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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0969008 | (X3) Date Survey Completed 01/23/2024 |
| Name of Provider or Supplier Planned Parenthood Of Pasadena | Street Address, City, State 1045 N Lake Ave, Pasadena, CA | |
| 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 |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of competency assessment documentation and interview with the office manager (OM) on the day of the survey, January 24, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the technical consultant (TC) and testing personnel (TP) competency for the years 2022 and 2023. Findings include: 1. The laboratory failed to provide documentation of competency assessment for six (6) out of eight (8) randomly selected patients' results reviewed on 01/24/2024. 2. This deficient practice stated in 1 was affirmed by interview with the OM on 1/24/2024, at approximately 12:15 p.m. 3. The laboratory reported to process and report 8,277 tests annually.</p> |
| D5441 | <p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system</p> |

performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory quality control (QC) records, randomly chosen patients' mycology and parasitology tests results, lack of QC documentation, and interview with the office manager (OM) and compliance officer (CO); it was determined that the laboratory failed to establish and perform quality control procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the correction and documentation of those QC performed in mycology and parasitology examinations. 1. On the day of the survey January 24, 2024, at approximately 12:00 p.m., the surveyor observed that QC was not performed for all of three (3) out of three (3) patients' records reviewed for mycology and parasitology. In addition, patients' samples were examined, and results were reported despite of lack of QC performed. 2. The OM and CO confirmed on January 24, 2024, that the laboratory lacked an established policy and procedure for QC and documentation for mycology and parasitology. 3. According to the annual test volume declared and signed by the laboratory LD on January 23, 2024, the laboratory performs approximately 8,002 mycology and parasitology tests annually.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory records, and interview with the office manager; it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: See D5209, D5441, and D6053.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on review of randomly chosen competency assessment records and the lack of

documentation for competency assessments for the years 2022 and 2023, and interview with the office manager and compliance officer; it was determined that the laboratory's technical consultant failed to perform and document the performance of individuals responsible for moderate complexity testing annually the individual tests for patient specimens. (See D5209).