Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0930353	11/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pasteur Inc Dba Sinai Labs	16530 Ventura Blvd, Ste 407, Encino, 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
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 Surveyor review of laboratory's policy & procedure, patient test records, and interview with the Laboratory Technical Consultant & testing personnel, the laboratory failed to include a timeframe in the procedure for reporting imminently life threatening results, or panic, or alert values and, the laboratory personnel failed to follow the existing critical value reporting procedure. The findings include: a. The laboratory had a procedure for reporting the critical value however, it lacked a timeframe in which the critical value must be reported. Moreover, the laboratory personnel did not follow the laboratory's procedure when reporting the critical value

	since the laboratory did not have any completed critical value form for the reported results. b. The laboratory Technical Consultant and testing person, on 11/20/2019 at 2: 30 pm, affirmed that the laboratory did not have any timeframe mentioned in its critical value reporting procedure, and the laboratory personnel failed to follow the laboratory's procedure in filling out the critical value form when reporting the critical value. c. The laboratory's testing declaration form, signed by the laboratory Director on 11/20/2019, stated that the laboratory performs 51,770 tests, annually.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient test records, and interview with the Laboratory Technical Consultant & testing personnel, the laboratory failed to alert the physician immediately after the patient's test results indicated the critical value, one patient was reviewed. The findings include: a. The patient, accession # 19-02040, had critically high glucose value of 423 mg/dl and critically low platelet value of 20,000 per microliter. The instrument printout showed that the glucose was run on 7/28/2019 at 11:18 am and platelet was run on 7/26/2019 at 7:02 pm. The results for all tests were reported on 7/28/2019 at unknown time. A computer generated log was printed out on 7/29/2019 at 1:27 pm, and a hand-written note on it shows that all called to Dr. However, the call date and time was not noted. It was determined that the laboratory did not alert physician immediately after the test results indicated an alert/critical value. b. The laboratory Technical Consultant and testing person, on 11/20/2019 at 2:40 pm, affirmed that the laboratory did not have any documents showing that it had reported the alert/critical value immediately. c. The laboratory's testing declaration form, signed by the laboratory Director on 11/20 /2019, stated that the laboratory performs 51,770 tests, annually.
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 Surveyor review of laboratory's policy & procedure, patient & quality control test records, critical value reporting process, testing personnel qualifications & training records, and interview with the Laboratory Technical Consultant & testing

	personnel, 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 postanalytic phases of testing. See D5403 and D5813.