

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0207076	(X3) Date Survey Completed 07/27/2023
Name of Provider or Supplier Kaiser Permanente Capitol Hill Lab	Street Address, City, State 700 2nd 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
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, interview with the quality specialist (QS) and the laboratory director (LD), the lab failed to ensure that all required corrective action procedures were performed for failed PT. Findings: 1. The lab performs Bacteriology testing. 2. Gram stain results for PT Event 2022 Bacti Viral1 were Bacteriology QA 60%, Gram Stain Morphology 40%, and Gram Stain Reaction 40%. 3. LD stated on the PT Survey follow up summery "review patient results to determine if results were affected". 4. The general supervisor failed to perform a patient look back to ensure accurate and reliable patient testing when PT failed. 5. Review of the PT Survey follow up summery did not show that a look back of patient test result were performed, nor were there any patient results attached to the PT writeup. 6. The QS and the LD confirmed on the day of the survey at 2:00 PM that the lab failed to ensure that all required corrective action procedures were performed for failed PT.</p>
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p>

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records, interview with the quality specialist (QS) and the laboratory director (LD), the LD failed to ensure that all corrective action procedures were performed for PT errors. Findings: Refer to D2026

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of quality assessment records, interview with the quality specialist (QS) and the laboratory director (LD), the LD failed to ensure that all quality assessment procedures were performed when the lab failed PT. Findings: 1. The lab manager performed a quality assessment and quality control review with the LD on May 19, 2022, when the LD visited the facility. 2. The PT records were reviewed and discussed for the PT Event 2022 Bacti Viral1 failure. Bacteriology QA 60%, Gram Stain Morphology 40%, and Gram Stain Reaction 40%. 3. The LD failed to ensure that the lab manager documented and discussed PT failures during the May 2022 monthly quality management report with all lab staff and managers. 4. The LD stated at the visit that the PT teacher should be used to ensure that the lab stays on top of performing PT. 5. Review of the May 2022 monthly quality management report did not show that the PT Event 2022 Bacti Viral1 failure was discussed. 6. The QS and the LD confirmed on the day of the survey at 2:00 PM that the LD failed to ensure that the lab manager documented and discussed PT failures during monthly quality reporting with all lab staff and managers.