

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0209076	(X3) Date Survey Completed 09/14/2023
Name of Provider or Supplier Planned Parenthood Of Metropolitan	Street Address, City, State 1225 4th Street, Ne, Washington, DC	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, laboratory personnel failed to maintain attestations needed to ensure PT was performed in the same manner as patient testing. Findings: Repeat Deficiency 1. The laboratory performs Red Cell RH, HIV and KOH testing. 2. The LD and the testing personnel failed to review and sign the PT attestation for the API 2022 3rd event Hematology/Coagulation. 3. The laboratory director (LD) failed to review and sign the PT attestation for the API 2023 2nd event Hematology/Coagulation. 4. The LD failed to review and sign the PT attestation for the API 2022 1st event Hematology /Coagulation. 5. The practice manager confirmed on the day of the survey at 1:00 PM that lab personnel failed to maintain attestations needed to ensure PT was performed in the same manner as patient testing.</p>
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</p>

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.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records and interview with the practice manager, the laboratory failed to maintain all documents and records acquired during the 2023 and 2022 PT testing events for Hematology/Coagulation. Findings: Repeat Deficiency 1. The laboratory performs Red Cell RH, HIV and KOH testing. 2. The lab failed to maintain PT raw data for the API 1st and 2nd event 2023 Hematology /Coagulation. 3. The lab failed to maintain PT raw data for the API 2nd and 3rd event 2022 Hematology/Coagulation. 4. The practice manager confirmed on the day of the survey at 1:00 PM that the lab did not maintain all documents and records acquired during the 2023 and 2022 PT testing events for Red Cell RH, HIV, and KOH testing.

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 proficiency testing records and interview with the practice manager, The laboratory director failed to ensure that PT was returned to the PT agency in time for grading and resulted in a score of "0" for the testing event (refer to D2043).

D2043

MYCOLOGY
CFR(s): 493.827(c)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records and interview with the practice

	<p>manager, The laboratory director (LD) failed to ensure that PT was returned to the PT agency in time for grading and resulted in a score of "0" for the testing event. Findings: 1.The laboratory performs KOH testing. 2. The lab failed to return the API 2nd event PT 2022 KOH testing in the time required by the PT agency. 3. The practice manager stated that the API 2nd event PT 2022 KOH testing was not performed. 4. The practice manager confirmed on the day of the survey at 1:00 PM that the LD failed to ensure that PT was returned to the PT agency in time for grading and resulted in a score of "0" for the testing event.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director failed to ensure that PT was returned to the PT agency in time for grading and resulted in a score of "0" for the API 2nd event PT 2022 KOH (refer to D6017); failed to review and evaluate PT performance (refer to D6018); and failed to ensure that approved corrective action procedures were performed when the lab failed to returned PT results in time for grading and resulted in a score of "0" for the API 2nd event PT 2022 KOH (refer to D6019).</p>
<p>D6017</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director failed to ensure that PT was returned to the PT agency in time for grading and resulted in a score of "0" for the API 2nd event PT 2022 KOH. Findings: Refer to D2043</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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;</p>

	<p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director (LD) failed to review and evaluate PT performance. Findings: Repeat Deficiency 1. The laboratory performs Red Cell RH, HIV and KOH testing. 2. The LD failed to review and evaluate PT performance for the API 2023 2nd event hematology/coagulation. 3. The LD failed to review and evaluate PT performance for the API 2023 1st event hematology/coagulation. 4. The LD failed to review and evaluate PT performance for the API 2022 2nd and 3rd event hematology /coagulation. 5. The practice manager confirmed on the day of the survey at 1:00 PM that the LD failed to review and evaluate PT performance.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the practice manager, The laboratory director failed to ensure that approved corrective action procedures were performed when the lab failed to returned PT results in time for grading and resulted in a score of "0" for the API 2nd event PT 2022 KOH. Findings: Repeat deficiency, Refer to D2043</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of training records, educational records, and interview with the practice manager, the technical consultant failed to ensure that all laboratory testing personnel recieved the appropriate education to perform moderate complex testing (refer D6045); failed to ensure that all testing personnel were trained and competent to perform patient Red Cell RH testing historical data look back(refer to D6046); failed to perform competency assessments of problem solving skills of testing personnel (refer to D6052);failed to perform semiannual competency checks for all laboratory testing personnel (refer to D6053); and failed to perform annual competency checks for all laboratory testing personnel (refer to D6054).</p>
<p>D6045</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p>

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on review of training records, educational records, and interview with the practice manager, the technical consultant (TC) failed to ensure that all laboratory testing personnel (TP) received the appropriate education to perform moderate complex testing. Findings: 1. The laboratory performs red cell Rh, HIV, KOH and wet prep testing. 2. Since the last survey performed in the year 2021 the lab hired twelve TP to perform moderate complex laboratory testing. 3. During the survey the practice manager failed to provide documentation of education for the twelve TP. 4. The practice manager confirmed during the time of the survey at 1:30 PM that the TC failed to ensure that all laboratory testing personnel had the appropriate education to perform moderate complex testing.

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 review of training records, interview with the practice manager, and the nurse practitioner (NP), the technical consultant (TC) failed to ensure that all testing personnel (TP) were trained and competent to perform patient Red Cell RH testing historical data look back. Findings: 1. The laboratory performs Red Cell RH testing. 2. The TC failed to ensure that TP reviewed and attested that they read procedures on how to perform a historical data look back prior to rechecking the patient RH on revisit to the facility. 3. The NP stated that if the patient has been to the facility before and RH testing was performed the patient did not need to be retested. TP are supposed to check the patient information for previous RH testing. 4. The NP stated that TP must sign an attestation that they have read and understand the standards and guidelines for performing the patient historical data look back. 5. The NP confirmed on the day of the survey at 1:30 PM that the TC failed to ensure that all TP were trained and competent to perform patient Red Cell RH testing historical data look back.

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of training records and interview with the practice manager, the technical consultant (TC) failed to perform competency assessments of problem solving skills of testing personnel (TP). Findings: 1. The laboratory performs Red Cell

	<p>Rh and HIV testing. 2. Review of training records failed to show that the TC performed an assessment of the TP problem solving skills when performing Red Cell Rh and HIV testing. 3. The practice manager confirmed on the day of the survey ay 1:30 PM that the TC failed to perform competency assessments of TP problem solving skills when performing Red Cell Rh and HIV testing.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of training records and interview with the practice manager, the technical consultant (TC) failed to perform semiannual competency checks for all laboratory testing personnel (TP). Findings: 1.The laboratory performs red cell Rh and HIV testing. 2. The TC failed to perform semiannual competency checks for three out of the twelve TP hired since the last survey performed in the year 2021. 3. The practice manager confirmed on the day of the survey at 1:30 PM that the TC failed to perform semiannual competency checks for three out of the twelve TP hired since the last survey performed in the year 2021.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of training records and interview with the practice manager, the technical consultant (TC) failed to perform annual competency checks for all laboratory testing personnel (TP). Findings: 1.The laboratory performs red cell Rh and HIV testing. 2. The TC failed to perform annual competency checks for one out of the twelve TP hired since the last survey performed in the year 2021. 3. The practice manager confirmed on the day of the survey at 1:30 PM that the TC failed to perform annual competency checks for one out of the twelve TP hired since the last survey performed in the year 2021.</p>