to a new laboratory director. 2. At the time of the survey, the new laboratory director did not approve, sign or date any of the laboratory procedures.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by:

	Based on review of the Daily and Weekly Maintenance and Cleaning Checklist and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 07/12/2023, the laboratory failed to perform and document daily microscope maintenance for two out of two days of testing reviewed from March 2023. The findings include: 1. The laboratory's Daily and Weekly Maintenance and Cleaning Checklist stated the following for daily microscope maintenance: *Clean Microscope: wipe down control knobs and stage [NA if not used] 2. Patient identifier E had a wet mount examination performed on 03 /15/2023. 3. Patient identifier F had a wet mount examination performed on 03/21 /2023. 4. Review of the laboratory's Daily and Weekly Maintenance and Cleaning Checklist from March 2023 showed "NA" written on the log for daily microscope maintenance from 03/15/2023 and 03/21/2023. 5. At the time of the survey, personnel identifier #9 confirmed the laboratory did not have documented microscope maintenance for 03/15/2023 and 03/21/2023.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test records, the IUC Visit Quick Guide, and confirmed by laboratory personnel identifier #9 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 07/12/2023, the laboratory failed to include the identity of testing personnel for four out of four patients reviewed who had Rh typing performed in March 2023. The findings include: 1. Patient identifier A had Rh typing performed on 03/01/2023. 2. Patient identifier B had Rh typing performed on 03/02/2023. 3. Patient identifier C had Rh typing performed on 03/16/2023. 4. Patient identifier D had Rh typing performed on 03/24/2023. 5. The IUC Visit Quick Guide showed that when testing personnel enter patient test results in the Lab Module of the electronic health record (EHR), they are to enter their first initial, last name, and credentials into the result comment field. 6. At the time of the survey, the laboratory did not have records documenting the identity of the testing personnel for the patients listed above.