Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0489594	(X3) Date Survey Completed 10/31/2023
Name of Provider or Supplier Planned Parenthood Gulf Coast, Inc	**Street Address, City, State** 4600 Gulf Fwy, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the the laboratory's policy, the laboratory's records, patient results from 8/31/2023 to 10/27/2023, and confirmed in an interview, the laboratory failed to to have temperature documentation to ensure the temperature was maintained between 2-30C with each of received specimen for two of two test: CT/NG on the Cobas 5800 System. The findings were: 1. Review the manufacturer's instructions titled cobas CT/NG Qualitative nucleic acid test for use on the cobas 5800/6800/8800 systems (09199543001-01En Doc Rev 1.0) under Specimen collection, transport, and storage revealed "Specimen transport: All specimen type listed in the "Specimen collection" section above can be transported at 2-30C." 2. Review of the laboratory's policy titled CHLAMYDIA AND GONORRHEA (SOP# LAB_02) under Specimen Transport and Swab Storage for Endocervical, Vaginal rectal and Pharyngeal Samples revealed "Following specimen collection, transport and store the COBAS PCR Media tube containing the collection swab at 2C to 30C. Endocervical and vaginal swab specimens are stable at 2C to 30 C for up to 12 months. Rectal and pharyngeal are stable at Room Temperature up to 14

	days. 3. Review the laboratory's records revealed the laboratory failed to to have temperature documentation to ensure the temperature was maintained between 2-30C with each of received specimen for two of two test: CT/NG on the Cobas 5800 System. 4. Reviewed the patient results revealed the first patient testing on Cobas 5800 system was on 8/31/2023, 5. Further review of patient results from 08/31/2023 to 10/27/2023 revealed total of 4155 patients had CT/NG testing performed on Cobas 5800 system. (Refer to 083123 Patient List, September 2023 Patient List, and October 2023 Patient List). 8/31/2023 119 patients had CT/NG testing 9/1/2023-9/30/2023 2128 patients had CT/NG testing 10/1/2023-10/27/2023 1908 patients had CT/NG testing 6. An interview with the Laboratory Technical Supervisor on 10/30/2023 at 1: 15 pm in the conference room confirmed the above findings. The laboratory technical supervisor acknowledged the facility did not take temoerature when received CT/NG specimens and the CT/NG samples via transporatation were transported by a courier bag with 2-3 ice packs in it. She also acknowledged the courier bag using for transportation was not temperature validated. Key: CT=Chlamydia Trachomatis NG=Neisseria Gonorrhea C=Degree Celsius