Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0098438	11/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ynhh Saint Raphael Campus Laboratory	1450 Chapel 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 YNHH SRC Department Laboratory Medicine was conducted on 11/5/18 pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to retain the platelet unit testing record to include the full segment identifying information for all testing performed on the unit by the laboratory. Findings include: 1. Record review on 11/5/18 of the Yale New Haven Hospital St. Raphael's Campus (YNHH-SRC) 'Platelet PGD Worksheet' from 10/4/18 revealed: a) Donor identification number (DIN) W200418811063 appeared twice on the worksheet as follows: i. W200418811063 ii. W200418811063 07 b) Three other units also had 07 on the worksheet after the DIN. c) One unit had 06 after the DIN. 2. Record review on 11/5/18 of the YNHH Transfusion records for single donor platelets, DIN W200418811063 revealed: a) DIN W200418811063 used for transfusion for patient #1 had a product code of PASI E7007. b) DIN W200418811063 used for transfusion for patient #2 had a product code of PASI E7006. 3. During staff interview on 11/5/18 at 12:45 PM, the blood bank supervisor stated: a) "When 2 units are received with the same DIN and they are irradiated, they are given a product code that ends in 06 or 07." b) "If 07 is written after the DIN on one line of the Platelet PGD Worksheet, and nothing after the same DIN that is listed on another line, it is assumed that it is 06. The full DIN and product code are not written on the log sheet." c) Confirmed the above findings in 1 and 2 above.

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 record review and staff interview, the lablratory failed to solicit the time of collection for Verax Pan Genera (PGD) test specimens. Findings include: 1. Record review on 11/5/18 of the 'Softbank Inventory Test Order -Results' printout for Verax PGD testing revealed the time of collection was not documented. 2. Record review on 11/5/18 of the 'Verax PGD testing of Platelets' procedure revealed, "Samples may be kept in tubes at 15-30 degrees Celsius up to 2 hours prior to testing." 3. Record review on 11/5/18 of the 'Verax Biomedical Platelet PGD Test,' package insert revealed, "Samples may be kept at 15-30 degrees Celsius for up to 2 hours prior to testing. 4. Staff interview with the blood bank section supervisor (BBS) on 11/5/18 at 12:45 PM: a. Confirmed the time of collection for Verax PGD testing on samples received from Yale New Haven Hospital (YNHH) is not documented. b. BBS stated, "Specimens are collected at YNHH by the 6:30 AM testing personnel and are sent over to St. Raphael's (SR) via the 7:00 AM courier. SR knows about when they should receive the specimens because the courier leaves at the same time every day. Specimens are rejected if SR staff feel it may have been over 2 hours."
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a written policy for rejection of specimens received from apheresis donor units. Findings include: 1. Record review on 11/5/18 of the laboratory's 'VERAX PGD testing of Platelets Procedure' revealed, the procedure does not include instructions to be followed when specimens are rejected. 2. Staff interview on 11/5/18 at 12:30 PM with the blood bank supervisor revealed: a. The first batch of specimens received for

	testing on 10/4/18 were rejected due to specimens being received over the 2 hour limit required in the procedure. b. Documentation for the above rejected samples was unavailable. c. Confirmed the aforementioned procedure does not include instructions to be followed when specimens are rejected.
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 and by the laboratory director before patient testing began.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to verify the performance characteristics of new laboratory tests prior to patient testing. Findings include: 1. Record review of the Verax PGD Validation studies on 11/5/18 revealed the validation review and acceptance was not signed by the technical consultant listed on the laboratory's personnel report. 2. Staff interview with the regulatory compliance specialist on 11/5/18 at 1:05 PM confirmed the above findings.