

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2298862	(X3) Date Survey Completed 05/27/2026
Name of Provider or Supplier Linda Veneman, Md	Street Address, City, State 4343 Yellow Pine Hill, Mariposa, 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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:</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's protocol for record retention, eighteen patient test records, lack of preventive maintenance (PM) records for the microscope, and an interview with the laboratory director on May 27, 2026, it was determined that the laboratory failed to retain PM records for the microscope used in testing for at least 2 years. The findings include: 1. The laboratory's policy was to perform PM on the microscope prior to patient testing on an as-needed basis, in addition to the annual service PM provided by an external service provider wherein records will be kept for at least 2 years. 2. The surveyor reviewed a total of eighteen patient records that required the use of the microscope for test performance. All eighteen patient records had a lack of microscope PM records for the years 2024, 2025 and 2026. 3. During an interview on May 27, 2026, at approximately 10:00 a.m., the laboratory director confirmed that the laboratory lacked the microscope PM records for the years 2024, 2025 and 2026. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 3,998 cases annually including the time when the laboratory failed to retain PM records for the microscopes for at least 2 years. .</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test</p>

system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy and procedure, eighteen patient records, lack of preventive maintenance (PM) documentation, observations during the laboratory tour, an interview with the laboratory director (LD) and an email communication with the compliance manager, it was determined that the laboratory failed to ensure performed tests and function checks were documented or maintained prior to patient testing. The findings include: 1. The laboratory's policy was to perform PM on the microscope prior to patient testing on an as-needed basis, in addition to the annual service PM from an external service provider. However, no documentation was available to verify that these PM activities were performed. 2. The PM service reports provided by the laboratory was for the Olympus BX40 with SN: 3A01509. This did not match the microscope observed during the laboratory tour (Olympus BX40, SN: 8C23998), which displayed a sticker indicating the last service was performed on March 2, 2020. 3. Eighteen records were reviewed by the surveyor wherein there was a lack of corrective action documentation for the missing PM of the microscope for the years 2024, 2025 and 2026. 4. During an interview on May 27, 2026, at approximately 10:00 a.m., the LD confirmed that PM documentation was maintained by an external office and was not available at the time of the survey. 5. In an email dated June 1, 2026, at approximately 11:25 a.m., the Compliance Manager stated that the laboratory was unable to provide PM records for the microscope (Olympus BX40, SN: 8C23998) used by the LD for pathology case interpretation. 6. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 3,998 tests annually, which included the period when the PM was missed as mentioned in this deficiency.

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 survey findings, deficiencies cited, interview and email communication, this deficiency is herein cited for the laboratory director due to failure to ensure that the quality system assessment records were followed, documented and retained. 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 document the preventive maintenance of the microscope used prior to patient testing. See D5435.