

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0666696	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Planned Parenthood	Street Address, City, State 700 S Tustin St, Orange, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: . Based on observation of the EldonCard Rh Typing test system and the Microscope, review of 2021-2023 API (American Proficiency Institute) proficiency test (PT) reports, the lack of laboratory testing records, and interview with a laboratory administrative person, it was determined the laboratory failed to have the PT samples tested by personnel routinely testing patients. Findings included: 1. The document CMS209, Laboratory Personnel Report (CLIA), 3/13/24, named seven persons performing the Rh Typing test and Wet Mount/ KOH test. 2. The laboratory failed to provide for review test records for PT samples for all events in 2021-2023. 3. The laboratory administrative person affirmed (3/14/24 at 10:00 AM) the laboratory didn't use API's forms or any records when testing PT samples and that Rh Typing controls were routinely tested by the same person; and thus, the laboratory failed to have the PT samples tested by personnel routinely testing patients specimen. 4. The reliability and quality of patients' results could not be assured when the laboratory failed to integrate PT samples into the regular workload for testing. The laboratory annually reported 2,532 Rh Typing results and 54,823 Wet Mount/KOH results (CLIA Application, 3/13/24). .</p>
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</p>

laboratory's routine methods.

This STANDARD is not met as evidenced by:

. Based on the lack of laboratory proficiency testing Attestation documents for Rh Typing and Wet Mount/KOH for all events in 2021 - 2023, and interview with the laboratory administrative person, it was determined the Laboratory Director and Testing Person for each event failed to attest to the routine testing of the PT samples with the regular workload. Findings included: 1. The laboratory failed to provide for review 2021-2023 Attestation documents signed by the Laboratory Director and the Testing Person for Rh Typing and Wet Mount/KOH. 2. The reliability of the laboratory to incorporate PT samples into the patient workload could not be assured in the absence of Attestation Statements signed by the Laboratory Director and Testing Person. .

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(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.

This STANDARD is not met as evidenced by:

. Based on review of 2021-2023 API proficiency testing reports, the lack of laboratory proficiency testing records, and interview with the laboratory administrative person, it was determined the laboratory failed to document and maintain copies of all PT test records for all events for Rh Typing and Wet Mount/ KOH. Findings included: 1. The laboratory failed to provide for review: API instructions and laboratory records documenting the handling, preparing, processing, and testing of each PT sample. There were no records identifying the Testing Person performing each step in the testing and the API form for recording results was not used. See D2007. 2. The laboratory failed to provide Attestation documents for review. See D2009. 3. The laboratory failed to retain API's Data Summary to evaluate laboratory performance in each event. 4. The laboratory administrative person affirmed (3/14/24 at 12:00 PM) the aforementioned lack of records and that PT test results were relayed verbally or on a sticky note that was subsequently discarded. 5. The reliability of the laboratory to test PT samples as instructed and obtain results as reported could not be assured in the absence of the aforementioned PT records. .

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on review of 2022-2023 laboratory and API (American Proficiency Institute) proficiency testing records and patients test records; and interview with the laboratory administrative person, it was determined the laboratory failed to verify the accuracy of testing for Wet Mount and KOH. Findings included: 1. The laboratory chose to enroll in API's Hematology, Microscopy proficiency testing program as the means to fulfill the requirement to verify the accuracy of testing. API provided two samples for each event: Vaginal Wet Preparation and KOH. 2. The laboratory reported 1 Unacceptable (*) out of 2 results, as follows: a. Event 3/ 2022 PT sample: VA-03 Lab reported: No yeast, Trich or clue cells* Expected: Yeast seen b. Event 3/ 2023 PT sample: VKP-03 Lab reported: No yeast seen* Expected: Yeast seen 3. The laboratory administrative person affirmed (3/14/24 at 12:00 PM) the aforementioned findings of inaccuracy. 4. The laboratory failed to provide for review records for alternate or additional method for verifying the accuracy of performing Wet Mount/ KOH during the timeframes of the failed PT events. 5. The reliability and quality of "Yeast Negative" results reported for patients Wet Mount/ KOH could not be assured when the laboratory failed to verify the accuracy of testing. The laboratory reported 54,823 results annually (CMS116, CLIA Application, 3/13/24) or 13,708 results during the last trimester. One example selected at random for review was reported on 11/09/22 at 8:50AM. .