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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0601323 | (X3) Date Survey Completed 03/03/2026 |
| Name of Provider or Supplier Charles Hanson Md | Street Address, City, State 1855 San Miguel Dr, Ste 15, Walnut Creek, 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 |
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| D2020 | <p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) evaluation documentation and an interview with the testing personnel (TP), it was determined that the laboratory failed to obtain an overall testing event score of at least 80 percent (%) in Bacteriology for the third event of 2023 (Q3-2023). The findings include: 1. The laboratory was enrolled in AAB-MLE PT program and received an overall unsatisfactory score of 0% for the Bacteriology subspecialty in the Q3-2023 event. 2. The TP affirmed by an interview on March 3, 2026 at approximately 9:15 a.m. that the laboratory obtained the unsatisfactory score as mentioned in statement #1. The quality and accuracy of patient testing results cannot be assured. 3. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported approximately 80 patient samples for Bacteriology including the time the laboratory obtained the unsatisfactory scores for proficiency testing. .</p> |
| D3039 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, five patient</p> |

records, preventive maintenance (PM) records, an interview with the testing personnel (TP) on March 3, 2026, it was determined that the laboratory failed to retain the quality system assessment records for at least two years. The findings include: 1. The laboratory's policy and documentation indicated that the preventive maintenance for the microscope was performed annually by Western Scientific Company, Inc. 2. The surveyor reviewed the PM records and found that the laboratory had the 2025 service record but was unable to retrieve the 2023 and 2024 documentation potentially affecting at least all five patient records reviewed. 3. The TP stated in an interview on March 3, 2026, at approximately 9:45 a.m. that the PM service records for the microscope for the years 2023 and 2024 were not located. 4. According to the laboratory testing declaration form (Lab-144) submitted on March 3, 2026, the laboratory performed and reported approximately 107 patient samples annually including the time when quality system assessment records were not properly retained for 2023 and 2024. .

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policy and procedure, ten randomly chosen patient records, lack of personnel competency documentation, and an interview with the testing personnel (TP) on March 3, 2026, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform the personnel competency assessment prior to patient testing. The findings include: 1. The laboratory had no written and approved policy for personnel competency assessment as defined in this subpart with elements specified under 493.1413 regulation. 2. The surveyor reviewed five patient records wherein the tests were performed by the TP. The laboratory lacked competency assessment records for the years 2023, 2024, and 2025 and that no corrective action documentation was available at the time of the survey. 3. The quality and reliability of patient samples processed and reported could not be assured including the five randomly chosen records reviewed. 4. The TP affirmed in an interview on March 3, 2026, at approximately 10:00 a.m. that the competency assessments for the years 2023, 2024 and 2025 were not performed. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory reported and performed approximately 107 patient samples annually, including the time when the competency assessment policy was not established and followed resulting to missing records for the years 2023, 2024 and 2025. .

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's proficiency testing documentation

and an interview with the testing personnel on March 3, 2026, this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. The findings include: 1. The laboratory obtained unsatisfactory score for the Bacteriology proficiency testing. See D2020. .

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(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 surveyors' review of the laboratory's policies and procedures, lack of quality assessment documentation, ten patient records, and an interview with the testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services. The findings include: 1. The laboratory failed to retain preventive maintenance records for the microscope for the years 2023 and 2024. See D3039. 2. The laboratory lacked personnel competency policy and documentation for the years 2023, 2024 and 2025. See D5209.