

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0370794	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Summit Women's Center	Street Address, City, State 15801 W McNichols Road, Detroit, MI	
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
D5445	<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, lack of documentation, and interview with the laboratory liaison (LL), the laboratory failed to ensure the immunohematology Rh quality control was documented before patient testing for 8 days (8/17/2021 to 11/16/2022) of 18 months of testing reviewed. Findings include: 1. A record review for 8 days of 18 months of testing reviewed revealed a lack of documentation on the daily log for the positive and negative immunohematology Rh quality control testing result before patient testing as follows: a. 8/17/2021 - 8 patients tested b. 9/07/2021 - 3 patients tested c. 9/08/2021 - 3 patients tested d. 9/11/2021 - 5 patients tested e. 9/21/2022 - 10 patients tested f. 9/24/2022 - 10 patients tested g. 11/02/2022 - 8 patients tested h. 11/04/22 - 11 patients tested 2. A record review of the "Quality Control Policy" states "We document the results of all controls and will take appropriate actions when the controls do not perform as expected." "All quality control testing is satisfactorily completed prior to patient testing." 3. A interview on 11/16/2022 at 10:25 am, the LL confirmed the Rh positive and negative control was not documented on the daily log for the above listed dates. ***Repeat Deficiency from the 11/09/2017 survey***</p>