

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0268310	(X3) Date Survey Completed 06/05/2024
Name of Provider or Supplier Planned Parenthood Of South East And North Florida	Street Address, City, State 5978 Powers Ave, Jacksonville, 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	<p>An announced recertification survey was conducted on 6/5/2024 at Planned Parenthood of South East and North Florida, a clinical laboratory in Jacksonville, Florida. Planned Parenthood of South East and North Florida was NOT in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory was not in compliance with Federal licensure requirements to perform testing for the analytes "Beta-hCG (human chorionic gonadotropin)" since testing began in December of 2023. The findings include: The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) obtained during survey showed the laboratory performs testing in the following specialty/subspecialties: Mycology, and ABO Group & Rh Group. The CLIA certificate provided at the time of survey confirmed the same specialties were on the license. Review of the laboratory test menu showed the laboratory performs testing for the analyte Beta-hCG on the Abbott I-stat instrument. Review of the FDA (Food and Drug Administration) web site for CLIA testing complexity showed that since 2015, the FDA has classified the testing system "Abbott i-STAT 1 Analyzer Systems" for the analyte "Beta-hCG" to be "Moderate Complexity" under the specialty of Endocrinology. The interview with Testing Person B on 6/5/2024 at 9:00 am confirmed the laboratory was not licensed for Endocrinology and approximately 180 tests had been since performed between December 2023 and June 2024.</p>

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director failed to ensure that when unsatisfactory and unsuccessful proficiency test scores were received that a corrective action plan was written and followed by the laboratory personnel. The findings include: There are three locations testing under this CLIA number using a multiple site exception. Proficiency testing was reviewed for all sites. The findings below occurred at the 2618 W Tennessee St, Tallahassee Florida. 1. Review of the American Proficiency Institute (API) proficiency test "Performance Summary" for the 2022 Immunology/Immunoematology - 3rd event, the laboratory scored an 80% for the analyte D (Rho) type. The documented corrective action states "Staff to be observed performing + & - testing. Staff failed 1 of 2 tests." The laboratory was unable to provide documentation of the corrective action. 2. Review of the American Proficiency Institute (API) proficiency test "Performance Summary" for the 2023 Immunology/Immunoematology - 2nd event, the laboratory scored an 80% for the analyte D (Rho) type. The documented corrective action states "Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. 1 on 1 training and creating developmental procedures/processes by Health Center leadership to review and analyze data to document progress and improvement efforts". The laboratory was unable to provide documentation of the corrective action. The interview with Testing Person B on 6/5/24 at 12:30pm confirmed they were unable to locate further corrective action for the failed proficiency tests.

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 record review and staff interview, the technical consultant failed to evaluate and document at least semiannually the performance of Testing Personnel (TP) #V, #W, #X who perform direct wet mount testing during the first year of employment. The findings include: Review of the laboratory's competency evaluation records for TP #V and #W showed that the laboratory had documented the initial training performance evaluation June 2023. The initial training performance evaluation for TP #X was documented in October 2023. There was no semiannual performance evaluation documented. During an interview on 6/5/24 at 12:46 PM, Testing Person #B confirmed that the Technical Consultant had not ensured that the semiannual performance evaluation was documented for the three testing personnel.