Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0978663	02/24/2021
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on record review and interview with the new Laboratory Director (LD), the LD failed to approve, sign, and date for 4 (10/17/2020 to 2/17/2021) of 4 months since taking the director position the "Laboratory Manual" that included the immunohematology Rh group procedures. Findings include: 1. A record review revealed for 4 (10/17/2020 to 2/17/2021) of 4 months in the LD position, the "Laboratory Manual" with the immunohematology Rh group procedures were not approved, signed, and dated. 2. A interview on 2/17/2021 at approximately 10:31 am, the LD confirmed he did not approve, sign, and date the procedures located in the "Laboratory Manual."
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Director (LD) and Testing Personnel (TP) #4, the laboratory was using expired blood drawing tubes for 3 (Becton Dickinson (BD) vacutainer plasma separator tube (PST) Gel and lithium heparin, BD vacutainer serum separator tube (SST), and BD vacutainer dipotassium

	ethylenediaminetetraacetic acid (K2EDTA) of 3 tubes expired. Findings include: 1. On 2/17/2021 at 9:20 am, during a tour of the laboratory, the surveyor randomly pulled tubes from the storage container in the blood drawing station and the tubes had expired: a. BD vacutainer PST Gel and lithium heparin - lot 9315457 expired 11/30 /2020 b. BD vacutainer SST - lot 9196157 expired 7/31/2020 c. BD vacutainer K2EDTA - lot 8276808 expired 3/31/2020 2. A interview on 2/17/2021 at 9:20 am, the LD and TP4 confirmed the blood drawing tubes had expired.
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 days (10/11/2019 and 10/12/2019) of 2 years of documents reviewed. Findings include: 1. A record review of the "Daily Laboratory Checklist" revealed for 2 days (10/11/2019 and 10/12/2019) of 2 years of documents reviewed, the laboratory did not perform and document the positive immunohematology Rh quality control before patient testing as follows: a. 10/11/2019 - no documentation of the positive Rh control, no patient testing performed b. 10/12 /2019 - no documentation of the positive Rh control, 4 patients were tested 2. A interview on 2/17/2021 at approximately 12:45 pm, the LD confirmed the Rh positive control was not performed and documented. *** Repeat Deficiency from the 5/22 /2018 survey***
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to document corrective action for improper storage of the ALBA clone Anti-D blend immunohematology Rh group reagent for 5 months (March - June 2019 and February 2020) of 2 years of records reviewed. Findings include: 1. A record review of the "Daily Laboratory Checklist" revealed for 5 months (March - June 2019 and February 2020) of 2 years of records reviewed the refrigerator that stored the ALBA clone Anti-D immunohematology Rh group reagent the temperature was outside of the stated range of 35.6 - 46.4 on specific days with no corrective action taken or no temperature taken on that day as follows: a. 3/16/2019 -

	temperature 35 b. 3/19/2019 - temperature 34 c. 4/17/2019 - temperature 35 d. 4/20 /2019 - temperature 35 e. 4/23/2019 - temperature 34 f. 4/24/2019 - temperature 34 g. 4/25/2019 - temperature 30 h. 4/26/2019 - temperature 32 i. 4/27/2019 - temperature 32 j. 4/30/2019 - temperature 34 k. 5/2/2019 - temperature 35 l. 5/4/2019 - temperature 34 m. 5/7/2019 - temperature 34 n. 5/8/2019 - temperature 34 o. 5/9/2019 - temperature 34 p. 5/10/2019 - temperature 35 q. 5/16/2019 - temperature 34 r. 5/18 /2019 - temperature 34 s. 5/21/2019 - temperature 35 t. 5/22/2019 - temperature 35 u. 5 /23/2019 - temperature 35 v. 5/24/2019 - temperature 34 w. 5/30/2019 - temperature 35 x. 5/31/2019 - temperature 35 y. 6/1/2019 - temperature 35 z. 6/5/2019 - temperature 33 aa. 2/12-14/2020 and 2/19-21/2020 - marked "NA" bb. 2/15/2020 and 2/18/2020 - no documentation 2. A interview on 2/17/2021 at 12:05 pm, the LD confirmed that no corrective action was taken for the temperatures outside the stated range.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the Technical Consultant (TC) failed to evaluate the competency of testing personnel performing the immunohematology Rh testing for 8 (TP1 - TP5, TP7-8, and TP11) of 12 testing personnel listed on the CMS-209 form. Findings include: 1. A record review revealed the policy "Personnel Competency Policy/Procedure" states "The director is responsible for ensuring that the testing personnel have completed proper training and that the training is documented and reviewed by him/her. The director may delegate this responsibility to the technical consultant (moderately complex labs)." 2. A record review of testing personnel competency assessments revealed competencies were assessed by a "Evaluator" for 8 (TP1 - TP5, TP7-8, and TP11) of 12 testing personnel assessments. The "Evaluator" is TP11 and TP12 from the CMS-209 who do not qualify as a Technical Consultant to perform competency assessments as follows: a. TP1 assessed by TP11. assessment dates of 10/10/2019 and 10/20/2020 b. TP2 assessed by TP11, assessment dates of 14/29/2019, 7/2020, and 2/2021 c. TP3 assessed by TP11, assessment date of 1/26/2021 d. TP4 assessed by TP11, assessment dates of 10/10/2019, 3/19/2020, and 8/14/2020 e. TP5 assessed by TP11, assessment dates of 7/29/2020 and 9/23/2020 f. TP6 assessed by TP11, assessment dates of 8/22 /2019, 11/19/2019, and 4/20/2020 g. TP7 assessed by TP11, assessment date of 1/26 /2021 h. TP8 assessed by TP11, assessment dates of 6/13/2020 and 8/26/2020 i. TP9 assessed by TP11, assessment dates of 9/2/2020 and 1/6/2021 j. TP10 assessed by TP11, assessment dates of 3/2/2020 and 9/2/2020 k. TP11 assessed by TP12, assessment dates of 6/13/2019 and 6/2020 l. TP12 is not performing laboratory testing 3. A interview on 2/17/2021 at 10:07 am, the LD confirmed the "Evaluator" was not qualified to perform competency assessments.