Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2174613	03/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Palo Alto Medical Foundation-	701 E El Camino Real, 3rd Fl, Mountain View, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on the review of the laboratory's protocol for retention of records, a total of 17 patient test records, lack of preventive maintenance (PM) records, and interviews with the office manager (OM) on March 11, 2026; it was determined that the laboratory failed to retain the PM records for the micrscopes used for testing. The findings include: 1. The laboratory's policy was to perform PM for the microscopes annually through their internal biomedical equipment department. 2. The surveyor reviewed a total of seventeen patient records that required the use of the micrscope for test performance. Sixteen out of seventeen were potentially affected due to lack of records from 8/16/2022 to 1/28/2026. The records as followed: Identifier Date of service Test 56551216 08/16/2022 KOH 23-931 12/08/2022 Mohs 23-088 01/27/2023 Mohs 56382214 02/01/2023 KOH and scabies 23-1106B 10/19/2023 Mohs 56661360 11/06 /2023 KOH 24-231 02/15/2024 Mohs 56537106 03/12/2024 KOH 24-1417 11/14 /2024 Mohs 60012805 12/06/2024 KOH and scabies 52671519 01/30/2025 scabies 25-207 03/05/2025 Mohs 25-806 09/24/2025 Mohs 67703378 11/10/2025 KOH 54770816 01/13/2026 KOH 26-050 01/28/2026 Mohs 3. During an interview on March 11, 2026, at approximately 9:30 a.m., the OM confirmed that no PM records were available for review at the time of the survey. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 150 Mycology tests, 50 Parasitology tests and 1,000 Dermatopathology cases annually including the time when the laboratory failed to retain PM records for the microscopes. .

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 laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) documentation from 2022 to 2025, lack of laboratory records, and an interview with the office manager on March 11, 2026, it was determined the laboratory failed to at least twice annually verify the accuracy of the tests performed in 2023. The findings include: 1. The surveyor reviewed the laboratory's proficiency testing documentation and found that they were enrolled with the WSLH PT program for 2022, 2024 and 2025, but missed 2023 for the Provider Performed Microscopy tests. 2. The office manager stated in an interview on March 11, 2026 at 11:50 a.m., that the laboratory was not enrolled in 2023 which was verified from an email they received from the WSLH PT program that stated "This site was actually not enrolled with WSLH PT in 2023. They were enrolled previously since at least 2018, and have been enrolled every year since 2023. It doesn't look like an order was ever placed for 2023, however, so no enrollment was processed nor samples sent". 3. Further findings included a lack of corrective action documentation for the failed enrollment in 2023 with the WSLH PT program. 4. According to the laboratory testing declaration (Lab-144) form submitted at the time of survey, the laboratory failed to comply with the CFR 493.1236(c) that stated the minimum requirement of at least twice annually, the laboratory must verify the accuracy of any test or procedure it performed. The laboratory performed approximately 150 tests for Mycology and 50 tests for Parasitology annually. .
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's reporting policy and procedure, nine randomly chosen patient test records from August 16, 2022 to March 2, 2026, and interviews with the office manager (OM) and histology technician (HT) on March 11, 2026, it was determined that two out nine reports had mismatched information and the laboratory failed to address these errors prior to finalizing reports. The findings include: 1. The surveyor reviewed nine randomly selected patient test records for potassium hydroxide (KOH) and scabies tests dated from August 16, 2022 to March 2, 2026, two out of nine had a mismatch of patient information from the patient log entry against the electronic final report record. a. Patient MRN:56551216, examined on November 16, 2023, recorded at the back area but was documented in the final report at the neck, abdomen and extremities locations. b. Patient MRN67703378, examined on November 10, 2025, was documented in the patient log at left leg but

	was reported at left foot area. 2. There was a lack of corrective action documentation for the two out of nine patient records reviewed as mentioned in statement #1. 3. During an interview on March 11, 2026, at approximately 9:30 a.m., the OM and HT confirmed that the two records with errors lacked a corrective action or an addendum. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 150 tests for Mycology and 50 tests for Parasitology annually, including the time when the discrepancy in the patient record occurred that the laboratory failed to address prior to finalizing the reports. .
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing documentation, enrollment, testing menu and interviews with the office manager and histology technician on March 11, 2026, the laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed in 2023. The findings include: 1. The laboratory failed to meet the minimum requirement of at least twice annually, the laboratory must verify the accuracy of the testing performed due to failure to enroll with the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing program in 2023. See D5217 .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 the surveyor's review of the laboratory's policy and procedure, errors in selected patient test records, lack of preventive maintenance records, and interviews with the office manager and histology technician on March 11, 2026, this deficiency in herein cited for the laboratory director due to failure to ensure that the quality system assessment records were followed and retained with the least frequency required in CFR493.1105. The findings include: 1. The laboratory failed to follow their policy to retain preventive maintenance records for the microscopes used in testing. See D3031. 2. The laboratory failed to ensure that the information matched in all their records prior to finalizing reports. See D5821.