

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0369410	(X3) Date Survey Completed 02/18/2021
Name of Provider or Supplier Planned Parenthood Of Michigan	Street Address, City, State 3100 Professional Drive, Ann Arbor, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>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 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</p>

	<p>Quality, Risk and Compliance confirmed the laboratory did not record the laboratory room temperature and refrigerator each day of clinic operation.</p>
<p>D5445</p>	<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 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 "Rh Lab Log."</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>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."</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL</p>

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.

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 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 immunohematology 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 and not a US Equivalency.