Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0617581	02/14/2020
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of 2018 - 2019 proficiency reports from API (American Proficiency Institute), laboratory proficiency testing records for i-STAT, and laboratory reports for Blood gases and ACT (Activated Clotting Time); and interview with Laboratory Person-5, it was determined that the proficiency testing samples were not tested with the regular patient workload by personnel routinely testing at point-of-care and Interventional Radiology. Findings included: a. The i-STAT hand-held analyzers were routinely used by point-of-care nursing staff to provide Blood gas results using the Abbott G3+ cartridges and by Interventional Radiology staff to provide clotting times using the ACT-Kaolin cartridges; both classified Non-waived complexity. A few examples selected at random were as follows: Date Accession Test ---------- 7/20/18 GMRC-576785 Blood gases 1/11 /19 GMRC-632930 ACT 3/28/19 ACCHA002065 ACT 8/20/19 GMRC-711438 Blood gases b. Attestation Statements of laboratory proficiency testing records for i-STAT Blood gases and ACT Kaolin documented that all samples in 2018-2019 were tested by Testing Person-5 and Testing Person-37 in the laboratory. c. Laboratory Person-5 affirmed (1/14/20 @ 12pm) the afforementioned findings; and thus, the proficiency testing samples were not tested as required with the regular patient workload by personnel routinely performing testing at point-of-care and Interventional Radiology. d. The reliability and quality of patients' results for Blood gases and ACT could not be assured without proficiency testing by personnel

	routinely testing patients specimen. Annual test volumes were as follows: Analyte Year Volume ---------- Blood gases 2018 60 specimen " " 2019 142 specimen ACT 2018 11 tests " 2019 22 tests .
D2057	VIROLOGY CFR(s): 493.831(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of 2018 laboratory reports for HIV Ag Ab Combo, laboratory proficiency testing records, and proficiency testing evaluations from CAP (College of American Pathologists); and interview with Laboratory Person-5, it was determined that the laboratory failed to participate in Event C of 2018, testing for HIV. Findings included: a. Laboratory reports for HIV were randomly selected from 2018, as follows: Date ID- Acct ---------- 5/30/18 8579064 6/11/18 8598894 7/17/18 8661045 8/10/18 8701546 9/14/18 8761190 9/18/18 8766714 b. Laboratory proficiency testing records documented all 5 out of 5 samples were tested for HIV on 9/13/18 with acceptable QC. c. However, the CAP Evaluation revealed the laboratory reported "code 11, Unable to analyze" for HIV, for 5 out of 5 proficiency samples. d. Laboratory Person-5 affirmed (1/14/20 @ 12pm) the aforementioned findings, that the proficiency samples were tested, but results were not reported to CAP; and thus, the laboratory failed to participate in proficiency testing for HIV. e. The reliability and quality of results reported for HIV could not be assured without performing proficiency testing. The laboratory reported 3,875 results for HIV during the timeframe May - October 2018. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of PFA (Platelet Function assays) test records, the lack of laboratory documents, and interview with Testing Person-5, it was determined that the laboratory failed to at least twice annually verify the accuracy of testing in 2018 - 2020. Findings included: a. Seven test records and reports randomly selected from 2018, 2019, and 2020 were reviewed. (See D5447). b. The laboratory was unable to provide records and documents verifying the accuracy of testing in the timeframe 2018 to 2/12/20. c. Laboratory Person-5 affirmed (2/12/20 @ 2:29pm) the lack of aforementioned records; and thus the laboratory failed to at least twice annually verify the accuracy of the PFA test. d. The reliability and quality of results reported could not be assured

	when the laboratory failed to at least twice annually verify the accuracy of testing as required. Based on the laboratory's tally for 2018, the laboratory reported approximately 32 results annually for the timeframe 2018 to 2/12/20. .
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory written procedure and manufacturer's instructions for RPR, the lack of written procedure, and interview with Laboratory Person-5, it was determined that the laboratory failed to provide written procedure for titering Reactive control material. Findings included:. a. The laboratory used a commercial test kit for performing RPR. b. The manufacturer's instructions included procedure to titer reactivity, but did not specify titering Reactive control material for quality control purpose. c. The laboratory written procedure failed to include instructions for titering quality control when titering reactive specimen. d. Laboratory Person-5 affirmed (1/14 /20 @ 3pm) the aforementioned findings; and thus, the laboratory's failure to provide required written procedures not provided by the manufacturer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patients PFA (Platelet Function analysis) test records from 2018 - 2020, the lack of laboratory QC records, and interview with Laboratory Person-5, it was determined that the laboratory failed to include two control materials of different concentrations at least once each day of testing patient specimen. Findings included: a. The laboratory test for Platelet function using the Siemens PFA-100 instrument included membranes coated with Collagen and Epinephrine (EPI) followed by membranes coated with Collagen and ADP (Adenosine diphosphate). Records selected at random were as follows: Date ID Tests reported ---------- 7/24/18 T350278 PFA Collagen/ EPI 8/27/18 M372779 PFA Collagen / EPI 10/30/18 T380361 PFA Collagen / EPI (continued) 1/13/19 X454111 PFA Collagen / EPI 5/13/19 M460341 PFA Collagen / EPI and " " PFA Collagen / ADP 6/28/19 F373922 PFA Collagen / EPI 1/02/20 H472290 PFA Collagen / EPI b. Laboratory QC records documented that No control materials were tested on the aforementioned dates. c. Laboratory Person-5 affirmed (2 /12/20 @ 5:09pm) the lack of QC records for the aforementioned dates; and thus the laboratory failed to perform quality controls each day of testing as required. d. The reliability and quality of results reported could not be assured without the required

	quality control materials each day of testing. Based on the laboratory's test volume for 2019 (email, 2/12/20), the laboratory reported approximately 24 collagen/ EPI results and 8 Collagen/ ADP results annually. .
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory RPR worksheet and 2018-2019 proficiency testing records, the lack of laboratory quality control records, and interview with Laboratory Person-5, it was determined that the laboratory failed to test Reactive QC for titered reactivity when titering patients specimen. Findings included: a. The laboratory titered RPR Reactive patients specimen and proficiency testing samples. b. The laboratory QC records failed to include results of titered Reactive control material when patients specimen were titered for their reactivity: Date ACC # RPR result ---------- 6/17/19 M469371 Reactive 1:2 Dilution " F368993 Reactive 1:8 Dilution c. The laboratory failed to provide for review QC records of titered Reactive Control results when titering Reactive proficiency testing samples from API (American Proficiency Institute) for 6 out of 6 events in 2018-2019. d. Testing Person-5 affirmed (1/14/20 @ 3pm) the aforementioned findings and that it was not the laboratory's practice to titer the Reactive Control when titering Reactive specimen. e. The reliability and quality of titered RPR results could not be assured in the absence of titered Reactive QC. The laboratory reported 1,005 RPR results annually. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory tests list, observation of two Stago Compact Max analyzers, the automated Hologic test system, manual bacterial cultures, the OSOM test kits for HcG, and the Abbott Architect analyzer; the lack of laboratory documents, and interview with Laboratory Person-5, it was determined that the laboratory failed to have systems that twice a year evaluated the relationship of test results using different instruments or methodologies. Findings included: a. Coagulation 1) The laboratory had two Stago Compact Max analyzers for Fibrinogen, Partial Throboplastin Time (PTT), and Prothrombin Time (ProTime). Laboratory Person-5 affirmed (1/14/20 @ 5pm) that the two Stago analyzers were used interchangeably. 2)

	The laboratory failed to provide records or documents correlating results between the two Stago analyzers in 2018 and 2019. b. Gc (Gonnococcus, Neisseria gonnorhoeae) 1) The laboratory tested for Gc by two different methods: routine bacterial culture and the Hologic automated molecular method. 2) The laboratory failed to provide records or documents correlating Gc results between the culture and molecular methods in 2018 and 2019. c. hCG (Human chorionic gonadotropin, Pregnancy test) 1) The laboratory tested serum specimen for hCG by two different methods: the manual OSOM test kit and the automated Abbott Architect analyzer. 2) The laboratory failed to provide records or documents correlating hCG results between the manual and automated methods in 2018 and 2019. d. Laboratory Person-5 affirmed (1/14/20 @ 5: 30pm) the aforementioned findings and that the laboratory lacked an overall written policy and specific procedures for correlating results in Coag, Gc, and hCG. e. The reliable correlation and quality of results obtained from interchangeable instruments or different methods could not be assured in the absence of twice annual comparative analyses for Coag, Gc, and hCG. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of pathology reports, the lack of testing laboratory information, and interview with laboratory personnel, it was determined that pathology reports failed to state the address of the laboratory performing special histological stains. Findings included: a. The pathology report on 4/03/18 for Path#18-2560 included results reported by another laboratory, Integrated Oncology, but failed to state the reference laboratory's address. b. Laboratory personnel affirmed (1/15/20 @ 11am) that the Addendum Report named the laboratory as Integrated Oncology, but did not include it's address. c. The reliability and quality of pathology reports to incorporate addresses of other laboratories performing testing could not be assured. The laboratory annually received approximately 352 reports from other laboratories. .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration to ensure that the proficiency testing samples are tested as required. Findings included: a. The Laboratory Director failed to ensure that proficiency testing samples for i-STAT were tested with the regular workload by personnel routinely testing patients specimen. b. The testing personnel for i-STAT Blood gases and ACT reported a combined total of 71 results in 2018, and 164 results in 2019. .
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Personnel Reports (1/13/20) and laboratory records, the lack of laboratory documents, and interview with Laboratory Person-5, the Laboratory Director is herein cited for deficient practice in ensuring that prior to testing patients' specimens, all personnel demonstrated all testing reliably to obtain accurate results. Findings included: a. Upon request for laboratory personnel records for Testing Person-21, the laboratory provided records titled "Clinical Laboratory Scientist STUDENT TRAINING OBJECTIVES", dated May 2018 to June 2019. b. The laboratory was unable to provide records documenting Testing Person-21's demonstrations of reliable testing with accurate results after attaining CLS/Testing Person status on 9/24/19, prior to testing and reporting results. c. Laboratory Person-5 affirmed (1/14/20 @ 5:30pm) the aforementioned lack of records, that the laboratory had a Student Training program, and that it was the practice of the laboratory to regard Student training records for this purpose. d. The reliability, accuracy, and quality of results reported could not be assured when the Testing Personnel failed to demonstrate such performances of all testing after completing training as Students and attaining the level of Testing Persons as defined by State and federal requirements. .