

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0569189	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Planned Parenthood	Street Address, City, State 2017 First Ave, Ste 100, San Diego, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour of reagent materials used in the laboratory and interviews with the laboratory personnel (LP); it was determined that the laboratory failed to label various reagents used for test performance to indicate the reagent's received date, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on August 15, 2024, at approximately 2:30 pm.; no received date, opening, preparation, or expiration date labels were used or documented for all test reagents used for potassium hydroxide (KOH) and 6.5 % NaCL (saline) solution used for mycology and parasitology microscopic preparations from direct specimens. 2. The laboratory's LP affirmed in an interview conducted on August 15, 2024, at approximately 2:45 p.m. that the reagents KOH and saline solutions used in the laboratory were not labeled with the received date, opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 52,182 mycology and parasitology patients' specimens for which testing reagents were not labelled.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the surveyors' observation during the laboratory tour and interviews with the laboratory's personnel (LP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for small equipment used in the laboratory. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The LP confirmed on August 15, 2024, at approximately 4:30 p.m. that the laboratory failed to follow SOP for maintenance and calibration of timers for time dependent diagnostic tests used in the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/25/2024 stated that the laboratory performed 53,797 tests, annually.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review and the lack of documentation of Quality Control (QC) performance for mycology procedure of potassium hydroxide (KOH) test and parasitology saline preparation for microscopic examination and interview with the laboratory personnel (LP), it was determined that the laboratory failed for each qualitative procedure, include a negative and positive control materials; the laboratory must document all control procedures performed. The findings included: 1. The laboratory lack the documentation and performances at least once per day patients' specimens are assayed or examined include negative and positive control materials for KOH and saline preparations. 2. For two (2) out of two (2) randomly selected patient samples result reviewed (8/22/2022 and 3/15/2023) for KOH and saline preps; the laboratory analyzed and reported mycology and parasitology microscopic tests without performing QC. 3. The LP affirmed on August 15, 2024, at approximately 4:00 p.m. that the laboratory did not include negative and positive control materials for the above tests.

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:
The laboratory director is herein cited for deficient practice in overall administration of the laboratory to ensure that reagents are labeled with expiration and opening date, preventive maintenance of small equipment such as timers is performed as indicated by the manufacturer, and that the frequency of testing of Quality Control materials for KOH and saline preparations for microscopic examination are established. See D5415, D5429, and D5449.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
The laboratory director is herein cited for deficient practice in overall administration of the laboratory to ensure that the frequency of testing of Quality Control materials for KOH and saline preparations for microscopic examinations in mycology and parasitology subspecialties are established. See D5449.