Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0617581	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oroville Hospital Dept Of Pathology	2767 Olive Hwy, Oroville, 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
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) (a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing records, five (5) patient test record for Parathyroid hormone (from 3/5/2025- 3/5 /2026) and interview with the laboratory general supervisor (GS) and the administrative laboratory director on June 10, 2026, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses in endocrinology for 1 out of 3 proficiency testing (PT) events in 2025 for the analyte Parathyroid hormone (PTH). The findings included: 1. The laboratory enrolled in the API proficiency testing program for endocrinology testing using ORTO VITROS XT 7600. According to the API evaluation, the laboratory attained an unsatisfactory score of %0 for the analyte PTH in the third event of 2025. 2. On June 10, 2026, at approximately 10:00 am, the laboratory general supervisor confirmed that the laboratory received the above unsatisfactory scores. 3. The laboratory's testing declaration form, signed by the laboratory director on May 29, 2026, stated that the laboratory performed approximately 22,398 endocrinology tests, including 5,809 PTH tests, annually.
D2109	TOXICOLOGY CFR(s): 493.845(a) (a) 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.

	This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing records and interview with the laboratory general supervisor (GS) and the administrative laboratory director on June 10, 2026, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses in Toxicology for 1 out of 3 proficiency testing (PT) events in 2025 for the analyte Phenytoin. The findings included: 1. The laboratory enrolled in the API proficiency testing program for Toxicology testing using ORTO VITROS XT 7600. According to the API evaluation, the laboratory attained an unsatisfactory score of %60 for the analyte Phenytoin in the second event of 2025. 2. On June 10, 2026, at approximately 10:00 am, the laboratory general supervisor confirmed that the laboratory received the above unsatisfactory scores. 3. The laboratory's testing declaration form, signed by the laboratory director on May 29, 2026, stated that the laboratory performed approximately 246,083 Toxicology tests, including Phenytoin, annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of preventive maintenance (PM) records, ten (10) patient pathology test records (from 2/29/2024-2/28/2026), and interview with the laboratory general supervisor (GS) and the administrative laboratory director on June 10, 2026, the pathology laboratory failed to perform the required annual preventive maintenance for all three (3) Olympus BX43 microscopes for two (2) months in 2025 and five (5) months in 2026. The findings included: 1. The pathology laboratory utilized OLYMPUS BX43 microscope for microscopic examination of the slides for the evaluation and diagnostics interpretation in the pathology department. Scheduled preventive maintenance is required for the Olympus BX43 microscope. 2. During the survey, laboratory preventive maintenance records showed that the Olympus BX43 microscope was due for maintenance in October 2025. The laboratory did not complete the required maintenance during that period and continued to use the microscope for testing without performing the scheduled preventive maintenance. On June 11, 2026, at approximately 10:30 am, the administrative laboratory director confirmed that the microscope was still actively used for testing despite missing maintenance. 3. The laboratory's testing declaration form, signed by the laboratory director on May 29, 2026, stated that the laboratory performed approximately 10,206 pathology tests, annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of routine chemistry Quality Control (QC) record, analyzer QC range setting for five(5) selected analytes, and interviews with the laboratory Technical Supervisor (TS) and the administrative laboratory director on June 10, 2026, the laboratory failed to ensure that quality control results were evaluated using its established statistic parameter for the new QC lot for 5 analytes. The findings included: 1. The laboratory utilized MAS chemTRAK H Control, Unassayed (Tarmo Scientific) for monitoring moderate complexity routine chemistry tests conducted with the ORTO VITROS XT 7600 analyzer. The laboratory started using the new lot (lot#CHU2801) on February 1, 2026. 2. On the day of the survey, the QC range entered into the analyzer did not match the established ranges for alanine transaminase (ALT), creatinine, glucose, High-density lipoprotein (HDL) cholesterol and potassium. Glucose level 1: Instrument setting (m= 56.9& SD=2.0); calculated established range (m=56.9& SD=1.1005) Glucose level 3: Instrument setting (m= 305& SD=10.0); calculated established range (m=305& SD=4.94) Potassium level 1: Instrument setting (m=2.262& SD=0.1); calculated established range (m=2.62& SD=0. 0422) Potassium level 2: Instrument setting (m=6.1& SD=0.150); calculated established range (m=6.06& SD=0.0516) ALT level 1: Instrument setting (m=36.6& SD=1.5); calculated established range (m=35.5& SD=0.7071) ALT level 2: Instrument setting (m=211.3& SD=7); calculated established range (m=211.3& SD=2. 21) Creatinine level 1: Instrument setting (m=0.680& SD=0.05); calculated established range (m=0.612& SD=0.0092) Creatinine level 2: Instrument setting (m=7. 40& SD=0.2); calculated established range (m=7.37& SD=0.13) HDL level 1: Instrument setting (m=22.2& SD=2); calculated established range (m=24.4& SD=0. 9661) HDL level 2: Instrument setting (m=71.0& SD=3); calculated established range (m=70.1& SD=1.85) 3. On June 10, 2026, at approximately 1:30 p.m. the technical supervisor confirmed the data on the analyzer did not match the QC establishment spreadsheet that was maintained in the laboratory. 4. The laboratory's testing declaration form, signed by the laboratory director on May 29, 2026, stated that the laboratory performed approximately 3,709,875 routine chemistry tests, annually.
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 review of Quality Control (QC) records, QC range settings for analyzers, review of twenty (20) patient test reports from 11/8/2024 to 5/28/2026 in chemistry department, and interviews with the laboratory Technical Supervisor (TS) and the administrative laboratory director on June 10, 2026, the laboratory director did not ensure that the established quality control program was maintained. See D5441
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii)

	(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of preventive maintenance (PM) records, ten (10) patient pathology test records (from 2/29/2024-2/28/2026), and interview with the laboratory general supervisor (GS) and the administrative laboratory director on June 10, 2026, it was determined that the technical supervisor in pathology department failed to review preventive maintenance records for microscopes. See D5429