Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0978663	06/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Scotsdale Women's Center	19305 W 7 Mile 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to establish and implement a policy to assess testing personnel competency for 16 (February 24, 2021 to June 23, 2022) of 16 months reviewed. Findings include: 1. A review of the laboratory's policies and procedures revealed a lack of a policy regarding competency assessments for testing personnel. 2. A review of the laboratory's competency assessment documentation revealed a lack of competency assessment for 16 (February 24, 2021 to June 23, 2022) of 16 months as follows: 6 month assessment a. Testing Personnel #3 (TP3) - lack of documentation for the 6 month assessment which was due in 1/ 2021. Annual assessments due in 2021 a. TP4 - lack of documentation for 9/2021 b. TP5 - lack of documentation for 9 /2021 c. TP6 - lack of documentation for 7/2021 d. TP7 - lack of documentation for 9 /2021 3. When queried on 6/23/2022 at 10:50 am the LD was unable to provide the surveyor the documentation requested. 4. An interview on 6/23/2022 at approximately 10:50 am, the LD confirmed the laboratory failed to establish and properly implement TP competency assessments. ***Repeat Deficiency from the 4/14/2016 survey***
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure the immunohematology Rh quality control was performed and documented before patient testing. Refer to D5445.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to perform and document the function checks as required for the room temperature and refrigerator for 2 (2/25/2021 and 6/11/2021) of 16 days of patient testing reviewed. Findings include: 1. A record review revealed lack of documentation of the room temperature and refrigerator for 2 of 16 days reviewed as follows: a. 2/25/2021 - lack of documentation b. 6/11/2021 - lack of documentation 2. A record review of the "Quality Assurance Program Specifics" policy, the laboratory failed to follow procedures for completing the daily checklist by "Record (Fahrenheit) temperature reading from the refrigerator and Record (Fahrenheit) room temperature of the lab area. Ambient temperature." 3. An interview on 6/23/2022 at 9:40 am, the LD confirmed the laboratory failed to follow procedure for recording the room temperature and refrigerator daily.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to ensure the immunohematology Rh quality control was performed and documented before patient testing for 2 (2/25/2021 and 6/11/2021) of 16 days reviewed. Findings include: 1. A record review of the "Daily Laboratory Checklist" revealed for 2 (2/25/2021 and 6/11/2021) of 16 days reviewed, the laboratory did not

	perform and document the positive and negative immunohematology Rh quality control before patient testing as follows: a. 2/25/2021 - 16 patients tested b. 6/11/2021 - 15 patients tested 2. A record review of the "Quality Assurance Program Specifics" policy, the laboratory failed to follow procedures for completing the daily checklist by "Run a positive and negative control for Rh Typing as per Rh Testing Protocol." 3. A interview on 6/23/2022 at 9:40 am, the LD confirmed the Rh positive and negative control was not performed and documented each day of testing. ***Repeat Deficiency from the 5/22/2018 and 2/24/2021 surveys***