

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D0076972	<b>(X3) Date Survey Completed</b> 08/14/2024
<b>Name of Provider or Supplier</b> Planned Parenthood League Of Massachusetts	<b>Street Address, City, State</b> 1055 Commonwealth Avenue, Boston, MA	
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 CLIA recertification survey was conducted for the Planned Parenthood League of Massachusetts laboratory on 8/14/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and the Technical Supervisor (TS) on 8/14/2024, the laboratory failed to indicate on the patient final test report the name and address of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed sixteen (16) patient final test reports between November 2022 and June 2024. The review revealed: The laboratory failed to indicate the name and address of the laboratory location where the test was performed on four (4) out of four (4) patient final test reports for Rh Type and two (2) out of two (2) patient final test reports for Wet Preps. The LD and TS confirmed through interview on 8/14/2024 at 2:12 PM that the patient final test reports did not indicate the name and address of the laboratory where the test was performed for Rh Type and Wet Preps. The laboratory performs 630 Rh Type tests and 5 Wet Preps tests annually.</p>