Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0960662	02/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Gulf Coast, Inc	12614 Southwest Freeway, Suite A, Stafford, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on a review of the manufacturer's instructions for the Siemens Uristix Reagent Strips, a review of the laboratory's quality control records from 2020, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for performing quality control testing on the Siemens Uristix Reagent Strips for urinalysis testing in 2020. Findings include: 1. A review of the manufacturer's instructions for the Siemens Uristix Reagent Strips (Document: 11306395 Rev. A) under the section titled 'Quality Control' revealed the following: "Test known negative and positive specimens or controls whenever a new bottle is first opened." 2. A review of the laboratory's quality controls records from

	2020 for the Siemens Uristix Reagent Strips revealed a positive control sample was run, but there was no documentation of a negative control being run for the following Siemens Uristix Reagent Strips: Lot number: 904006 date: 1/6/20 Lot number: 904006 date: 1/9/20 Lot number: 904006 date: 1/13/20 Lot number: 904006 date: 1/20 /20 Lot number: 905025 date: 1/27/20 Lot number: 905025 date: 2/3/20 Lot number: 905025 date: 2/10/20 3. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 12:40 p.m. in office #116, after review of the records, confirmed that the laboratory did not run a negative urinalysis control. II. Based on a review of the manufacturer's instructions for the Insti HIV-1/HIV-2 Antibody Test Kit and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature in 4 of 4 exam rooms where laboratory testing supplies were stored in 2018 and 2019. Findings include: 1. During a tour of the facility on 2/14/20 at 1:15 p.m. the following laboratory testing supplies were found in the patient exam rooms: a) Exam room #1: 3 packages- Insti HIV-1/HIV-2 Antibody Test Kit (lot number:1019190429/expiration date: 03/03/21) b) Exam room #2: 6 packages- Insti HIV-1/HIV-2 Antibody Test Kit (lot number:1019190429/expiration date: 03/03/21) c) Exam room #3: 8 packages- Insti HIV-1/HIV-2 Antibody Test Kit (lot number:1019190429/expiration date: 03/03 /21) d) Exam room #4: 8 packages- Insti HIV-1/HIV-2 Antibody Test Kit (lot number: 1019190429/expiration date: 03/03/21) 2. A review of the manufacturer's instructions for the laboratory testing supplies stored in the exam rooms revealed the manufacturers required the following conditions for operation: Insti HIV-1/HIV-2 Antibody Test Kit Manufacturers Instructions (50-1080D, 2014) "Store unused INSTI kits unopened at 15C - 30C." 3. The laboratory was asked to provide documentation of monitoring the temperature of the exam rooms for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 1:30 p.m. in office #116 revealed the facility did not monitor the temperature in the patient exam rooms. This confirmed the above findings. III. Based on a review of the manufacturer's instructions, a review of the laboratory's Room Temperature Monitoring Chart for 2020, and staff interview, it was revealed that the laboratory failed to have documentation of defining the correct acceptability criteria for for temperature ranges that are consistent with the manufacturer's instructions for patient testing using the following kit tests: a) Stanbio True 20 Plus One-Step Pregnancy Test b) Siemens Uristix Reagent Strips c) HemoCue Hb 201 Microcuvettes d) Insti HIV-1/HIV-2 Antibody Test Kit Findings include: 1. A review of the manufacturer's instructions for the following tests revealed the following storage requirements for patient testing: a) Stanbio True 20 Plus One-Step Pregnancy Test (Procedure: 1440, revision date: 03/15) "Each True 20 Plus test is stable until the expiration date on the foil pouch when stored at room temperature 59-86F (15-30C)." b) Siemens Uristix Reagent Strips (113063595 Rev A, 07-2017) "Store at temperatures between 15-30C (59-86F)." c) HemoCue Hb 201 Microcuvettes "The microcuvettes are to be stored at room temperature (15-30C, 59-86F)." d) Insti HIV-1/HIV-2 Antibody Test Kit (50-1080D, 2014) "Store at 15-30C, 59-86F." 2. A review of the Room Temperature Monitoring Chart from January 1, 2020 through February 14, 2020 revealed that the acceptable temperature range was documented as 18- 33C, which was not an appropriate range for the testing systems used in the laboratory. 3. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 12:40 p.m. in office #116, after review of the records, confirmed the above findings.
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 the laboratory's American Proficiency Institute proficiency testing records from 2018 and 2019 and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 1 of 10 attestation statements and testing personnel signing 1 of 10 attestation statements in 2018 and 2019. Findings include: 1. A review of the American Proficiency Institute's Attestation Statement form revealed the following: "Signatures required- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years." 2. A review of the laboratory's American Proficiency Institute proficiency testing records from 2018 (hematology events 2, 3 and immunology events 2, 3) and 2019 (hematology events 1, 2, 3 and immunology events 1, 2, 3) revealed the following missing signatures: a) Laboratory director 2019 Immunology event 2 This attestation statement form was signed by the testing person. There was no documentation of this responsibility being delegated to this testing person by the laboratory director. b) Testing personnel 2018 Hematology event 3 This attestation statement form was missing the signature of the testing person for the vaginal wet preparation test. 3. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 12:50 p.m. in office #116, after review of the records, confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on surveyor observation, a review of the operations manuals for the Labomed CXL Laboratory Microscope and the Unico G380 series Laboratory Microscope, and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature and humidity in 4 of 4 exam rooms where laboratory equipment was stored in 2018 and 2019. Findings include: 1. During a tour of the facility on 2/14/20 at 1:15 p.m. the following laboratory equipment was found in the patient exam rooms: a) Exam room #1: Labomed CXL Microscope b) Exam room #2: Labomed CXL Microscope c) Exam room #3: Unico G380 series Microscope d) Exam room #4: Labomed CXL Microscope 2. A review of the operations manuals for the laboratory equipment stored in the exam rooms revealed the manufacturers required the following conditions for operation: Labomed CXL Laboratory Microscope Operations Manual (document: 9135000-795, Issue 1.2, June 2015) "Ambient temperature: 5C to 40C Maximum relative humidity: 80% for temperature

	up to 31C , decreasing linearly through 70% at 34C, to 50% humidity at 4C" Unico G380 Series Laboratory Microscope Operations Manual - does not state any conditions for operation 3. The laboratory was asked to provide documentation of monitoring the temperature and humidity of the exam rooms for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 1:30 p.m. in office #116 revealed the facility did not monitor the temperature or humidity in the patient exam rooms. This confirmed the above findings. II. Based on a review of the manufacturer's instructions, a review of the laboratory's Room Temperature Monitoring Chart for 2020, and staff interview, it was revealed that the laboratory failed to have documentation of defining the correct acceptability criteria for for temperature ranges that are consistent with the manufacturer's instructions for patient testing using the ASI RPR Card Test. Findings include: 1. A review of the manufacturer's instructions for the following tests revealed the following temperature requirements for patient testing: ASI RPR Card Test (6004-900, 11-2016) "Allow all reagents and samples to warm to room temperature (20 -30 C) before use." 2. A review of the Room Temperature Monitoring Chart from January 1, 2020 through February 14, 2020 revealed that the acceptable temperature range was documented as 18- 33C, which was not an appropriate range for the ASI RPR Card Test. 3. An interview with technical consultant #2 (as indicated on the CMS 209 form, signed by the laboratory director on 2/13/20) on 2/14/20 at 12:40 p.m. in office #116, after review of the records, confirmed the above findings..
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 forms, a review of the laboratory's personnel records for 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments at least semiannually during the first year of testing for 3 of 12 testing personnel in 2019. Findings include: 1. A review of the laboratory's submitted CMS 209 forms (signed by the laboratory director on 2/13/20) revealed the laboratory identified 12 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records for 2018 and 2019 revealed the following testing personnel, their hire dates, and documentation of an initial competency assessment performed by the technical consultant: a) Testing personnel #2 (identified on CMS 209 form- Northwest HC Lab) Hire date: 12/2018 Initial competency assessment: 7/25/19 Based on the hire date, testing personnel #2 should have had at least 2 competency assessments performed prior to 12/2019. b) Testing personnel #1 (identified on CMS 209 form- Northville Health Center) Hire date: 5 /2018 Initial competency assessment: 1/22/19 Based on the hire date, testing personnel #1 should have had at least 2 competency assessments performed prior to 5 /2019. c) Testing personnel #2 (identified on CMS 209 form- Northville Health Center) Hire date: 11/2018 Initial competency assessment: 7/12/19 Based on the hire date, testing personnel #2 should have had at least 2 competency assessments performed prior to 11/2019. 3. The laboratory was asked to provide documentation of a second competency assessment being performed on the above testing personnel. No

	documentation was provided. 4. An interview with technical consultant #2 (as indicated on the CMS 209 form) on 2/14/20 at 12:15 p.m. in office #116, after review of the records, confirmed the above findings.