

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0369410	(X3) Date Survey Completed 03/11/2024
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Quality and Director of Risk and Compliance, the laboratory failed to maintain records of proficiency testing attestation statements showing proficiency testing samples were tested in the same manner as patient samples for 5 (2022 events 1 and 2, 2023 events 1, 2, and 3) of 6 testing events reviewed. Findings include: 1. A review of the laboratory's "Proficiency" policy revealed a section stating, "Health Center Manager receives test event samples. To coordinate testing HCM must: a. Monitor to ensure that scheduled shipments have arrived. b. Notify the Director of QRC if the samples have not been received with 5 days of the expected ship date. c. Notify DPCO and Directors of QRC if material is incomplete or damaged. d. Ensure that samples are stored in the refrigerator until testing begins. e. Complete of the API Proficiency Testing (PT) survey. f. Assign competent staff to complete PT event testing. g. Ensure that the samples are tested within the laboratory ' s regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory ' s routine methods. Document the testing of PT samples on the Lab Log. The personnel testing</p>

the samples and the Laboratory Director must be able attest to the routine integration of the samples into the patient workload using the laboratory ' s routine methods." 2. A review of the laboratory's proficiency testing records revealed a lack of signed attestation statement for 2022 events 1 and 2, 2023 events 1, 2, and 3. 3. An interview on 3/11/24 at 1:42 pm with the Director of Quality and Director of Risk and Compliance confirmed the laboratory did not maintain a signed attestation statement for 2022 events 1 and 2 and 2023 events 1, 2, and 3.

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 record review and interviews, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the immunohematology specialty analyte D (Rho) typing. Findings include: The laboratory failed to participate in 3 (2022 events 1 and 3, 2023 event 3) of 6 proficiency testing events. Refer to D2155.

D2155

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Director of Quality and Director of Risk and Compliance, the laboratory failed to participate in 3 (2022 events 1 and 3,

2023 event 3) of 6 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) Proficiency Testing records revealed proficiency testing results were not reported to API for 2022 events 1 and 3, 2023 event 3 for the immunohematology specialty analyte D (Rho) typing. 2. A review of the laboratory's "Proficiency" policies revealed a section stating, "The Director Quality and Director of Risk and Compliance work with API to enroll locations in annual PT test events and ensure samples are sent to PPMI laboratories. The Director of Quality also monitors results received from laboratories, ensures results are entered into API and collaborates with Laboratory Director for any testing or proficiency concerns." and "Health Center Manager receives test event samples. To coordinate testing HCM must: a. Monitor to ensure that scheduled shipments have arrived. b. Notify the Director of QRC if the samples have not been received with 5 days of the expected ship date. c. Notify DPCO and Directors of QRC if material is incomplete or damaged. d. Ensure that samples are stored in the refrigerator until testing begins. e. Complete of the API Proficiency Testing (PT) survey. f. Assign competent staff to complete PT event testing. g. Ensure that the samples are tested within the laboratory 's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory 's routine methods. Document the testing of PT samples on the Lab Log. The personnel testing the samples and the Laboratory Director must be able attest to the routine integration of the samples into the patient workload using the laboratory 's routine methods. h. Ensure that tests will be performed without consultation from any personnel. i. Review the results with the person who performed the proficiency test. j. Ensure that results are entered into the API website by the deadline. k. The HCM, testing personnel and Lab Director must sign the completed Result form and Comparative Evaluation. l. All paperwork from API must be saved this includes shipping labels, kit folder, result form, attestation statement, comparative evaluation, proficiency testing performance evaluation and performance summary. Annual API Certificate. m. External proficiency test results will be maintained and kept with the records from the same calendar year." 3. An interview on 3/11/24 at 2:37 pm with the Director of Quality and Director of Risk and Compliance confirmed the laboratory had not participated in 2022 events 1 and 3, 2023 event 3 for the immunohematology specialty analyte D (Rho) typing.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:
 . Based on observation, record review, and interview with the Director of Quality, the laboratory failed to follow written policies to ensure positive identification of 2 of 2 urine specimens observed. Findings include: 1. The surveyor observed two urine specimens in the laboratory on 3/11/24 at 1:05 pm labeled with initials and dates of birth. 2. A review of the laboratory's "Urine Test" policy revealed a section stating, "Label empty urine cup with 2 identifiers (ie. name and dob, no initials), date and time." 3. An interview on 3/11/24 at 1:09 pm with the Director of Quality confirmed the urine cups were labeled only with the initials and dates of birth.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interviews, the Laboratory Director failed to ensure proficiency testing samples were tested in the same manner as patients (refer to D6016), failed to ensure the laboratory reported proficiency testing results to the proficiency testing program (refer to D6017), failed to ensure proficiency testing reports received were reviewed by staff to identify problems requiring corrective action (refer to D6018), and failed to ensure quality assessment programs were maintained (refer to D6021).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure proficiency testing samples were tested in the same manner as patients. Refer to D2015.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure the laboratory reported proficiency testing results to the proficiency testing program. Refer to D2155.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Quality and Director of Risk and Compliance, the Laboratory Director failed to ensure proficiency testing reports received were reviewed by staff to identify problems requiring corrective action for 5 (2022 events 1, 2, and 3, 2023 events 1 and 2) of 6 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "Proficiency" policy revealed a section stating, "Health Center manager received test event samples. To coordinate testing HCM must: k. The HCM, testing personnel and Lab Director must sign the completed Result form and Comparative Evaluation. l. All paperwork from API must be saved this includes shipping labels, kit folder, result form, attestation statement, comparative evaluation, proficiency testing performance evaluation and performance summary. Annual API Certificate. m. External proficiency test results will be maintained and kept with the records from the same calendar year." 2. A review of the laboratory's proficiency testing records revealed a lack of Laboratory Director and testing personnel documented reviews for 2022 events 1, 2, and 3, 2023 events 1 and 2. 3. An interview on 3/11/24 at 1:42 pm with the Director of Quality and Director of Risk and Compliance confirmed the laboratory did not have documentation showing the Laboratory Director or the testing personnel reviewed the proficiency testing events listed above.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Director of Quality and Director of Risk and Compliance, the Laboratory Director failed to ensure quality assessment programs were maintained for 1 (2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Assessment Plan" revealed a section stating, "Annually, a QRC Plan is developed, and includes a QRC calendar. The plan and calendar outline and schedule regular quality, risk and compliance activities. The plan and calendar also include mitigation plans that may be developed as a result of annual risk assessment." 2. The surveyor requested the annual quality assessment documentation for 2022 on 3/11/24 at 4:18 pm for the Marquette, MI location and it was not made available. 3. An interview on 3/11/24 at 4:18 pm with the Director of Quality and Director of Risk and Compliance confirmed the documentation for the annual quality assessment plan in 2022 for the Marquette, MI location was not available.