STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23D0978663	A. BUILDING _____ B. WING _____	06/03/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCOTSDALE WOMENS CENTER/SWC-DETROIT	19305 W 7 MILE ROAD DETROIT, MI 48219

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of the Proficiency Testing (PT) data report (CASPER Report 155) and review of the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in immunohematology	D2016		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 08/25/2020

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D2016	Continued From page 1 analyte D (Rho) typing. The laboratory had unsatisfactory scores for the 3rd event 2017, 1st event 2018, 3rd event 2019, and the 1st event 2020. See D2163	D2016		
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on record review of the Proficiency Testing (PT) data report (CASPER Report 155) and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the analyte D (Rho) typing which has sustained a subsequent occurrence of unsuccessful participation in the speciality of immunohematology. Findings include: D (Rho) typing PT Event — Score 3rd event 2017 — 0% 1st event 2018 — 0% 3rd event 2019 — 80% 1st event 2020 — 0%	D2163		

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D5407 510M	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."	D5407		3/12/21
D5417 510M	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	D5417		3/12/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/18/2021

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D5417	Continued From page 1 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.	D5417		
D5445 510M	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.	D5445		3/12/21

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D5445	Continued From page 2 (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***	D5445		
D5785 510M	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),	D5785		3/12/21

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D5785	Continued From page 3 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	D5785		

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D5785	Continued From page 4 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.	D5785		
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	D6046		4/10/21

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D6046	Continued From page 5 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	D6046		

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D6046	Continued From page 6 perform competency assessments.	D6046		

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{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	{D6046}		

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{D6046}	Continued From page 1 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.	{D6046}		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

POST-CERTIFICATION REVISIT REPORT

PROVIDER / SUPPLIER / CLIA / IDENTIFICATION NUMBER	MULTIPLE CONSTRUCTION	DATE OF REVISIT
23D0978663 Y1	A. Building B. Wing Y2	3/18/2021 Y3

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE
SCOTSDALE WOMENS CENTER/SWC-DETROIT	19305 W 7 MILE ROAD DETROIT, MI 48219

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction, that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

ITEM Y4	DATE Y5	ITEM Y4	DATE Y5	ITEM Y4	DATE Y5
ID Prefix D5407	Correction	ID Prefix D5417	Correction	ID Prefix D5445	Correction
Reg. # 493.1251(d)	Completed	Reg. # 493.1252(d)	Completed	Reg. # 493.1256(d)(1)(2)(g)	Completed
LSC	03/12/2021	LSC	03/12/2021	LSC	03/12/2021
ID Prefix D5785	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. # 493.1282(b)(3)	Completed	Reg. #	Completed	Reg. #	Completed
LSC	03/12/2021	LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	
ID Prefix	Correction	ID Prefix	Correction	ID Prefix	Correction
Reg. #	Completed	Reg. #	Completed	Reg. #	Completed
LSC		LSC		LSC	

REVIEWED BY STATE AGENCY ☐	REVIEWED BY (INITIALS)	DATE	SIGNATURE OF SURVEYOR	DATE
REVIEWED BY CMS RO ☐	REVIEWED BY (INITIALS)	DATE	TITLE	DATE

FOLLOWUP TO SURVEY COMPLETED ON	CHECK FOR ANY UNCORRECTED DEFICIENCIES. WAS A SUMMARY OF UNCORRECTED DEFICIENCIES (CMS-2567) SENT TO THE FACILITY?
2/24/2021	☐ YES ☐ NO