

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0885687	<b>(X3) Date Survey Completed</b>  04/28/2021
<b>Name of Provider or Supplier</b>  Womens Center Of Flint	<b>Street Address, City, State</b>  5051 Villa Linde Parkway #29, Flint, MI	
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>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison (LL), the laboratory failed to ensure the immunohematology Rh quality control was performed and documented before patient testing for 3 days (01/16/2020, 06/22/2020, and 03/24/2021) of 2 years of documents reviewed. Findings include: 1. A record review of the "Blood-Urinalysis Tracking Sheet" revealed for 3 days (01/16/2020, 06/22/2020, and 03/24/2021) of 2 years of documents reviewed, the laboratory did not perform and document the positive and negative immunohematology Rh quality control before patient testing as follows: a. 01/16/2020 - no controls performed and documented, 6 patients tested. b. 06/22/2020 - no controls performed and documented, 5 patients tested. c. 03/24/2021 - no controls performed and documented, 13 patients tested. 2. A interview on 04/28/2021 at 10:47 am, the LL confirmed the Rh positive and negative controls were not performed and documented prior to testing patient specimens.</p>