Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0669354	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of The Heartland	4409 Stone Avenue, Sioux City, 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
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 lack of performance specification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) and approximately 10:30 am on 5/12/21, the laboratory failed to verify the performance specifications of accuracy and precision for the Eldon Rh typing test system that was introduced into the laboratory in September 2020.
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 and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 5/12/2021, the laboratory failed to include the identity of testing personnel for two out of two patients who had Rh typing performed in January 2021. The findings include: 1. Patient identifier #1 had Rh typing performed on 1/6/2021. 2. Patient identifier #2 had a Rh typing performed on 1/20/2021. 3. At the time of the survey, the laboratory did not have records documenting the identity of the testing personnel for the above patients.