

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0083662	(X3) Date Survey Completed 04/22/2022
Name of Provider or Supplier Planned Parenthood Of Southern New England	Street Address, City, State 175 Broad St, Providence, RI	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples by personnel who routinely perform the testing in the specialties of Immunohematology and Microbiology. Findings include: 1. Record review on 4/20/2022 of the laboratory's American Proficiency Institute (API) 2020 and 2021 Immunology /Immunohematology and Hematology/Coagulation (Microscopy) PT records revealed; a. 2020 i. Two Microbiology PT events were tested by Microbiology TP#1 and one Microbiology PT event was tested by Microbiology TP#2. ii. No Microbiology PT events were tested by Microbiology TP#3 through Microbiology TP#7 and Microbiology TP#9. iii. Immunohematology PT Event 1 was tested by TP#4, Immunohematology PT Event 2 was tested by TP#8 and Immunohematology PT Event 3 was tested by TP#1. iv. No Immunohematology PT events were tested by TP#2, TP#3, and TP#5 through TP#7. b. 2021 i. Two Microbiology PT events were tested by Microbiology TP#3 and one Microbiology PT event was tested by Microbiology TP#1. ii. No Microbiology PT events were tested by Microbiology TP#2 and Microbiology TP#4 through Microbiology TP#10. iii. Immunohematology PT Event 1 was tested by TP#2, Immunohematology PT Event 2 was tested by TP#2 and TP#10 and Immunohematology PT Event 3 was tested by TP#10. iv. No Immunohematology PT events were tested by TP#1 and TP#3 through TP#9. 2. Staff interview with the technical consultant (TC) on 4/20/2022 at 10:15 AM confirmed the</p>

above findings. The TC further stated that 2 TP do not perform Microbiology patient testing. 3. The laboratory performs 1,964 Immunochemistry and 910 Microbiology tests annually.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director (LD) and testing personnel (TP) failed to attest that proficiency testing samples were performed in the same manner as patient specimens. Findings include: 1. Record review on 4/20/2022 of the 2020 American Proficiency Institute (API) Immunology/Immunochemistry Event 1 attestation page revealed the page was not signed by the LD. 2. Record review on 4/20/2022 of the 2020 American Proficiency Institute (API) Hematology/Coagulation Event 1 attestation page revealed the page was not signed by 2 of 2 TP. 3. Interview with the technical consultant on 4/20/2022 at 10:30 AM confirmed the above findings.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant (TC) failed to ensure all testing personnel (TP) have tested unknown samples to demonstrate competency in performing laboratory tests in the specialties of Immunochemistry and Microbiology. Findings Include: 1. Record review on 4/20/2022 of the laboratory's American Proficiency Institute (API) 2020 and 2021 PT records revealed; a. Four of nine Immunochemistry TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in Immunology/Immunochemistry in 2020. b. Eight of ten Immunochemistry TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in Immunology/Immunochemistry in 2021. c. Five of seven Microbiology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in Microbiology in 2020. d. One of eight Microbiology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in Microbiology in 2021. 2. Record review of employee competency

records on 4/20/2022 revealed assessment of competency through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples is not documented as part of the TP annual competency for Immunohematology and Microbiology. 3. Staff interview on 4/20/2022 at 10:07 AM with the TC confirmed the above TP did not examine unknown samples or include PT material to accurately assess their skills in the specialties of Immunohematology and Microbiology in 2020 and 2021. 4. The laboratory performs 1,964 Immunohematology and 910 Microbiology tests annually.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the technical consultant (TC) failed to document annual competency of testing personnel (TP) to assess the knowledge and skills necessary to perform Immunohematology and Microbiology Testing. Findings include: 1. Record review on 4/20/2022 of the laboratory's 2020 and 2021 competency records revealed the laboratory did not have documented annual competency records for one Immunohematology and Microbiology TP. 2. Staff Interview on 4/20/2022 at 10:15 AM with the TC confirmed the laboratory did not have annual competency documentation for one Immunohematology and Microbiology TP in 2020 and 2021. 3. The laboratory performs 1,964 Immunohematology and 910 Microbiology tests annually.