Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0617581	02/14/2018
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
D2109	TOXICOLOGY CFR(s): 493.845(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 review of the second quarter (Q2-2016) of the American Proficiency Institute (API) proficiency testing records, and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the therapeutic drugs. The findings included: a. Q2-2016, API reported the following unsatisfactory proficiency testing scores: Analyte: Score: Event/Year: Acetaminophen 60% 2/2016 Carbamazepine 60% 2/2016 Digoxin 60% 2 /2016 Phenobarbital 60% 2/2016 Phenytoin 60% 2/2016 Salicylates 60% 2/2016 Theophylline 60% 2/2016 Vancomycin 60% 2/2016 b The laboratory's annual test volume declaration submitted for 2016-2017 for the above analytes approximately 19,654. c. The testing personnel affirmed (2/14/2018, 10:00 AM), that the laboratory received the above unsatisfactory proficiency testing scores.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for Serofuge Calibration (2016 and 2017), the laboratory has not established and follow its written policy procedure for record retention. The findings included: a. The laboratory has no documentation to

	show for how long it will retain its records for Blood Bank b. The laboratory uses Serofuge instrument for cells washing in Blood Bank, but there was no documentation shown from years 2016 and 2017 of Serofuge Calibration performance. c. Based on the annual test volume submitted by the laboratory, there were approximately 2,523 Antibody screen and Compatibility testing analyzed and reported. d. The testing personnel affirmed (2/14/2018, 10AM), that there was no documentation to show for the years 2016 and 2017 Serofuge Calibration.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on request and the lack of documentation for date and time the laboratory receives its specimen, random patient sampling test results and interview with the testing personnel it was determined that the laboratory failed to document the date and time it receives a specimen. The findings included: a. The laboratory lacked documentation to show for its date and time it receives the specimen physically in the laboratory. b. For thirty three (33) out of thirty three random patient test results reviewed covering period from 1/1/2016 to 2/7/2018, the laboratory analyzed and reported test results for all specialties without documenting its received date and time. c. The testing personnel affirmed (2/14/2018, 10:00AM) that the laboratory has no documentation to show its date and time of specimen receipt.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Critical Laboratory Value Notification Policy #PS 020/LAB 001, approved 10/30/2012, quality assurance report for 1/10/2018 reports and interview with the testing personnel, it was determined that the laboratory did not follow its own policy regarding the panic or alert values. The Findings included: a.

	The laboratory's Critical Laboratory Value Notification Policy #PS 020/LAB 001, approved 10/30/2012, stated: "A. The Clinical Lab Scientist documentation must include: 1. The critical laboratory value. 2. The time notification was first attempted and/or the time contact was completed. 3. The reporting laboratory personnel. 4. The person notified. 5. Request and document that "read back" was done." b. For twenty three (23) out of twenty eight (28) random patient test results reviewed covering 1/10 /2018 critical calls made by the laboratory, the laboratory did not document critical calls read back. c. The testing personnel affirmed (2/14/2018, 10:00AM), that the laboratory failed to follow its policy and procedure in regards to documenting read back policy.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review and the lack of Serofuge calibration performance documents for (2016 and 2017), interview with the testing personnel, and random patient sampling test results it was determined that the laboratory failed to establish and follow written policies and procedures for the Serofuge calibration performance. The findings included: a. The laboratory's Serofuge Calibration policy and procedure stated that: " A Sorval CW-1, CW-2 cell washers and (Clay Adams fixed speed) are uses in the blood bank. Spin Time and Calibration are done by the blood bank technologist after nay maintenance. Check of the appearance on routine testing of the cell button is to be recorded periodically, but at least annually for all phases." b. During the survey (2/13-2/14/2018) there were no documentation shown for the Serofuge Calibration performances for the years 2016 and 2017. c. For six (6) out of seven (7) random patient test results reviewed for Antibody screen and Compatibility testing covering period from 11/21/2016 to 1/3/2018, the laboratory analyzed and reported Antibody screen and Compatibility testing tests without the documentation performance for the Serofuge calibration. d. The testing personnel affirmed (2/14/2018, 10AM), that there was no performance documentation to show for the years 2016 and 2017 for the Serofuge Calibration.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review and the lack of Serofuge calibration performance documents for (2016 and 2017), interview with the testing personnel, and random patient sampling test results it was determined that the laboratory failed to establish and follow written policies and procedures for the Serofuge calibration performance. See D 5439.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for post analytic system quality assessment review, and interview with the testing personnel, it was determined that the laboratory failed to review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of post analytic systems quality assessment reviews with appropriate staff. See D 5403.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review and the lack of retention documentation for its Serofuge calibration (D 3039), not following its own policy and procedure for Serofuge calibration, (D 5404), (D5439), (D5791), critical call read back policy (D 5893) specimen receipt date and time, (D5313) and interview with the testing personnel it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review and the lack of retention documentation for its Serofuge calibration (D 3039), not following its own policy and procedure for Serofuge calibration, (D 5404), (D5439), (D5791), critical call read back policy (D 5893) specimen receipt date and time, (D5313) and interview with the testing personnel it was determined that the laboratory director failed to ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.