

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0722304	(X3) Date Survey Completed 09/30/2022
Name of Provider or Supplier Planned Parenthood Of South Florida & Treasure	Street Address, City, State 2300 N Florida Mango Rd, West Palm Beach, 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 South Florida & Treasure on 09/26/2022 to 09/30/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. On-site visits were made to all 6 multiple sites: Treasure Coast-1696 SE Hillmoor Drive in Port St. Lucie, Boca-8177 Glades Road Bay 25 in Boca Raton, FL Mango-2300 N FL Mango Rd. in West Palm Beach, Pembroke Pines-263 N University Drive in Pembroke Pines, Gold Glades- 585 NW 161st Street in Miami, and Kendall-8900 SW 117th Ave Suite 207B in Miami. 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 the Laboratory Director failed to delegate signing American Proficiency Institute (API) proficiency testing and performing competency evaluations on the Testing Personal to a person (Staff #PP) that would qualify as a Laboratory Director or a Technical Consultant for 2 out of 2 years (2020-2022) reviewed (See D6004).</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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</p>

and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and interview the Laboratory Director failed to delegate signing American Proficiency Institute (API) proficiency testing and performing competency evaluations on the Testing Personal to a person (Staff #PP) that would qualify as a Laboratory Director or a Technical Consultant for 2 out of 2 years (2020-2022) reviewed. Findings Included: Review of API proficiency testing revealed that Staff #PP signed the attestations and reviews. Review of Competency evaluations on all 41 Testing Personnel revealed that all were signed by Staff #PP. Review of Staff #PP education revealed that she has a Doctor of Nursing Practice degree which does not qualify her to be the Laboratory director or a Technical Consultant. Interview on 09/26/2022 at 3:30 PM the Laboratory Manager confirmed that Staff #PP was performing competency evaluations and signing the API proficiency testing.

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 the laboratory failed to verify the accuracy of 1 (Testing Person #N) out of 41 Testing personnel (#A-#OO). 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 the laboratory failed to verify the accuracy of 1 (Testing Person #N) out of 41 Testing personnel (#A-#OO). Findings Included: Review of Testing Personnel #N documentation of education revealed a High School

diploma from Jamaica with no foreign equivalency. She was hired on 04/18/2022. Interview on 09/30/22 at 8:51 AM the Laboratory Manager confirmed that Testing Person #N did not have a foreign diploma equivalency.