Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503535	05/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Cameron County	2140 Babcock Road, Suite 201, San Antonio, 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	An initial survey was conducted on May 17, 2021. The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel, moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to document lot number on aliquot containers of KOH (potassium hydroxide). The findings were: 1. Surveyor observation at Location A in the laboratory on May 17, 2021 at 13:00 hours found 1 aliquot container of KOH reagent in a brown dropper bottle. It was labeled as follows: KOH Solution Opened: 04-28-2021 Expiration: 05-27-2021 It was not labeled with a lot number. 2. Surveyor

	observation at Location B in the laboratory on May 17, 2021 at 15:00 hours found 1 aliquot container of KOH reagent in a brown dropper bottle. It was labeled as follows: KOH Solution Opened: 05-11-2021 Expiration: 06-11-2021 I was not labeled with a lot number. 3. An interview with the office manager on May 17, 2021 at 13:05 hours in the laboratory of Location A confirmed the findings. Key: Location A 712 North 77 Sunshine Strip, Suite 18 Harlingen, Texas 78550 Location B 870 East Alton Gloor Boulevard, Suite B Brownsville, Texas 78526
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for March and April 2021, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing at least two levels of qualitative quality control each day of serum pregnancy testing using the QuPID Stanbio test kit. The findings were: 1. Review of the laboratory's quality control records from March 1, 2021 to April 30, 2021 found the laboratory failed to provide documentation of performing at least two levels of quality control on the following days: Location A March 24, 2021 April 21, 2021 Location B March 25, 2021 April 23, 2021 April 28, 2021 2. Review of patient final reports found the following patient results were reported on days when the laboratory failed to provide documentation of performing at least two levels of quality control: Location A March 24, 2021 Last 4 digits of Patient ID: 2317 Serum Pregnancy Result: Positive April 21, 2021 Last 4 digits of Patient ID: 5167 Serum Pregnancy Result: Positive Location B March 25, 2021 Last 4 digits of Patient ID: 5551 Serum Pregnancy Result: Negative April 23, 2021 Last 4 digits of Patient ID: 5429 Serum Pregnancy Result: Negative April 28, 2021 Last 4 digits of Patient ID: 6055 Serum Pregnancy Result: Negative 3. The laboratory was asked to provide documentaiton of the missing quality control documentation. No documentation was provided. 4. An interview with the office manager on May 17, 2021 at 14:00 hours in the conference room of Location A confirmed the findings. Key: Location A 712 North 77 Sunshine Strip, Suite 18 Harlingen, Texas 78550 Location B 870 East Alton Gloor Boulevard, Suite B Brownsville, Texas 78526
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by:

	Based on review of the laboratory's records, and staff interview, it was revealed the facility failed to have documentation of education of qualify 1 of 6 testing personnel who performed moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the facility failed to have documentation of education of qualify 1 of 6 testing personnel who performed moderate complexity testing. The finding were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 6 testing personnel. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of education to qualify testing personnel number 4 (as listed on Form CMS 209). 3. The laboratory was asked to provide the missing records. No documentation was provided. 4. An interview with the president on 05/17/2021 at 1000 hours in the conference room - after her review of the records - confirmed the findings.