

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0706286	(X3) Date Survey Completed 08/20/2024
Name of Provider or Supplier Porterville Developmental Center	Street Address, City, State 26501 Avenue 140, Porterville, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the survey on August 20, 2024, at approximately 3:30 p.m., a review of the laboratory's policy and procedure, College of American Pathologists (CAP) proficiency testing (PT) records, and an interview with the technical supervisor (TS), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for Calcium analyte in 2023. The findings include: 1. Based on review of PT records for the first event of 2023 (Q1-2023), CAP reported an unsatisfactory score report as follow: Calcium PT Q1-2023 Overall score: 40% Specimen Reported Expected CHM-01 9.60 8.46 - 10.47 CHM-02 *3.40 4.96 - 6.97 CHM-03 *0.40 11.69 - 13.70 CHM-04 7.10 5.85 - 7.86 CHM-05 *1.70 10.90 - 12.91 2. The TS affirmed on August 20, 2024, at approximately 3:30 p.m. that the laboratory obtained PT scores mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 11,184 Routine Chemistry test samples, including Calcium analyte, during the time the laboratory had unsatisfactory proficiency testing results. Thus, the reliability and quality of the Chemistry patient results reported cannot be assured.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p>

This STANDARD is not met as evidenced by:
 Based on the survey on August 20, 2024, at approximately 3:30 p.m., review of the laboratory's policy and procedure, College of American Pathologists (CAP) proficiency testing (PT) records, and an interview with the technical supervisor (TS), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for Thyroxine (T4) analyte in 2024. The findings included: 1. Based on review of PT records for the first event of 2024 (Q1-2024), CAP reported an unsatisfactory score report as follow: T4 PT Q1-2024 Overall score: 60% Specimen Reported Expected CHM-01 5.3 4.8 - 7.4 CHM-02 5.3 5.2 - 7.9 CHM-03 13.9 12.1 - 18.3 CHM-04 *1.3 1.6 - 3.7 CHM-05 *4.4 4.5 - 6.8 2. The TS affirmed on August 20, 2024, at approximately 3:30 p.m. that the laboratory obtained PT scores mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 486 Endocrinology test samples, including 39 test samples for T4 analyte, during the time the laboratory had unsatisfactory proficiency testing results. Thus, the reliability and quality of Endocrinology patient results reported cannot be assured.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's policies and procedures, ten (10) randomly chosen patient records, and an interview with the technical supervisor (TS), it was determined that the laboratory failed to perform and document an ocular micrometer calibration. The findings included: 1. Based on the surveyor's observation during the laboratory tour and review of records documentation on August 20, 2024, at approximately 3:30 p.m., it was determined that the laboratory failed to perform an ocular calibration on the microscope used in the laboratory during the analytical phase of testing. 2. It was the practice of the laboratory to use the Nikon Eclipse 50i for manual differential count tests and the Leitz Laborlux D for urine sedimentation microscopy tests. However, no ocular calibration of the eyepiece on either one of the microscopes was found. 3. Based on the interview with the TS on August 20, 2024, at approximately 3:30 p.m., it was determined that the laboratory was not aware regarding the ocular calibration needed for testing as mentioned in statement #1. 4. According to the laboratory's testing declaration submitted at the time of the survey, the laboratory performed approximately 293 urine microscopy tests and 9 manual differential count tests annually, for which no calibration of the ocular eyepiece was found.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on the interview with the technical supervisor, observations during the laboratory tour, review of the laboratory's policies and procedure, preventive maintenance, proficiency testing (PT) records and review of ten randomly selected patient records on August 20, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the analytic, and postanalytic phases of the laboratory testing were monitored. 1. Less than 80 percent in Routine Chemistry PT results. See D2087 2. Less than 80 percent in Endocrinology PT results. See D2098 3. Missing ocular calibration of microscope. See D5429