Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0098656	11/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Yale-New Haven Hosp/Dept Lab Medicine	20 York St, New Haven, CT	

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
D0000	A complaint investigation of the Yale New Haven Hospital/Department of Laboratory Medicine was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 observation, record review and staff interview, the laboratory failed to have a step by step procedure for all testing. Findings include: 1. Surveyor observation on 11/5/18 at 12:05 PM of the specimen preparation for VERAX PanGenera Detection (PGD) testing revealed: a) Specimens are prepared and

	separated from platelet units, packaged and transported to another laboratory for VERAX PGD testing. b) Specimens are brought to a second location to await courier pickup. c) If the tubing attached to the unit is not long enough for a segment of 4 inches to be made, a sterile tubing welder is used to fuse additional tubing to the unit. d) A purple dot sticker is placed on all negative units, when results are received by the laboratory. 2. Record review on 11/5/18 of the laboratory's 'VERAX PGD testing of Platelets' procedure revealed, the procedure: a) Failed to include steps to be taken when specimens are rejected. b) Contained steps that are not performed by the laboratory. c) Failed to contain steps to be followed if the tubing attached to the unit is not long enough for a 4 inch segment to be made. d) Failed to contain steps to be followed for timing, packaging and transporting specimens to a reference laboratory for testing. e) Failed to contain steps to be followed when negative results are received. 3. Record review on 11/5/18 of the laboratory's procedure manual revealed, the laboratory failed to have a procedure for processing single donor apheresis platelet units. 4. Staff interview with blood bank testing personnel #1 and the blood bank manager on 11/5/18 at 12:05 PM confirmed the above findings. 5. Staff interview with the regulatory specialist on 11/5/18 at 1:00 PM revealed, Yale New Haven Health System uses the same VERAX policy for all sites even though the laboratories have different CLIA numbers and does not detail which steps are/are not performed at each laboratory.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to approve new laboratory procedures before they were put into use in the blood bank laboratory. Findings include: 1. Record review of the 'Verax PGD Testing of Platelets' procedure's signature page on 11/5/18 revealed the procedure was signed by the laboratory director on 3/22/17. 2. Record review of the 'Verax PGD Testing of Platelet Products' validation data on 11/5/18 revealed Verax PGD testing began on 3/6/17. 3. Staff interview with the regulatory compliance specialist on 11/5/18 at 1:00 PM confirmed the above procedure was not signed by the laboratory director before patient testing.