

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 47D0663518	<b>(X3) Date Survey Completed</b> 05/25/2022
<b>Name of Provider or Supplier</b> Planned Parenthood Of Northern New England	<b>Street Address, City, State</b> 173 St Paul St, Burlington, VT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted at Planned Parenthood of Northern New England (PPNNE) locations at 443 Congress St in Portland, Maine on 5/24/2022 and 79 South Main St in White River Junction, VT on 5/25/2022.
<b>D2160</b>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(e)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview conducted at the PPNNE location in Portland, ME on 5/24/2022, the laboratory failed to perform and document remedial action for a score of 80% they received for ABO/RHO and D(RHO) American Proficiency Institute (API) proficiency testing (PT) 2021 Event 1. Findings include: 1. Record review conducted on 05/24/2022 of CASPER 155D Report revealed that laboratory received a score of 80% for ABO/RHO and D(RHO) for API 2021 Event 1. 2. Record review conducted on 05/24/2022 of the laboratory's documentation for ABO/RHO and D(RHO) for 2021 Event 1 revealed no documented evaluation or remedial action(s) for the unacceptable PT Event scores. 3. Interview with the Clinical Quality Coordinator (CQC) on 05/24/2022 at 10:40 am confirmed the above findings. The CQC further revealed that the ABO/RHO and D(RHO) for 2021 Event was performed at a Vermont PPNNE location.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on staff interview and record review conducted at the PPNNE location in Portland, ME on 5/24/2022, the Laboratory Procedures and Infection Prevention Manual Updates and Revisions Procedures implemented on May 20, 2016 were not signed, approved, and dated by the current laboratory director (LD). Findings include: 1. Record review conducted on 05/24/2022 of the Laboratory Procedures and Infection Prevention Manual Updates and Revisions Procedures implemented on May 20, 2016 were not signed, approved, and dated by the current laboratory director (LD). 2. Interview with the Clinical Quality Coordinator on 05/24/2022 at 12:00 pm confirmed this finding.

**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 at the PPNNE location in White River Junction, VT on 5/25/2022, the Technical Consultant failed to perform competency assessments semiannually in the first year of immunohematology patient testing for 3 of 3 new testing personnel in 2021 and 2022. Findings include: 1) Review on 5/25/2022 of personnel records revealed 3 new personnel (TP1, TP2, TP3) who performed Rh blood group typing at this location. TP1 completed training March 2020, had a semiannual competency assessment September 2020 but did not have a second competency assessment (semiannual) in the first year of testing in 2020 or 2021. TP2 completed training February 2021 and did not have documentation of semiannual competency assessments in 2021 or 2022. TP3 completed training May of 2021 and did not have documentation of semiannual competency assessments in 2021 and 2022. 2) Interview on 5/25/2022 at 10:50 a.m. with the Clinical Quality Coordinator confirmed the above finding.

**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 at the PPNNE location at White River Junction, VT on 5/25/2022, the Technical Consultant failed to perform competency assessments annually for 2 of 2 testing personnel performing immunohematology testing in 2021 and 2022. Findings include: 1) Review on 5/25/2022 of personnel records for this location revealed there was no documentation of competency

assessment in 2021 for 1 (TP4) of 2 testing personnel and there was no annual competency assessment for 1 (TP1) of 2 testing personnel in 2022. 2) Interview on 5/25/2022 at 10:50 a.m. with the Clinical Quality Coordinator confirmed the above finding.