

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0083662	(X3) Date Survey Completed 02/08/2024
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: REPEAT DEFICIENCY 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 testing personnel (TP) who routinely perform the testing in the specialties of Immunohematology and Microbiology. Findings include: 1. Record review on 02/08/2024 of the laboratory's American Proficiency Institute (API) 2022 and 2023 Immunology/Immunohematology and Hematology/Coagulation (Microscopy) PT records revealed: a. In 2022 i. 4 of 5 fully trained TP did not participate in Immunohematology PT. ii. 3 of 5 fully trained TP did not participate in Microbiology PT. b. In 2023 i. 3 of 4 fully trained TP did not participate in Immunohematology PT. ii. 2 of 4 fully trained TP did not participate in Microbiology PT. 2. Staff interview with the technical consultant (TC) on 02/08/2024 at 10:15 AM confirmed the above findings. The TC stated, "I realized at the end of 2023 the PT was not rotated." 3. The laboratory performs 1,499 Immunohematology and 694 Microbiology tests annually.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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</p>

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:
REPEAT DEFICIENCY Based on record review and staff interview, the laboratory director (LD), or their delegated designee, 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 02/08/2024 of the 2022 American Proficiency Institute (API) Hematology/Coagulation Event 2 attestation page revealed: a. The attestation statement was not signed by the LD or delegated designee. b. The attestation statement was not signed by 2 of 3 TP. 2. Interview with the technical consultant on 02/08/2024 at 10:15 AM confirmed the above findings. 3. The laboratory performs 694 Microbiology tests annually.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on record review and staff interview with the technical consultant (TC), the laboratory failed to document room temperature to ensure the proper storage of EldonCards in 2023. Findings include: 1. Record review on 02/08/2024 of the 'DOCTOR'S KIT DKS RhD' package insert revealed, "EldonCards should be stored between 5 and 37 C." 2. Record review on 02/08/2024 of the laboratory's 2023 'Room Temperature Log' revealed: a. "EldonCard must be stored at room temperature (5-37C, 41-99F)" b. No room temperatures were recorded from August 11, 2023 through December 26, 2023. 3. Staff interview with the TC on 02/08/2023 at 10:35 PM confirmed the above findings. 4. The laboratory performs 1,499 Immunoematology tests annually.

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:
REPEAT DEFICIENCY 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 Immunohematology and Microbiology. Findings Include: 1. Record review on 02/08/2024 of the laboratory's American Proficiency Institute (API) 2022 and 2023 PT records revealed: a. 3 of 4 Immunohematology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in 2022. b. 1 of 4 Immunohematology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in 2023. c. 3 of 4 Microbiology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in 2022. d. 1 of 4 Microbiology TP did not examine PT material or test previously analyzed or blind samples to accurately assess their skills in 2023. 2. Record review of employee competency records on 02/08/2024 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 02/08/2024 at 10:45 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 2022 and 2023. The TC stated, "I have not been doing it as part of thier competency." 4.The laboratory performs 1,499 Immunohematology and 694 Microbiology tests annually.