Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2106320	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aumt Laboratory	1000 E Dominguez Street, Suite 104, Carson, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory policy and procedures, nineteen (19) of twenty-nine (29) randomly selected patient test requisition and patient testing records, and interview with the laboratory technical consultant and a testing personnel, the laboratory failed to document the test(s) to be performed and date, time of the specimen collection . The findings include: 1a. On 08/14/2018 (survey date) the laboratory failed to document the test(s) to be performed on the patients' testing requisitions for nineteen patients for the dates of 05/24/2018 and 05/29/2018 yet complete automated CBD (CBCD) with Differential were performed on the Horiba 60 hematology analyzer. Date Pt ID test 05/24/18 7707 CBCD 05/24/18 7708 CBCD 05 /24/18 7709 CBCD 05/24/18 7710 CBCD 05/24/18 7711 CBCD 05/24/18 7712 CBCD 05/24/18 7713 CBCD 05/24/18 7714 CBCD 05/24/18 7715 CBCD 05/24/18 7716 CBCD 05/24/18 7717 CBCD 05/24/18 7718 CBCD 05/24/18 7719 CBCD 05/24

	/18 7720 CBCD 05/24/18 7721 CBCD 05/24/18 7722 CBCD 05/29/18 7725 CBCD 05 /29/18 7725 CBCD 05/29/18 7726 CBCD 05/29/18 7736 CBCD 05/29/18 7737 CBCD 1b. On 08/14/2018, 12:00 AM (survey date) the laboratory's technical consultant affirmed that automated CBCD testing was performed, resulted and reported without test requisition offers. 1c. The laboratory testing declaration form, signed by the laboratory Director on 08/14/2018 7, 2017, indicates that the laboratory performs approximately 5,800 automated CBCD tests annually. Based on Surveyor review of laboratory policy and procedures, nineteen (19) of twenty-nine (29) randomly selected patient test requisition and patient testing records, and interview with the laboratory Technical Supervisor and a testing personnel, the laboratory failed to document the date, time of the specimen collection . The findings include: 2a. On 08 /14/2018 (survey date) the laboratory failed to note the date, time of the specimen collection on the testing requisitions for nineteen patients for the dates of 05/24/2018 and 05/29/2018 yet performed an automated complete blood count with differential (CBCD) with on the Horiba 60 hematology analyzer. 2b. The laboratory policy and Procedure manual under General QA Policy, DEFINITIONS and Procedures: Pre-Analytical: B. Specimen Collection Manual as applicable should include: "Need for special timing for collection; and Need for special handling between time of collection and time received by the laboratory." The Horiba 60 hematology User Manual under 4. Limitations, 4.2 Blood Specimens, Sample Stability states: "Well mixed Whole Blood specimens, collected in EDTA anti-coagulant and run with eight hours after collection, provide the most accurate results for all parameters. The White cell size distribution may shift when species are assayed between 5 and 20 minutes after collections and more than 8 hours after collection." Date Pt ID Time collected 05/24 /18 7709 No Col. Time No Date 7714 No Col. Time 05/24/18 7718 No Col. Time No Date 7737 No Col. Time 2c. On 08/14/2018, 12:00 AM (survey date) the laboratory's technical consultant affirmed that either the date and/or collection time for the automated CBCD testing was performed, resulted and reported was not documented of the patient testing requisitions. The quality and reliability of the patient test requests could not be assured. 2d. The laboratory testing declaration form, signed by the laboratory Director on 08/14/2018 7, 2017, indicates that the laboratory performs approximately 5,800 automated CBCD tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing moderate complexity testing, laboratory director was not met, the laboratory director responsible for moderate complexity testing, failed to ensure that the overall operation and administration of the laboratory, including a quality assessment programs were established and maintained to assure the quality of laboratory services provided (D5305), failed to ensure that the employment of personnel who are competent to perform test procedures (D6004), failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided (See D6007), failed to ensure that procedures were

	established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintained their competency (See D6054).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's records, and interview with the technical consultant and a laboratory personnel, it was determined that the laboratory director failed to be 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. The findings included: D-6064
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) 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 review of the laboratory records and interview with the laboratory staff, it was determined that the laboratory director failed to 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. The findings included: D-5305
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review and lack of documentation of annual personnel competency records and interview with the technical consultant, it was determined that the technical consultant failed to evaluate and document competencies for one testing personnel responsible for moderate complexity testing. The findings included: a. No evidence could be retrieved for annual competencies for two (2) testing personnel of moderate complexity testing in the year 2017 performing moderate complexity testing for Complete blood counts with differential (CBCD) on the Horiba 60 analyzer. b. The laboratory technical affirmed 08/14/2018, 1200 AM (survey date) that testing personnel competency records could not be retrieved for the annual performance of the testing personnel for the year 2017. c. The laboratory testing declaration form, signed by the laboratory Director on 08/14/2018 that the laboratory performs approximately 5,800 automated CBCD tests annually.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories performing moderate complexity testing, testing personnel was not met. See D6064.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on Surveyor review of twenty-nine (29) randomly selected patient test requisition and patient testing records, testing personnel records and interview with the laboratory Technical Supervisor and a testing personnel on 08/14/2018, 2018, the laboratory failed to ensure that the testing personnel performing patient testing on Complete Blood Cell Count with automated differential (CBCD) possess an appropriate current license issued by the State of California (State Requirement.). The findings include: a. The laboratory failed to employee each individual performing moderate complexity testing to hold a current license issued by the State in which the laboratory is located, if such licensing is required for performing moderate complexity testing. The laboratory performed automated CBCD on the Horiba 60 hematology analyzer. b. On 08/14/2018 30, 12:00 AM (survey date) the laboratory Technical Supervisor affirmed that the two testing personnel listed on the CMS-209 form performed patient automated CBCD testing on the Horiba 60 hematology analyzer. c. The laboratory testing declaration form, signed by the laboratory Director on 08/14 /2018 that the laboratory performs approximately 5,800 automated CBCD tests annually.