

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2049862	<b>(X3) Date Survey Completed</b>  01/18/2023
<b>Name of Provider or Supplier</b>  Physicians For Women's Health Llc	<b>Street Address, City, State</b>  328 Shrewsbury Street, Ste 100, Worcester, 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 Physicians for Women's Health, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 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, the laboratory failed to indicate on the patient final test report the correct name of the laboratory and address where testing was performed as evidenced by the following: a) A review was performed of fifteen (15) final patient test reports issued between 1/7/22 and 11/21/22. The review revealed the fact that the current name of the laboratory was not indicated for all 15 reports reviewed. In addition, the address where the testing was performed was not correctly indicated for four (4) of the fifteen (15) reports reviewed. Three of the reports indicated the testing address as 340 Maple St., Suite 125, Marlborough, MA 01725-3288 (test orders and dates: 52783715-1/7/22, 56003998-4/29/22, and 59393034-4/23/22). One of the reports indicated the testing address as 340 Thompson Ave., Webster, MA 01570-1589 (55297631 order and 4/6/22 order date). a) The Technical Consultant confirmed in a telephone interview on 1/19/23 at 9:45 A.M. that the patient final test</p>

reports did not indicate the correct name of the laboratory and address where the testing was performed. The laboratory issues reports based on 6,731 tests performed annually. .