Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0977736	12/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Illinois-Loop	17 N State St - Ste 500, Chicago, IL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory procedure manual, patient test results and an interview with the technical consultant (TC); the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for the testing of the Rhesus Factor (RhD) testing, affecting patient treatment. Findings Include: 1. The laboratory failed to meet the following analytic systems requirement: *Failed to establish written quality assurance (QA) policies and procedures to perform assessment of all analytic system. See D5791.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, patient test results and an interview

	with the technical consultant (TC); the laboratory failed to establish written policies and procedures to adequately identify the need for possible corrective actions for Rhesus Factor (RhD) testing, affecting patient treatment. Findings Include: 1. Review of laboratory's procedures manual and ELDON RhD card test results on 12 patients, revealed the following: *One (1) patient (Patient CTP4) test result from the Eldon card was incorrectly interpreted and recorded onto the patients' test log. See D5800 & D5801. *Both the test log worksheet and test card sheet had written notations indicating these documents had been reviewed. 2. The laboratory's current quality assurance procedure failed to identify and correct the test result error. 3. On a Recertification survey conducted on 12/12/2019 at 12:30 PM, the TC confirmed the above findings.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, direct observation and an interview with the technical consultant (TC1); the laboratory failed to meet the applicable postanalytic systems requirements in 493.1291 that provides equivalent quality testing in the subspecialty of Rhesus (RH) Factor typing. 1. The laboratory failed to accurately and reliably transcribe test results into the laboratory's test log and the patients' electronic medical records (EMR). See D5801.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on direct observation, record review, and an interview with the technical consultant (TC1); the laboratory failed to accurately and reliably transcribe Rhesus Factor (RhD) test results, affecting 1 (Patient-CPT4) out of 12 patients. Findings include: 1. The laboratory's procedures manual, patients' test logs, patients' Eldon Test Cards, and their electronic medical records (EMR) were reviewed. 2. The ELDON RhD card test kits were used for Rhesus factor testing. The interpretation of the test cards' results are as follow: *Visible agglutination of the blood spot means positive (+); and *No Visible agglutination of the blood spot means negative (-) for the RhD

	factor. 3. The review of 12 patients' Eldon test cards, test result log and EMR documents revealed the following: *Visual review of Patient CPT4's Eldon card revealed no agglutination or (-) for the RhD factor, however a positive (+) result was written on the card. *The positive result was also written in the test log and entered into the EMR of Patient CPT4. 4. The laboratory failed to accurately record the correct test result for Patient CPT4 in the test log and in their EMR chart. 5. On a Recertification survey conducted on 12/12/2019 at 12:30 PM, the TC1 visually confirmed Patient CPT4 test result was negative, and the positive results written on the test log and in the EMR were incorrect.