

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2133980	(X3) Date Survey Completed 02/04/2021
Name of Provider or Supplier Planned Parenthood Of Southwest & Central Fl	Street Address, City, State 236 East Bearss Ave, Tampa, FL	
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 announced CLIA recertification survey was conducted at Planned Parenthood of Southwest and Central FL, Inc. on 01/28/2021 and 02/04/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6000-Moderate Complexity Laboratory Director: 493.1403 D6063-Laboratory Testing Personnel: 493.1421
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Senior Manager of Compliance, Quality & Risk Management the Laboratory Director failed to verify the education of 2 (#B and #E) out of 7 (#A, #B, #C, #D, #E, #F, and #G) Testing Personnel (See D6028).</p>
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the Senior Manager of Compliance, Quality & Risk Management the Laboratory Director failed to verify the education of 2 (#B and #E) out of 7 (#A, #B, #C, #D, #E, #F, and #G) Testing Personnel. Findings Included: Review of personnel files revealed no proof of education for Testing Person #B and #E. Interview on 02/04/2021 at 8:39 AM via email from the Senior Manager of Compliance, Quality & Risk Management confirmed that the laboratory did not have proof of high school diplomas for Testing Person #B and #E.

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 record review and interview with the Senior Manager of Compliance, Quality & Risk Management the laboratory failed to verify the education of 2 (#B and #E) out of 7 (#A, #B, #C, #D, #E, #F, and #G) Testing Personnel (See 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 record review and interview with the Senior Manager of Compliance, Quality & Risk Management the laboratory failed to verify the education of 2 (#B and #E) out of 7 (#A, #B, #C, #D, #E, #F, and #G) Testing Personnel. Findings Included: Review of personnel files revealed no proof of education for Testing Person #B and #E. Interview on 02/04/2021 at 8:39 AM via email from the Senior Manager of Compliance, Quality & Risk Management confirmed that the laboratory did not have proof of high school diplomas for Testing Person #B and #E.