

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D0087317	(X3) Date Survey Completed 01/26/2021
Name of Provider or Supplier Feminist Health Center Of Portsmouth	Street Address, City, State 559 Portsmouth Ave, Greenland, NH	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform a positive and negative Rh antigen control on 8 of 8 days of patient testing between October 1, 2020 to January 26, 2021. Findings include: 1) Review on 1/26/2021 of the laboratory's procedure titled "Lab Quality Control" revealed on page 1, paragraph 1: "Rh Controls will be run each day that Rh testing occurs in the laboratory." The procedure failed to specify a positive and negative control. 2) Review on 1/26/2021 of control records for Rh antigen typing from October 2020 to January 26, 2021 revealed one positive control had been run on 12/30/2020 for test kit lot #20161 (expiration date: 2/28/2022). The laboratory could not provide documentation of control testing for previous test kit lot(s) used between 10/1/2020 through 12/29/2020, and could not provide quality control test results for dates when patient testing had been performed. 3) Interview with the Technical Consultant on 1/26/2021 at approximately 1030 a.m. revealed the laboratory only performed a positive control one time for each new shipment. 4) Review of patient records from 10/1/2020 through 1/26/2021 revealed a combined total of 29 patient Rh tests had been performed on the following dates (# patient tests): 10/3/2020 (7), 10/6/2020 (2), 11/5/2020 (3), 12/4/2020 (2), 12/12/2020 (3), 12/18/2020 (3), 1/8/2021 (4), and 1/23/2021 (5). 5) Interview with the Executive Director on 1/26/2021 at 10:45 a.m. confirmed the above findings.</p>