

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2023688	(X3) Date Survey Completed 06/20/2020
Name of Provider or Supplier Planned Parenthood South Texas	Street Address, City, State 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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program; 493.807 (a) reinstatement after failure; 493.1403 laboratories performing moderate complexity testing; laboratory director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a desk review of proficiency testing records obtained from the Casper 155 Report and verified with the proficiency testing company, College of American Pathologists (CAP) it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of routine chemistry for the analyte BUN (Blood Urea Nitrogen). Refer to D2096. Key: CLIA - Clinical Laboratory Improvement Amendments HHS - Health and Human Services

D2017

REINSTATEMENT OF NONWAIVED LABORATORIES
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:
Based on a desk review of proficiency testing scores from College of American Pathologists (CAP) and review of the Casper 155 Report found the laboratory failed to participate successfully for the analyte BUN (Blood Urea Nitrogen). Findings included: 1. The laboratory received the following failing scores (passing is greater than or equal to 80%) for the analyte BUN: CAP 2019 - 1st event laboratory received an unsatisfactory score of 40% for BUN CAP 2019 - 3rd event laboratory received an unsatisfactory score of 40% for BUN CAP 2020 - 1st event laboratory received an unsatisfactory score of 60% for BUN 2. These failures result in a third unsuccessful performance for the analyte BUN. 3. The laboratory must demonstrate sustained satisfactory performance (>80%) on two consecutive testing events for reinstatement.

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of CMS 155 Report and College of American Pathologists (CAP) records found that the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for each analyte in the subspecialty of chemistry. Findings included: 1. CAP 2019 - 1st event laboratory received an unsatisfactory score of 40% for BUN 2. CAP 2019 - 3rd event laboratory received an unsatisfactory score of 40% for BUN 3. CAP 2020 - 1st event laboratory

received an unsatisfactory score of 60% for BUN 4. CAP 2019 - 3rd event laboratory received an unsatisfactory score of 0% for Glucose 5. CAP 2020 - 1st event laboratory received an unsatisfactory score of 0% for Sodium 6. CAP 2020 - 1st event laboratory received an unsatisfactory score of 60% for Chloride 7. CAP 2020 - 1st event laboratory received an unsatisfactory score of 20% for Total Protein 8. CAP 2020 - 2nd event laboratory received an unsatisfactory score of 20% for Total Bilirubin 9. CAP 2020 - 2nd event laboratory received an unsatisfactory score of 20% for HDL Cholesterol Key: CMS - Centers for Medicare and Medicaid BUN - Blood Urea Nitrogen HDL - High Density Lipoprotein

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a desk review of College of American Pathologists (CAP) proficiency testing (PT) records and the Casper 155 Report, it was determined that laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events. The laboratory failed to achieve satisfactory performance in the specialty of chemistry for the analyte BUN (Blood Urea Nitrogen). Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings included: 1. CAP 2019 - 1st event laboratory received an unsatisfactory score of 40% for BUN 2. CAP 2019 - 3rd event laboratory received an unsatisfactory score of 40% for BUN 3. CAP 2020 - 1st event laboratory received an unsatisfactory score of 60% for BUN

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on desk review of laboratory proficiency testing it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2096