Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449434	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Comp Health Of Planned Parenthood Great Plains	4401 W 109th St, Suite 100, Overland Park, KS	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed in 2020, 2021 and interview, the laboratory failed to attest on three of six events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of the attestation pages for PT from API revealed no signatures of the testing personnel was present on following API Events: a. 2020 Immunology/Immunohematology 2nd Event b. 2020 Immunology /Immunohematology 3rd Event c. 2021 Immunology/Immunohematology 1st Event 2. Interview with testing personnel #15 (TP15) on 4/20/2022 at 2:00 p.m. confirmed, the laboratory failed to attest on three of six events that proficiency testing samples were handled in the same manner as patient samples.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records or certificates of accuracy, protocols for thermometer function checks and interview with the TP15, the laboratory failed to define and perform a function check protocol for two of two thermometers. Findings: 1. No documentation was available for function checks on two of two thermometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on two of two thermometers at the time of survey. 3. Protocols for the function checks of thermometers were not made available at the time of survey. 4. Interview with TP15 on 4/20/22 at 3:30 p.m. confirmed, the laboratory failed to define and perform a function check protocol for two of two thermometers.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of the delegation of duties for the Technical Consultant (TC), quality control records, patient test records, temperature logs from 9/1/2020 to date of survey and interview with TP15 revealed the TC failed to ensure acceptable levels of analytic performance were maintained throughout the testing process. Findings: 1. Review of the TC delegation of duties include: "Establishes a quality control program appropriate for the testing performed, establishes the acceptable levels of analytic performance, and ensures these levels are maintained throughout the testing process." 2. Review of the Eldon Card Rh quality control records and patient test records revealed no review documentation by the TC from 9/1/2020 to date of survey 3. Review of temperature logs for reagent storage and testing area revealed no review documentation by the TC from 9/1/2020 to date of survey. 4. Interview with TP15 on 4 /20/22 at 2:45 p.m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained throughout the testing process.