STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	23D0369410	A. BUILDING _____ B. WING _____	02/18/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF MICHIGAN	3100 PROFESSIONAL DRIVE ANN ARBOR, MI 48104

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D5413 510M	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Quality, Risk and Compliance, the laboratory failed to monitor and document the room temperature and refrigerator each day of clinic operation for 4 (Ann Arbor, Marquette, Petoskey, and Traverse City) of 5 locations reviewed for 2 years (February 2019 to February 2021). Findings include: 1. A review of the laboratory's "Controls" procedure revealed the lack of a policy for the monitoring of laboratory room temperature and a disconnect between the "Vaccine Refrigerator Temperature Log" and the "Non-Vaccine Refrigerator Temperature Log" for documenting room temperature. 2. A record review of the laboratory's temperature monitoring log "Vaccine Refrigerator Temperature	D5413		3/5/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/09/2021

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D5413	Continued From page 1 Log" and "Non-Vaccine Refrigerator Temperature Log - 2020" revealed for 4 (Ann Arbor, Marquette, Petoskey, and Traverse City) of 5 locations a lack of documentation of the room temperature and/or refrigerator on the days as follow: a. Ann Arbor 1. Room temperature - 11/6/2019, 1/8/2020, 10/20/2020, and 1/15/2021 2. Refrigerator + room temperature - 7/12/2019 and 2/2/2021 b. Marquette 1. Room temperature - 12/5/2019 2. Refrigerator - 4/13/2020 3. Refrigerator + room temperature - 9/19/2019 and 7/19/2019 c. Petoskey 1. Room temperature - 3/2/2020 2. Refrigerator - 7/9/2020 d. Traverse City 1. Room temperature - 2/6/2019, 7/31/2019, and 9/11/2019 3. A interview on 2/18/2021 at approximately 4:00 pm, the Director of Quality, Risk and Compliance confirmed the laboratory did not record the laboratory room temperature and refrigerator each day of clinic operation.	D5413		
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	D5445		3/6/21

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D5445	Continued From page 2 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 Director of Quality, Risk and Compliance, the laboratory failed to ensure the immunohematology Rh quality control was performed and documented before patient testing for 4 (chart #1 - #4) of 9 patient charts reviewed for the Traverse City location. Findings include: 1. A record review for 4 (chart #1 - #4) of 9 patient charts reviewed revealed the laboratory did not perform and document the immunohematology Rh quality control before patient testing as follows: a. chart #1 on 2/6/2019 b. chart #2 on 2/19/2020 c. chart #3 on 7/31/2019 d. chart #4 on 9/11/2019 2. When queried on 2/10/2021 via email, the Director of Quality, Risk and Compliance returned an email on 2/13/2021 at 1:38 pm revealed "it looks like they weren't doing it right at that time." 3. During the exit interview on 2/18/2021 at approximately 4:00 pm, the Director of Quality, Risk and Compliance confirmed the location was testing the controls but did not document on the	D5445		

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D5445	Continued From page 3 "Rh Lab Log."	D5445		
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 Director of Quality, Risk and Compliance, the Technical Consultant failed to evaluate the competency of testing personnel performing the immunohematology Rh testing for 2 (Testing Personnel [TP] #14 and #16) of 21 TP listed on a spreadsheet provided by Planned Parenthood of Michigan. Findings include: 1. A review of records received on 2/10/2021 at 1:48 pm labeled "Rh Competencies 2019-2021" revealed lack of documentation of competency assessments for 2 (TP #14 and #16) of 21 TP listed on a spreadsheet as follows: a. TP #14 - no 2020 annual assessment b. TP #16 - no semi-annual assessment from 2020 2. An interview on 2/18/2021 at approximately 4:00 pm, the Director of Quality, Risk and Compliance stated "she felt all competencies had been completed."	D6046		3/6/21
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of	D6063		3/30/21

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D6063	Continued From page 4 individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Director of Quality, Risk, and Compliance, the laboratory failed to ensure the testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified to perform moderately complex immunohematology Rh testing. Refer to D6065.	D6063		
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the	D6065		3/30/21

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D6065	Continued From page 5 military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a review of records and lack of documentation provided by the Director of Quality, Risk and Compliance, the laboratory failed to ensure testing personnel were qualified to perform moderately complex immunohematology Rh testing for 1 (Testing Personnel (TP) #4) of 9 testing personnel listed on the laboratory's CMS-209 form for the Ann Arbor location. Findings include: 1. The surveyor requested qualification credentials and documentation for all staff listed on the CMS-209 for each location (Ann Arbor, Marquette, Traverse City, Petoskey, and Warren) showing they were qualified for moderately complex immunnohematology Rh testing on 2/03/2021 at approximately 10:30 am. 2. A record review of personnel records submitted to the surveyor from the Director of Quality, Risk and Compliance on 2/09/2021 at approximately 3:35 pm revealed lack of documentation of the US Equivalency for 1 (TP #4) of 9 TP at the Ann Arbor location. 3. The laboratory was provided 7 days to supply documentation and it was not made available to the surveyor. 4. An email conversation with the Director of Quality, Risk and Compliance on 2/16/2021 at 1:00 pm, the surveyor informed the Director that the documentation presented was a translation	D6065		

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D6065	Continued From page 6 and not a US Equivalency.	D6065		

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{D6063}	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Director of Quality, Risk, and Compliance, the laboratory failed to ensure the testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified to perform moderately complex immunohematology Rh testing. Refer to D6065.	{D6063}		
{D6065}	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official	{D6065}		

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

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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{D6065}	Continued From page 1 military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a review of records and lack of documentation provided by the Director of Quality, Risk and Compliance, the laboratory failed to ensure testing personnel were qualified to perform moderately complex immunohematology Rh testing for 1 (Testing Personnel (TP) #4) of 9 testing personnel listed on the laboratory's CMS-209 form for the Ann Arbor location. Findings include: 1. The surveyor requested qualification credentials and documentation for all staff listed on the CMS-209 for each location (Ann Arbor, Marquette, Traverse City, Petoskey, and Warren) showing they were qualified for moderately complex immunnohematology Rh testing on 2/03/2021 at approximately 10:30 am. 2. A record review of personnel records submitted to the surveyor from the Director of Quality, Risk and Compliance on 2/09/2021 at approximately 3:35 pm revealed lack of documentation of the US Equivalency for 1 (TP #4) of 9 TP at the Ann Arbor location. 3. The laboratory was provided 7 days to supply documentation and it was not made available to the surveyor. 4. An email conversation with the Director of Quality, Risk and Compliance on 2/16/2021 at	{D6065}		

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{D6065}	Continued From page 2 1:00 pm, the surveyor informed the Director that the documentation presented was a translation and not a US Equivalency.	{D6065}		