NEW YORK BLOOD SERVICES
150 AMSTERDAM AVENUE
NEW YORK, NY 10023
EI: 10/29...12/20/96
ET, JD, JL, PA

Summary of Findings

This limited inspection of New York Blood Services was conducted as part of the NYK-DO October 1996 Workplan, to verify corrections promised by the firm in their response to the Warning Letter received during the 8/25....12/9/94 inspection. However, due to several developments that surfaced at this firm, a limited inspection was conducted, as it only covered the firm's Component Lab, Viral Testing Lab, and the Olympus Laboratory. On October 29,1996 an FDA 482 was issued and credentials were presented to Bonnie Lupo, Director of Quality Laboratories, by investigators Evelyn Taha and Jacqueline Diaz-Albertini. On November 2,1996 Investigator Peter Abel joined the inspection. Credentials were presented and an FDA 482 was then issued to Mary Jo Anzel, Director of Central Laboratory. On November 22, 1996, Investigator Joan Loreng, from PHI-DO joined the inspection. Credentials were presented and an FDA 482 was issued to Bonnie Lupo, Director of Quality Laboratories.

The previous inspections of 8/94 and 2/96 revealed significant deficiencies relating to but not limited to the following; Re-reading of plates on the [redacted] used to perform the HTLV-1, HIV 1/2, and Hepatitis B Surface Antigen assays. Plates were routinely re-read without any written procedure addressing the criteria under which a plate should be re-read or a documented explanation for the re-read. The firm routinely failed to maintain data for the HIV 1/2, Hepatitis B Surface Antigen, and the HTLV-1 assays. Lack of security throughout the computer automated test systems in that with the [redacted] version [redacted] and [redacted] used to perform the HCV and Core assays, technologists were able to pre-screen optical densities of the controls using the "scan plate only" option. Pre-viewing optical densities in cases where the OD's of a control is out of range, allows technologists to manipulate micro-plate controls instead of voiding the entire plate and re-running the test. Failure to maintain standard operating procedures for various procedures including but not limited to, managerial review of test data, invalidation of test results for assays performed in the Olympus laboratory which performs syphilis, ABO/ RH and CMV testing, traceability of test tubes that have been mis-scanned, Qualification of the in-house reference control used in viral testing and the editing of plates on the [redacted] tomated test system which is used for the assay of viral markers HCV, HBC (Core) and HBsAg (in 1991). The firm received a warning lett- dated 3/17/95 for this inspection

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The inspection of 2/96 was conducted as a follow-up to a Blood products Error/Accident filed by the firm on 2/13/96 which involved the release into inventory and the transfusion of blood and blood products prior to the completion of the correct test algorithm for Hepatitis B Surface Antigen, due to a supervisor's failure to follow standard operating procedure for the Validation of Results for Laboratory Assays. The internal investigation conducted regarding this error was inadequate in that there was no documentation to support information stated in the report. Documentary sample number DCC-96-752-647 was collected and submitted to CBr.

The current limited inspection of October 29, 1996 through December 20, 1996, although originally intended to be comprehensive, only covered the viral testing lab, the component lab, and the Olympus Laboratory. This was due to numerous developments that surfaced at this West side location. This inspection revealed the following deficiencies related to the following, but not limited to: the firm failed to address, investigate and respond to allegations pertaining to the manipulation of test controls in the [redacted] and [redacted] computerized test systems in which the viral markers are assayed, lack of supervision of technicians /technologists during testing in the Central laboratory facility, failure to validate the DI water system in various areas of the Central laboratory facility, failure to address and correct discrepancies found in the DI water testing logs, failure to identify and initiate corrective action for warning message displayed on the [redacted] PC, failure to maintain a written standard operating procedure for the preparation of platelet rich plasma from CPD-1 units of whole blood, failure to document critical in process testing data at the time of testing, failure to perform daily and weekly calibration of the laboratory scales, failure to perform quarterly maintenance check for the [redacted] equipment used for ABO/Rh, syphilis, CMV and anti-body testing, failure to identify persons making corrections to maintenance logs throughout the laboratory, failure to notify FDA of upgrades of the computer software for the [redacted] PPC version [redacted] and FPC version [redacted] and the [redacted] Software version [redacted]. failure to perform the monthly maintenance quality control check for the [redacted], which is the computerized monitoring of temperatures for various equipment through out the laboratory.

An FDA 483 was issued to and discussed with Jenni Lee Robins, Vice President/Responsible Head Blood Operations and other members of management on 12/20/96 pertaining to these deviations.

Responses were made to some points, which are noted, and management informed us that they would respond in writing.

Samples Collected

Physical sample numbers 97-751-362/364 were collected as controls for sample numbers 97-751-361/363 which contained 3 units of Recovered Plasma collected during the inspection to determine whether the samples contained the additive solution, Adsol. In addition, physical samples of Immune Globulin in Intravenous (Human) 5% Solution, Solvent Detergent Treated numbers 97-751-901...913 were collected at [redacted], as per CBER assignment, dated December 19, 1996, to be tested for anti-HIV, anti-HCV and HBsAg.

Persons Interviewed and Administrative Procedures

On October 29, 1996, Investigators Evelyn Taha and Jacqueline Diaz-Albertini presented credentials and issued a Notice of Inspection, FDA-482, to Ms. Bonnie (NMI) Lupo, Director of Quality Laboratories, New York Blood Center/Blood Services Laboratory, 150 Amsterdam Avenue, New York, NY 10023. Ms. Lupo stated that during the absence of the Medical Director/Responsible Head, Celso Bianco, M.D., she was authorized to accept the FDA-482. Credentials were also presented to the following individuals: Mary Jo Anzel, Director of Central Laboratory facility, and Beverly (NMI) Williams, Manager of Quality Control.

On November 2, 1996, CSO Peter Abel, and on November 22, 1996, CSO Joan A. Loreng, joined in on the on-going inspection. Ms. Bonnie Lupo assisted us throughout the inspection, and provided us with most of the information in this report. We were provided with information relevant to daily laboratory operations by the following persons:

Mary Jo Anzel - Director of Central Laboratory facility - She reports directly to Jenni Lee Robins, Vice President and Responsible Head of Blood Operations.

Joseph (NMI) Gardner - Manager for Special Project - He reports directly to Mary Jo Anzel.

Katherine (NMI) Sewveryn - Manager of Component Laboratory - She reports directly to Mary Jo Anzel.

Randy Spiro - Assistant Manager/Data Management - She reports directly to Mary Jo Anzel.

The following information pertains to the current employees that were interviewed during the inspection in the presence of management. In some cases the New York Blood Center Attorneys were also present.

On November 18, 1996, at 1:45 PM, the following NYBS employees were interviewed regarding laboratory practices at the Virology Testing area. Present during this interview were: Mary Jo Anzel, Director of Central Lab facility and Bonnie Lupo, Director of Quality Laboratory. Also present were CSO's Evelyn Taha, Peter Abel, and Jacqueline Diaz-Albertini.

Interviewed during the 8:00 AM to 4:00 AM Shift were:

Mr. Ignacio Ayala - a Technologist for 24 years
Ms. Jean Williams - a Technician for 10 years
Mr. Gaspard Benjamin - a Technologist for 23 years
Ms. Randy Spiro - Data Manager, worked for NYBS since January 1993
Mr. Teofilo Makalintal a/k/a "Teo" - a Supervisor, worked for NYBS for 25 years

On November 19, 1996, at 11:30 AM, the following NYBS employees were interviewed regarding laboratory practices at the Virology Testing area. Present during this interview were: Miriam Sparrow and Steve M. Byers, Legal Counsel for New York Blood Center. Also present were CSO's Evelyn Taha, Peter Abel and Jacqueline Diaz-Albertini.

Interviewed during the 8:00 AM to 4:00 AM Shift were:

Mr. Ignacio Ayala - a Technologist for 24 years
Ms. Jean Williams - a Technician for 10 years
Mr. Dario Hernandez - a Technician for 5 years

On November 19, 1996, at 10:30 PM, the following NYBS employees were interviewed regarding laboratory practices at the Virology Testing area. Present during this interview were the New York Blood Center's Legal Counsel, Miriam Sparrow, Robert P. Charrow and CSO's Evelyn Taha, Peter Abel and Jacqueline Diaz-Albertini.

Interviewed during the 4:00 PM to 12:00 AM Shift were:

Mr. Dawood Khan - a Technologist for 17 years
Ms. Roger Johnson - a Technician for 2 years
Mr. Ernst Prophete - a Technician for 20 years

Interviewed during the 11:00 PM to 8:00 AM Shift were:

Ms. Rosa Gonzalez - the current Shift Manager and a laboratory employee of NYBS since 1974

Mr. Eleazar Maniago a/k/a "Joey" - Assistant Manager for the past 5 years and a NYBS employee for 13 years

The following individuals declined to be interviewed by the FDA:

Mr. Patricio Maldonado - Supervisor for the 5:00 PM to 1:00 AM Shift
Mr. Chito Magparangalan - a Technologist for the 4:00 PM to 12:00 AM Shift
Ms. Kalpana Patel - a Technologist for the 4:00 PM to 12:00 AM Shift

Note that the above employees received instructions from NYBC Management that if approached by the FDA inspectors, they have the right to refuse or decline to be interviewed.

Please note that the interviews of current as well as former employees of NYBS, regarding unscrupulous testing practices, were conducted off-site during the month of November 1996.

Individual Responsibilities

Dr. John Adamson, President of New York Blood Center, located at 310 East 67th Street, New York, NY 10021 is the most responsible person. He was not available during the inspection and he was not present during the discussion with management.

Ms. Lupo provided us with the current NYBC/NYBS Organizational Chart (Exhibits T1 & T1a). The most responsible person for the NYBC/NYBS Laboratories is Dr. Celso Bianco, Medical Director. He was not available during the inspection, but was present during the discussion with management.

According to Bonnie Lupo, the former Medical Director for the laboratory, Dr. Merci Kuriyan, left the firm in 1995. Subsequently, Dr. Celso Bianco took over the position and responsibilities as Medical Director for the NYBC testing laboratories (Center West and Center East). Bonnie Lupo stated that Dr. Celso Bianco's responsibilities are: Attends to any medical issues and discussions for the laboratory. He is responsible for the review of the laboratory SOP's and signs off on all of the Standard Operating Procedures for all the laboratories. Dr. Bianco reports to Dr. John Adamson, President of NYBC Inc.

Bonnie Lupo - Director Quality Laboratories, stated that she is responsible for the review of the laboratory Q/C SOPs, and attends laboratory operational meetings. Part of her duties are to serve as the FDA Liaison. Ms. Lupo reports to Jenni Lee Robins, Vice President.

Mary Jo Anzel - Director of Central Laboratory facility, stated that she is the current Director for the Central Lab in place of the former Director of Central Lab, Bill Slimak, who left in March 1995. Ms. Anzel stated that all of the laboratory managers, including the Long Island Blood Services facility reports directly to her. She is responsible for the overall administrative and technical day-to-day operations of the Central Laboratory facility.

According to Mary Jo Anzel, the following personnel has a PC terminal at home with an access level onto Safeblood, with regards to testing, component reports, void reactive, void duplicate and transmission of reactive in Safeblood. They are Joe Gardner, Bonnie Lupo, Jay Valinsky, and Rosa Gonzalez.

She further stated that if a technologist re-reads a plate, the technologist will have to call her at home via telephone for an approval. Ms. Anzel further stated that Joe Gardner, Manager of Special Projects has the same functions as hers, and that Joe Gardner can handle any lab problems. In addition, Mr. Gardner can log into Safeblood from home, and that he would be able to void a reactive and void any duplicate transmission.

She further stated that she and Dr. Jay Valinsky, Director of Scientific & Technical Services are the only individuals that can delete reactive transmissions in Safeblood. She reports to Jenni Lee Robins, Vice President.

Jay E. Valinsky, Ph.D. - Director of Scientific and Technical Services is the assigned Quality Director for the Center West Laboratory. His responsibilities are: To ensure all laboratory QA/Regulatory requirements are met; monitor the effectiveness and efficiency of the process. He is responsible for the day-to-day operations of the quality control personnel. He reports to Dr. Celso Bianco and Jenni Lee Robins.

Carol A. Brown - Quality Manager - Ms. Brown's primary duty station is New Jersey Blood Services, but she is typically at the New York Blood Services 2 days each week. According to Ms. Brown, some of her responsibilities are to conduct in-house audits of the laboratory; assist in training technologist(s); monitor laboratory processes and assist in the review of the SOP Manual. Ms. Brown reports to Bonnie Lupo, Director of Quality Laboratories.

Jenni Lee Robins - Vice President, Blood Operations/Responsible Head, is responsible in developing the company's quality program, including policies, plans, organization and procedures. She has the full authority to make decisions and take action necessary to carry out the responsibilities assigned. In addition, she is fully accountable for the fulfillment of responsibilities and their proper interpretation. Ms. Robins reports to Dr. Celso Bianco and Dr. John Adamson.

Joseph Gardner - Manager of Special Projects - According to Mr. Gardner, he is responsible for reviewing the service attendance report; oversees the cleaning of the laboratory instruments; responsible for the disposal of reactive sample tubes; works with Abbott and Ortho computer consultants. Mr. Gardner reports to Mary Jo Anzel.

Randy Spiro - Data Manager is responsible for the validation for all software system upgrade; coordinates the training for the computer software validation. She oversees the Safeblood for Management Information System (MIS). Ms. Spiro stated that she is one of the supervisors that works on week-ends, or as needed. Ms. Spiro reports to Mary Jo Anzel.

Katherine Sewvryn - Manager of the Component Lab, stated that she is responsible for the day-to-day technical operations of the Component Lab. She also updates and reviews the SOPs. She reports to Mary Jo Anzel.

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Issue involving Recovered Plasma containing Adsol.

The NYK-DO District Director, and the Director, Investigations Branch [redacted]

[redacted] However, it contains additional adenine and mannitol which is not indicated for newborns. Consequently, in instances where hospital requests RBC's without Adsol such as PEDI Packs, Adsol remains in the satellite bag intended for plasma. Since NYBS collects Adsol free RBC's only from closed system Triple blood collection bags, plasma ends up in the plasma bag with 100 ml Adsol, platelets in platelet bag and RBC's in primary collection bag. According to the firm, in cases where platelets are not separated, platelet rich plasma is expressed into platelet bag (without Adsol and plasma bag with 100 ml unused Adsol is discarded). (see Exh #P18 & #P19 normal and PEDI Pac procedure to separate components from whole blood).

[redacted]. The firm ships Recovered Plasma containing 100 ml. Adsol per bag to [redacted] in case where plasma is recovered from whole blood drawn into triple AS-[redacted] Collection Bags (Barcode 53) (Exhibit #P9, pages 4-6).

In cases where whole blood is converted to CPD red blood cells (for pediatric or special use where no Adsol is permitted), and to platelets and recovered plasma (product code 19501 - Recovered Plasma Liquid, or 19601 - Recovered Plasma), plasma ends up separated into satellite bag (PL146, Bar Code 06, Exhibit #P9, page 5) containing 100 mL. of Adsol.

On November 5, 1996, during the inspection, investigators Peter Abel and Jacqueline Diaz-Albertini observed component technician Patrick Shakes demonstrate how platelet rich plasma (Recovered Plasma) is made from a CPD-1 unit. A CPD-1 unit is a unit of whole blood which is collected in a blood bag which contains the anti-coagulant CPD. Usually the units used for pediatric transfusions are those red cells which do not contain the anti-coagulant Adsol. The anti-coagulant used in these units are CPD. These CPD units are collected in a triple blood bag.
These triple blood bags contain three bags, the bag in which the whole blood is collected in the CPD anti-coagulant, the plasma bag which contains the Adsol and a platelet bag for when a platelet product is made. When a pediatric unit is requested without the anti-coagulant Adsol, the red cells are labeled CPD and the plasma bag containing the Adsol is labeled recovered plasma. The platelet bag is used if platelets are made.

During the observation of this tech making a recovered plasma unit from this CPD unit, there was no standard operating procedure which addressed the preparation of this recovered plasma product which can contain up to 100 mL of Adsol.

The firm uses double (Barcode 52), triple (Barcode 53), and quad (Barcode 54) [redacted] blood collection bags (Exhibit #P9) however only triple collection bags are used for PEDI pack component separation.

NYBC has a Short Supply Agreement with [redacted] to supply Recovered Plasma, Frozen and Liquid (Exhibit #P10). The agreement does not have provisions for shipping Recovered Plasma containing Adsol. Furthermore, product is not labeled to contain Adsol (Exhibit #P11 - Examples of Recovered Plasma, Units #6744948, #6738174, #7629018, #6744961, containing 100 Adsol, and Exhibit #P12 - Labeling for Recovered Plasma Bar Code 19801, 19601, and 19501, with product insert).

Examples of Recovered Plasma collected into satellite bag after Adsol was expressed into primary RBC bag thus recovered plasma would contain only individual Adsol, is Exhibit #P13, pages 1,3, and 4 - Unit #6735715, and #6745380. Recovered Plasma collected into platelet bag with no Adsol as Unit #6746332 is submitted as Exhibit #P13, page 2. Example of Shipment of Recovered Plasma to [redacted] is submitted as Exhibit #P14. Only Recovered Plasma with bar code 19601 or 19501 would contain 100 mL Adsol per satellite bag.

Mrs. Jenni Lee Robins provided summary of shipment of Recovered Plasma to [redacted] from April 1995 to October 1996 (Exhibit #P15). The incidence of Recovered Plasma shipped to [redacted] for fractionation was calculated to be approximately [redacted] of total shipped (Exhibit #P15) based on information from shipments during April 1, 1996 and September 15, 1996 (1,871 units converted to CPD red cells, platelets, and Recovered Plasma 19501/19601) (See Exhibit #P16 for code description of blood product components and collection bags and component lab processing report for October 30-31, 1996 (Exhibit #P17). On November 8, 1996, Mrs. Robins stated that as of November 16, 1995, NYBC will change the process so Adsol does not end up in the plasma. She further stated that all Recovered Plasma with Adsol will be quarantined ([redacted]) and will not be shipped to [redacted] until the issue is resolved.

According to management, the weight of the Adsol is deducted from the total weight of the Recovered Plasma collected. Consequently, the volume of the Recovered Plasma collected is correctly recorded on the label.

Physical Sample Number 97-751-362/364 were collected as controls for sample numbers 97-751-361/363, which contained three (3) units of Recovered Plasma collected during the inspection to determine whether the samples contained the additive solution Adsol.

Other Physical Samples Collected

Physical samples of Immune Globulin in Intravenous (Human) 5% solution, Solvent Detergent Treated numbers 97-751-901...913 were collected at [redacted] a/k/a [redacted] as per CBER assignment, dated December 19, 1996, to be tested for HIV, HCV, and HBsAg.

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Information received from CBER that New York Blood Center was the supplier of various lots of plasma (Fresh Frozen Plasma, and Liquid Plasma) to [redacted] for fractionation. The last shipment of fresh frozen plasma, and liquid plasma received by [redacted] frm New York Blood Center, was January 31, 1994.

Physical samples were collected in an attempt to determine whether these products manufactured from recovered plasma, tested by NYBC were reactive for any viral markers. These samples were submitted to CBER for analysis.

Laboratory Personnel Training

The laboratory employee signature list (exhibit L1) for each shift was obtained. I (JAL) performed a general review of the training files for current laboratory personnel and in particular, checked for training in the system log-off. On 12/13/96, we (PA and JAL) observed operations from 4:00am until approximately 7:30am on the night shift (midnight to 8:00am). I (JAL) checked training records for every person testing on that shift.
The records documented that every tech had been trained in the testing they were observed performing. Competency Training in every test assay includes proper procedure for test invalidation. Exhibit L5 is a print-out from "Training Tracker" a software program to aid in the management of the training program. Exhibit L6 is the competency summary for the lab technicians. Note that the competency training for each test includes the proper procedure for test invalidation.

Laboratory operations were observed after the blood center began using monitors to observe test operations. Monitoring began 11/20/96. The SOP is shown in exhibit L7. Monitoring on all three shifts was observed. We spoke with techs, monitors, and supervisory personnel. Monitors oversee production, walk around, observe the read phase. Exhibit L8 is the floor plan of the laboratory and exhibit L9 is a list of monitors and their experience.

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Laboratory Test Equipment and Interfaces with Safeblood

The viral marker test laboratory uses [redacted] and [redacted] test kits. The [redacted] kits are used for HBsAg, anti-HIV- 1/2, and anti-HTLV-1. [redacted] kits are used for HIV-1 p-24 antigen, anti-HCV, and anti-HBc. Laboratory instrumentation include the [redacted] FPC version [redacted] PPC version [redacted] pipettor and reader version [redacted]

PPC version [redacted] was installed on July 10, 1996, and is configured for verify mode of TPC, total process control. The configuration allows no re-reads. The configuration is pass-word protected; only Dr. Valinsky and [redacted] can change the configuration. Prior to version [redacted] re-reads were allowed by configurable criteria--paper-out or DMS down, were the only valid reasons allowed by their configuration. The PPC needs to be re-initialized after [redacted] plates. Data from the PPC's are transmitted to DTS (PPC Data Transmission System), developed in-house.

DTS replaced [redacted] DMS in September, 1996. DTS captures instrument invalidated runs, which was not possible with DMS. The DMS was only able to retain instrument void reports electronically for one month, so data was overwritten every [redacted] days. DTS captures the electronic record, formatted like the PPC tape. The data retained includes any PPC error messages. The DTS data is archived and backed-up.

When each [redacted] plate is read it is automatically transmitted to the printer and to the IIP (Intelligent Interface Peripheral). The IIP is a pass-through system from the reader to SafeBlood. Once a plate is read it is sent to the printer and SafeBlood. An [redacted] plate cannot be read twice or deleted after reading. An error message is generated if one attempts to read a plate twice. The only exception to this is if the power switch to the PC controlling the reader is turned off after reading.

Non-useable plates include plates that are invalid per instrument criteria (controls out of range, processing time exceeded, jammed trays, etc.) and those with non-reactive in-house reference controls. Data from non-useable plates are saved electronically--since 9/96 for [redacted] tests and since 7/91 for [redacted] tests. The IIP sends non-useable [redacted] plate data directly to SafeBlood; the DTS retains non-useable [redacted] plate data in the DTS mini-mainframe. The DTS retains on-line history 3-6 months and is then archived. The on-line and archived data can be searched for non-useable plates which can then be printed in PPC format.

Data from IIP and DTS are sent to and held in a temporary table in SafeBlood. Each hour SafeBlood checks the temporary file for any plates that had been sent within the hour and populates the test measurement tables, writes to the unit record. From the plate, batch, and time a concatonnated key is calculated as a unique identifier for a run (since plate and batch numbers may be recycled.

The SafeBlood computer system provides an audit trail of data added to or deleted from the database. Data is time-stamped when inserted into the [redacted] database. See example in exhibit L15. The audit trail includes the system time when each test result is entered and the time when each test was performed. The time of the test is listed under worksheet_id info--taken from the header of the batch information.

Once data is committed to SafeBlood, personnel with the proper system security access can void a single test result, plate batch, or worksheet, but never a reactive result. A SafeBlood "void report" was requested for the period October to December, 1996, and reviewed. The "void report" provides an audit trail of voided data; it lists all batches, plates, worksheets or individual units that have been voided. A brief reason for the void is given on the report. Supporting documentation for some of the less obvious reasons was requested.

The majority of these were explained after some research; however, the effort was hampered by the invalidation reports being copied off-site and holiday vacations of personnel knowledgable about particular voids. Exhibit L2 shows lab employee user number, group, and access level; exhibit L4 shows the SafeBlood menu access by group and level.

HCV test records for the period October 1 to October 18 were reviewed. Repeat reactive units were appropriately discarded and donors deferred.

Internal Audits

There are procedures for performing internal audits. The general procedure and policy statement are found in the Quality Manual, Internal Assessment (exhibit L10). Specific guidance for audits of the test laboratory is found in documents describing inspection items for a QA audit of the laboratory (exhibit L11) and key elements and system checks for testing (exhibit L12).

Documentation exists that internal audits have been conducted (exhibit L13) in addition to routine QC and QA functions (exhibit L14). Audits are also conducted by customers for whom testing is performed.

QC Trending

Ms. Beverly Williams, Manager, QC, provided disks (exhibits L21a-c) containing test cut-off values, reference control values, and voided runs. (Voided runs include runs invalidated by the test instrument criteria and runs voided for other reasons.) The disks contain Excel files for trending. Ms. Williams stated that the data is downloaded from the SafeBlood mainframe into Excel.

Dr. Jay Valinsky, Director, Technical and Scientific Services, provided statistics on repeat reactive and confirmed positive rates for viral markers (exhibits L18-20). In addition to the hard-copy data, Dr. Valinsky also provided a disk (exhibit L21d) with Lotus files for these rates for 1992-1996.

Operations

The New York Blood Center changed its name to New York Blood Center Inc. in May 1995. The corporate headquarters is at 310 East 67th Street, New York, NY 10027. There are five (5) licensed locations registered with the FDA.

The NYBC serves the transfusion needs of Greater New York, an area of over [redacted] square miles, with a population of [redacted] people. Supporting some [redacted] hospitals in New York and New Jersey, the NYBC collects blood from approximately [redacted] donors each year, which includes [redacted]

The New York Blood Services a/k/a New York Blood Center, located at 150 Amsterdam Avenue, New York, NY, 10023 is identified as an importer, manufacturer and distributor of blood and blood products being used for human transfusion.

The NYBS Central Laboratory facility performs screen testing for HIV 1/2, HTLV, HBsAg, HCV, HBC, P-24, alanine amino transferase, serology testing for VDRL ABO Rh identification, and is responsible for all storage and distribution of blood products.

The NYBS is the largest testing and blood processing facility in the State of New York, approximately [redacted] samples are tested for viral assays per week (approximately [redacted] samples per year). All testing procedures at this facility are performed on automated equipment.

The [redacted] Systems with [redacted] Version [redacted] are used for the performance of CORE, P-24 Antigen, and HCV assays, while the [redacted] Programming Center (PPC) Software Version [redacted] and [redacted] Center (FPC) Software Version [redacted] are used for testing HIV 1&2, HTLV, and HBsAg assays.

According to Ms. Bonnie Lupo, the Central Laboratory facility tests approximately [redacted] samples annually. All blood samples received out of New York State, whether from licensed domestic sources, or imported from licensed donor centers in Europe, are subject to complete testing upon receipt prior to distribution.

The Central Laboratory facility of this firm is under the directorship of Mary Jo Anzel.

The Central Laboratory facility is divided into areas, such as:

a) Component Lab
b) Viral Testing Lab
c) Olympus Lab
d) Labeling Lab

The current inspection only covered the Component Laboratory, Olympus Lab, and the Viral Testing Laboratory.

The Viral Testing Lab operates seven days a week, 24-hours a day, three shifts per day. There are [redacted] laboratory personnel (technologists/technician, Supervisors and Managers) in the Viral laboratory alone. The Viral Marker testings performed on imported blood products as well as domestically collected products are conducted at the Viral laboratory also known as the Main Laboratory.

All testing procedures at this facility are performed on automated testing equipment. The main laboratory has both [redacted] and [redacted] testing systems.

There are [redacted] units of [redacted], [redacted] units of [redacted] Processing Centers, and [redacted] units of [redacted] Center in the main lab. Note that we found one (1) unit of FPC, and one (1) unit of PPC in the training room area. According to Mary Jo Anzel, the testing equipment are only used for training new employees.

The [redacted] Software Version [redacted] tests substantial amounts of sample for HCV, P-24, and CORE, while the [redacted] Software Version [redacted] tests samples for HIV 1&2, HTLV, and HBsAg assays. We observed during the inspection that the bulk of the testing is conducted during the 12:00 AM through 8:00 AM shift. There were [redacted] technicians working on different test assays, [redacted] supervisors [redacted] laboratory manager (Rosa Gonzalez) to supervise the whole operation during the midnight shift.

Ms. Rosa Gonzalez, Laboratory Manager (4:00 PM to 8:00 AM shift) stated to the investigator that there are [redacted] voids or invalid test results per shift. Each technician is required to test [redacted] to [redacted] test boards per shift, especially on the midnight shift.

This facility provides Viral Marker testing services for other facilities as requested. For example, [redacted] the [redacted] According to Ms. Bonnie Lupo, Director of Quality Laboratory, the recovered plasma produced by their facility are sold/shipped to [redacted] This facility has a short supply agreement with the [redacted] of the [redacted] to be the supplier of Recovered plasma for use in the manufacture of licensed fractionation products for injection.

Ms. Bonnie Lupo stated to the investigators that under the short supply agreement, [redacted] units of frozen recovered plasma, frozen liquid plasma, and recovered plasma are shipped weekly to [redacted] of the [redacted]

This facility imports [redacted] of their blood supply (Red Blood Cells only) from [redacted] via the [redacted], approximately [redacted] of blood supply is received from out-of-state domestic sources.

According to Mary Jo Anzel, Director of Central Laboratory, this facility purchases blood and blood products from the Blood Centers of America, which are located across the United States.

Additionally, [redacted] of this facility blood supply is received from other local sources (donor rooms, blood drives, etc....). This facility tests samples for [redacted] local hospitals and transplant centers in the New York Metropolitan area. Investigator Evelyn Taha reviewed the HIV 1&2, HTLV-1, and HbsAg test records for the period of October 1996 to November 1996. Repeat reactives were appropriately discarded and donors deferred.

Our inspection of the Viral Testing Lab found that the firm failed to address, investigate and respond to allegations pertaining to the manipulation of test controls in the [redacted] and [redacted] computerized test systems, in which the viral markers are assayed. There was lack of supervision of technicians/technologists during testing in the Viral Testing Lab. The firm did not correct discrepancies found in the DI Water Testing logs.

The firm also failed to identify and initiate corrective action for warning message displayed on the [redacted]

In addition, the firm failed to notify FDA of the upgrades of the computer software for [redacted] the [redacted] and the employment of a new Director for the Central Laboratory facility (Mary Jo Anzel) in April 1995.

The Olympus Laboratory is currently supervised by Mr. Andrew Opalka, newly hired manager for serology testing (ABO/Rh testing, compatibility, CMV and Syphilis testing). All testing procedures at this laboratory are performed on the [redacted] automated testing equipment. We observed [redacted] units of [redacted] test equipment situated in this laboratory area. Next to the main laboratory is the area where ALT testing procedures are performed on the [redacted] automated equipment.

Investigator Evelyn Taha's review of the equipment maintenance records during June 1995 to September 1996 showed that the firm failed to perform quality maintenance checks for the [redacted] equipment used for ABO/Rh, Syphilis, CMV, and antibody testing. Investigator Taha's review of records from June 1995 to September 1996 showed that the firm failed to identify persons making corrections to maintenance logs throughout the laboratory.

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The Component Laboratory, managed by Ms. Katherine Sewveryn, processes whole blood received from the collection sites, blood mobiles, donor room, blood drives, etc.

This facility manufactures/labels whole blood into different components such as Red Blood Cells, Plasma, Liquid Plasma, Fresh Frozen Plasma, Recovered Plasma, Platelets, Cryoprecipitate AHF (autologous only), Red Blood Cells Leukocytes removed via Centrifugation, Irradiated Blood and Platelet Rich Plasma.

Several GMP deficiencies were noted during the inspection of the Component Lab: Lack of SOP for the preparation of platelet rich plasma from CPD-1 units of whole blood; firm failed to document critical in-process testing data at the time of testing; failure to perform daily and weekly calibration of the laboratory scaler. In addition to the above, the firm failed to perform the monthly maintenance quality control check for the Mack Link System, a computerized monitoring of temperatures for various equipment throughout the laboratory. According to Mr. Joe Gardner, he is responsible for the maintenance Q/C of the Mack Link System.

At the conclusion of the inspection, a discussion with management was held at the NYBS, located at 150 Amsterdam Avenue, New York, NY. A List of Inspectional Observations, FDA-483, dated December 17, 1996, was issued to Jenni Lee Robins, Vice President and Responsible Head, Blood Operations.

The following individuals were also present:

Jay E. Valinsky, Ph.D. - Director of Scientific & Technical Services

Dr. Celso Bianco - Vice President of Medical Affairs
Mary Jo Anzel - Director of Central Lab Facility
Bonnie Lupo - Director of Quality Laboratories
Ruth Harkin - Director of Quality Operations
Miriam Sparrow - General Counsel for NYBC

Objectionable Conditions

VIRAL TESTING LABORATORY

1. The firms Quality Assurance system is inadequate in that it failed to address and respond to allegations that technicians are "fixing plates" by manipulating controls to avoid repeating the tests. These allegations were brought to managements attention during the 1994 FDA inspection as well as by various lab employees in 1995, prior to the current inspection.

NOTE: ON 12/20/96 the following correction was made to the above listed deviation: The firms Quality Assurance system was inadequate PRIOR TO 11/20/96 in that the firm failed to address and respond to allegations that technicians are "fixing plates" by manipulating controls to avoid repeating the tests.

On November 22, 1996, [redacted]

2. Supervision of technicians/technologist in the viral testing lab during performance of their duties was inadequate in that employees were not supervised on a continuous basis to assure that they do not deviate from established test procedures. According to lab technicians/technologists, supervisors (present) were overseeing lab techs for as little as a half hour per eight hour shift.

NOTE: On 12/20/96 the following correction was made to the above listed deviation: Supervision of technicians/technologists in the viral testing lab during performance of their duties was inadequate PRIOR TO 11/20/96, in that employees were supervised on a continuous basis to assure that they do not deviate from established test procedures.

[redacted]

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[redacted]

a. Due to lack of supervision, while performing assays on the Ortho ELISA system which is used for testing donors plasma for HBc (Hepatitis B Virus Core) and HCV Antibody detection and P24 HIV Antigen detection, employees have been able to circumvent the system where as a record of read plates could be obliterated before test results are transmitted and recorded in Safe Blood, the host computer system.

Employees have been able to turn the computer "off" and back "on" after pressing the F2 function key for "READ" and before pressing the F5 function which will automatically transmit final test results to the host computer system, Safe Blood. This has allowed techs to manipulate controls that were invalid by adjusting the color of the control(s), re-boot the computer and re-read the plate. Thus, the audit trail of the initial reading has been permanently lost. [redacted]

On November 19, 1996, Investigator Abel demonstrated to Randy Spiro, Bonnie Lupo, and Mary Jo Anzel that by turning computer "OFF" and back "ON" again after reading the plate (F2 function key, where results are displayed on the screen and before pressing the F5 function key for printing report and sending it to Safeblood), the PC reboots back to starting screen menu. Consequently, techs can read the plate many times thus preview the results and fix the plate if needed before any permanent records of reading is made on the PC's hard drive or in Safeblood. See Exhibit #P1 (Screen print-outs during demonstration) and Exhibit #P2 (SOP for reading plates).

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Mrs. Spiro was asked if the "off" and "on" in the PC terminal was evaluated for security risk concerning fixing plates. She stated "NO", because "I did not know about the computer's "off" and "on", nor have ever heard of any employees turning "off" and "on" the PC terminal to fix plates.

The system also allowed employees to scan the plate to be read and in cases where it had controls that were "out" replace it with previously read plate which had known passing controls. Consequently, the reader read plate with controls that were "in" (substituted plate) however, results were recorded for scanned plate number with controls that were "out".

[redacted]

DI WATER SYSTEMS:

3. There is no formal validation for the DI water system in the Virology ALT area (tank#07512606), Virology Washroom (tank#07512605), Virology Abbott Area (tank#07512610) and Olympus Lab Washroom area (tank#07512602).

4. On 11/18/96, sensors for [redacted] water tanks for low water indicators were noted to be disconnected from the Parallel Processing Center numbers #5,6,7, and 8. According to (Mr. Owen Blackwood) the tech performing testing at the time, these sensors were rigged inoperative because they are not reliable and often sound false alarms.

   During this time the screen displayed the message "Water Level Low". This problem with the sensors was not communicated to the supervisors or the Quality Control Staff.

5. DI water point of use hoses were noted coiled around the sink faucet with residual water trapped in the part of the tubing creating an environment for bacterial growth. On 11/12/96 the hoses were observed laying at the bottom of the sink exposed to contamination in the sink.

6. There is no standard operating procedure which establishes the criteria for changing the [redacted] micron filters on the DI water system (Exhibit #P3, pages 1-6 SOP).

A. Sanitization schedules for sanitization of the DI systems are not defined in the SOPs (See Exhibit #P3, Page 4, psts 6.10.3). Criteria for sanitization of the DI systems are not defined. The systems operated with TNTC counts (see Exhibit #P4) and was not sanitized until the 1½ months later in some instances (FDA-483, Point #7).

B. The standard operating procedure for Determining the Purity of Deionized water, CLF-04.0018.C, 10/95 - page 5, para.6.8.1 specifies "The pre-filter should be changed if the pressure drops bellow 30 psi, or ..." where as the DI water log specifies "Change Filters Every 6 Months or During Service Call (Exhibit #P4).

Virology ALT area:

7. The following discrepancies were noted in the DI water testing logs:

A On 3/28/96 (date appears to have been changed from 2/28/96 to 3/28/96) sterility count results were TNTC (too numerous to count). The comments section states "service called 2/28/96, results were TNTC-(too numerous to count). On 4/1/96 .22 micron filters were ordered. On 4/8/96 filter was changed and on 4/5/96 system sanitized."

This indicated that the system was operating out of specification between 2/19/96 and 2/28/96 when the last test showed 0 counts and 4/5-8/96 when the system was sanitized and the .2 micron filter was finally changed (Exhibit #P4, Page 1).

TNTC results were again found on 4/30/96 - no action was taken, and 5/29/96 - the filter was changed (Exhibit #P4, Page 1).

There is no documentation to show that the system was shut down for the periods when sterility of DI water was out of specifications (Exhibit #P3, pages 1-6 SOP, and Exhibit #P4).

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Olympus Washroom DI System discrepancies:

8. TNTC results were found on 3/38 and 4/30/96 - the filter was not changed until 4/8/96 and system not sanitized until 5/96 (Exhibit #P4, page 3).

   A. Seasonal variations of the municipal water and its impact on the DI water quality have not been determined through validation (Exhibit #P3, pages 30-52).

   B. There is no cleaning validation for the [redacted] system DI water tanks (Exhibit #P3).

9. On 11/12/96 [redacted] #4 displayed a warning message "Illegal Path Specified" after the tech read a plate for (P24 HIV Antigen). The technician did not notify the supervisor or question the message. The tech, supervisor nor Quality Control personnel were able to explain what this message indicates or the corrective action to be taken.

   Transmission to Safeblood was completed. According to technicians, this message has been appearing on PC screens in this area for several days.

Joe Gardner subsequently explained that data for P24 test results were collected on separate PC for verification against Safeblood data. That port was disconnected on November 11, 1996, causing the warning display.

10. Validation protocols for upgraded software on [redacted] system Ver. [redacted] (implemented 2/27/96) (Exhibit #P5) and [redacted] system [redacted] Ver. [redacted] (completed July 1996) (Exhibit #P6) do not contain diagrams or lists of hardware configurations and peripheral devices within the system.

    A. The validation team and individual responsibilities of team members are not specified in the protocol.

11. The standard operating procedure 02.0011.A, (Exhibit #P7, pages 1-6), effective 5/2/96 does not specify at what frequency passwords assigned to users for laboratory systems should be changed. User list, dated August 15, 1995 (Exhibit #P7, pages 7-10) and user list, dated October 3, 1996 (Exhibit #P7, pages 11-14) show that users/managers did not change their access passwords since August 15, 1996.

    A. Quality Control employees having full access to Ortho system were found to be unfamiliar with the system and were not able to follow the menu presented on the system.

On November 12, 1996, Beverly Williams, QC Manager, and Karen Clare, QC, both with "M" (manager) security access level were unable to explain to the investigator Abel warning on the screen "Illegal Path Specified" (FDA-483, Point #9). They could not follow the screen menus within their security access level.

12. The firm fails to maintain a written standard operating procedure for the preparation of platelet rich plasma from CPD-1 units of whole blood. Plasma is separated into a satellite bag containing 100 mL of Adsol (Exhibit #P8).

On November 5, 1996, during the inspection, investigators Peter Abel and Jacqueline Diaz-Albertini observed component technician Patrick Shakes demonstrate how platelet rich plasma (Recovered Plasma) is made from a CPD-1 unit. A CPD-1 unit is a unit of whole blood which is collected in a blood bag which contains the anti-coagulant CPD. Usually the units used for pediatric transfusions are those red cells which do not contain the anti-coagulant Adsol. The anti-coagulant used in these units are CPD. These CPD units are collected in a triple blood bag.

These triple blood bags contain three bags, the bag in which the whole blood is collected in the CPD anti-coagulant, the plasma bag which contains the Adsol and a platelet bag for when a platelet product is made. When a pediatric unit is requested without the anti-coagulant Adsol, the red cells are labeled CPD and the plasma bag containing the Adsol is labeled recovered plasma. The platelet bag is used if platelets are made. During the observation of this tech making a recovered plasma unit from this CPD unit, there was no standard operating procedure which addressed the preparation of this recovered plasma product which can contain up to 100 mL of Adsol.

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The firm uses double (Barcode 52), triple (Barcode 53), and quad (Barcode 54) [redacted] blood collection bags (Exhibit #P9). Investigation into allegation that the firm ships Recovered Plasma containing 100 mL. Adsol per bag to Swiss Red Cross confirmed that occurred in case where plasma is recovered from whole blood drawn into triple AS-1 Baxter Collection Bags (Barcode 53) (Exhibit #P9, pages 4-6), and from there it is separated into satellite bag (PL146, Bar Code 06, Exhibit #P9, page 5) containing 100 mL. of Adsol. This is done in cases where whole blood is converted to CPD red blood cells (for pediatric or special use where no Adsol is permitted), and to platelets and recovered plasma (product code 19501 - Recovered Plasma Liquid, or 19601 - Recovered Plasma). NYBC has a Short Supply Agreement with [redacted] to supply Recovered Plasma, Frozen and Liquid (Exhibit #P10). The agreement does not have provisions for shipping Recovered Plasma containing Adsol. Furthermore, product is not labeled to contain Adsol (Exhibit #P11 - Examples of Recovered Plasma, Units #6744948, #6738174, #7629018, #6744961, containing 100 Adsol, and Exhibit #P12 - Labeling for Recovered Plasma Bar Code 19801, 19601, and 19501, with product insert).

Example of Recovered Plasma collected into satellite bag after Adsol was expressed into primary collection bag containing red blood cells, thus recovered plasma contains only residual Adsol is Exhibit #P13, pages 1,3, and 4 - , Unit #6735715, and #6745380. Recovered Plasma collected into platelet bag with no Adsol as Unit #6746332 (Exhibit #P13, page 2). Example of Shipment of Recovered Plasma to Swiss Red Cross is submitted as Exhibit #P14. Only Recovered Plasma with bar code 19601 or 19501 would contain 100 mL Adsol per satellite bag.

Mrs. Jenni Lee Robins provided summary of shipment of Recovered Plasma to [redacted] from April 1995 to October 1996 (Exhibit #P15). The incidence of Recovered Plasma shipped to [redacted] for fractionation was calculated to be approximately [redacted] of total shipped (Exhibit #P15) based on information from shipments during April 1, 1996 and September 15, 1996 [redacted] units converted to CPD red cells, platelets, and Recovered Plasma [redacted] (See Exhibit #P16 for code description of blood product components and collection bags and component lab processing report for October 30-31, 1996 (Exhibit #P17). On November 8, 1996, Mrs. Robins stated that as of November 16, 1995, NYBC will change the process so Adsol does not end up in the plasma. She further stated that all Recovered Plasma with Adsol will be quarantined ([redacted] and will not be shipped to [redacted] until the issue is resolved.

According to management, the weight of the Adsol is deducted from the total weight of the Recovered Plasma collected. Consequently, the volume of the Recovered Plasma collected is correctly recorded on the label.

13. The firm fails to maintain a written standard operating procedure for the re-testing of individual samples voided by either the technician or the instrument. On 7/18/96 [redacted] #3 serial number 01657-96 was taken out of service, sample numbers 7600809, 7600810, 7600811, 7600813, 7591425, 7591431, 7591432, 7591433, 7591434, 7591435 and 7591436 were not listed on the Invalidation of Test results form.

NOTE: During review of this exhibit it was found that on pages 2 and 3 of exhibit #J2 a total of 38 samples, numbers 7652909 through 7652946 were also not documented on the Invalidation of test results.

Exhibit #J1 is a copy of the mechanical deficiency report, dated July 16, 1996, which indicates that [redacted] Serial Number 01657-96 was taken out of service due to an error code 2.1.1.3.0 "Internal Error" "No status on well". Attached to this exhibit is the maintenance record for the [redacted] for the month of July 1996.

Exhibit #J2 is a copy of the Invalidation of Test Results, dated July 18, 1996, which indicates that for the HBsAg test tray numbers 5048032, 5048035, 5048038, and 5048041 were invalidated due to PPC internal error (2.1.130). PPC #3 was taken out of service, tubes were pulled and re-tested. Pages 2 and 3 of this exhibit show that a total of 38 samples numbered 7652029 through 7652946 were not documented on the Invalidation of Test Results form.

Exhibit #J3 is a copy of the Invalidation of Test Results dated 7/18/96 which indicates that trays numbered 5092893, 5092902, 5092896, and 5092899 were invalidated. Page 3 of this exhibit has a total of 11 samples numbered 7600809 through 7591436 which are not documented on the Invalidation of Test Results form. All sample numbers are listed above in observation number 13.

14. The firms fails to maintain a standard operating procedure indicating the time interval at which the incubation schedule, substrate and conjugate addition, should be signed by the technician performing the assay. During the inspection it was observed that the technician had failed to sign the incubation schedule, at the time of testing, for plate identification number CA0805 dated 11/12/96. The technician was later requested by a supervisor to sign the test data.

During the inspection, it was observed that on November 12, 1996, the technician had failed to sign the incubation schedule, at the time of testing, for the HBC assay plate identification number CA0805, dated November 12, 1996. The technician, on November 14, 1996, informed the investigators that he was later requested by a supervisor to sign the test incubation schedule later that day (11/12/96) after testing was completed).

15. The Quality Control records at this facility shows that the component lab does not always perform the daily tare and weekly calibration of the laboratory scales as per SOP. For example: During the month of December 1995; March 1996; July 1996; and April 1996, there was no documentation of calibrations.

Investigator Taha's review of the firm's Component Lab Daily Tare and Weekly Calibration of Scales, from September 1995 through September 1996, revealed no documentation of calibration was performed during the month of September 1995, December 1995, March 1996, July 1996, and April 1996 (Exhibits #T2). The written SOP states that the quality control check for laboratory scales must be performed daily and weekly (Exhibit #T3).

Mary Jo Anzel, Director of Central Laboratory stated that she will speak with the manager of the component lab to correct the observation.

16. The component laboratory failed to identify the person responsible for the laboratory centrifuge(s) daily Quality Control testing records, dated March 3, 1996 and August 19, 1996.

Investigator Taha reviewed the firm's daily centrifuge quality control records from October 1995 through October 1996, revealed the records are not being signed by the responsible employee. For example: March 3, 1996, and August 19, 1996 (Exhibit #T4, 4 pages).

In addition, the timer check for centrifuge SN 6015477, was not performed on October 3, 1996. The temperature check was not performed for centrifuge(s) SN 8900697, SN 6015477, SN 6650, and SN 6642, on October 18, 1996 (Exhibit T4, 2 pages).

Mary Jo Anzel stated that she will review the records and speak with the manager of the Component Lab.

17. The Olympus Laboratory failed to perform the quarterly maintenance check for the [redacted] equipment used for ABO/Rh, syphilis, CMV and antibody testing. There was no maintenance performed for the following:

a) [redacted] - May 18, 1996
b) [redacted] - May 13, 1996; September 13, 1996
c) [redacted] - May 10, 1996; May 13, 1996

Please Note: Corrections for [redacted] date should be May 8, 1996, instead of May 18, 1996, and for PK 7100 #D, date should be September 13, 1996, instead of May 13, 1996.

According to Nancy Nikolis, Assistant Manager of the Olympus Lab, the firm employs [redacted] to perform the maintenance of the [redacted] equipment(s), located at the [redacted] Ms. Nikolis stated that the [redacted] service personnel is responsible for the quarterly maintenance and calibration for the three equipment. However, Ms. Nikolis stated that there is no written SOP available at the lab to show that the contract firm [redacted] conducts the quarterly maintenance.

Ms. Nikolis only provided to the investigators a copy of the [redacted] Maintenance Contract Agreement with New York Blood Center, dated April 24, 1996 (Exhibit #T5).

Investigator Taha's review of the [redacted] maintenance and calibration records revealed that no service was made on May 8, 1996 for [redacted], no check was made on May 13, 1996 and September 13, 1996 for [redacted] and no service was performed on May 10, 1996 and September 13, 1996.

The management made no comments for the above observation.

18. The Olympus Lab failed to perform the Preparation of Bi-Annual Plate cleaning solution for the [redacted] plates, as per SOP. There was no detergent/disinfectant solution prepared for October 1996.

    NOTE: On 12/20/96 an addendum was made to the above listed observation: RECORD FOR THE BIANNUAL CLEANING ON 10/31/96 WAS PROVIDED FOR THE ABOVE.

On October 31, 1996, Investigator Taha reviewed the firm's preparation log for the Bi-Annual Cleaning [redacted] plates. The preparation log showed that no disinfectant/detergent cleaning solution was prepared for October 1996 (Exhibit #T6). The firm's SOP 6.4, page #3 - Maintenance for the [redacted] plates, states "Preparation of Bi-annual plate cleaning solution (Exhibit #T7).

During the discussion with the management on December 20, 1996. Mary Jo Anzel, Director of Central Testing Laboratory stated to the investigators that Mr. Hendricks, Supervisor of Olympus Lab, prepared the cleaning solution on October 31, 1996, but did not have a chance to document on the preparation log sheet because at that time, Mr. Hendrick could not find the log sheet on October 31, 1996. Mary Jo Anzel stated that she has the signed preparation log sheet, dated October 31, 1996 for the investigator to review. Ms. Anzel provided this log sheet to us as Exhibit #T8.

19. The firm failed to date and identify the responsible person making corrections to the sterile connecting device work log records on March 27-28, 1996; and April 17 & 20, 1996 (Exhibit #T9).

Management made no comments to the above observation.

20. Failure to identify the responsible person making corrections to the [redacted] daily temperature sheets for July 1995, September 1995, December 1995, and March 1996 (Exhibit #T10). In addition, the weekly and monthly maintenance records for the [redacted] were not reviewed and dated by the responsible supervisor for October 1995 (Exhibit #T11).

Mary Jo Anzel stated that she will speak with the managers and supervisors of the viral laboratory with regards to the observation.

21. The firm failed to perform the monthly maintenance Q/C of the [redacted] during March 1996, May 1996, and July 1996.

The [redacted] (Software Version [redacted]) is a computerized system used to monitor temperatures of the entire laboratory facility of the Central Testing Lab, which includes all laboratory equipment(s).

According to Mr. Joe Gardner, Manager of Special Projects, he oversees the overall operation of the [redacted] data collector and is responsible for its monthly maintenance check.

The SOP (6.0) for the [redacted] data collector states that a monthly test for the following: High temperature, low temperature, power failure/battery test, etc. should be performed (Exhibit #T12).

Investigator Taha reviewed the data sheets for the maintenance check of the [redacted] collector from January 1996 through October 1996, and found no maintenance check was conducted for the month of March 1996, May 1996, and July 1996. Mr. Gardner stated during the inspection that "he missed a few months".

22. Notification has not been submitted to CBER prior to initiating changes in a timely fashion, as follows:

a) Employment of a new Director for the Central Laboratory facility (Mary Jo Anzel) in April 1995.

According to Mary Jo Anzel, in April 1995, NYBC management appointed her as Director of the Central Laboratory facility, which includes the Viral Testing Lab, Components Lab, Olympus Lab, and Labeling Lab. She is responsible for the overall administrative day-to-day operations for the whole laboratory.

During the inspection, we asked Bonnie Lupo if CBER was notified of the change in the administrative personnel in the production and testing facility of NYBS. Ms. Lupo stated "NO". Investigator Taha stated that NYBS is a licensed facility, and any changes in management or administrative personnel in the manufacturing facility , a Notification of Change should be relayed to CBER.

b) Upgrade of the computer software for [redacted] Version [redacted] Version [redacted] and [redacted] Version [redacted]

According to Bonnie Lupo, in July 1996 a software upgrade to [redacted] was made on the [redacted] and in May 1996, a software upgrade Version [redacted] was installed on the [redacted] For the [redacted] a software update was put in place in 1996, to Version [redacted] which includes the latest P24 antigen assay. The validation of the software upgrade was performed by Randy Spiro, Data Manager.

Mrs. Bonnie Lupo stated to the investigator that Notification of Software Changes/Upgrades for the manufacturing/testing equipment(s) was not reported to CBER. Ms. Lupo stated that Mr. Edwin Strum, V.P. of NYBC Regulatory Affairs is in charge of notifying CBER if need be.

23. Written Standard Operating Procedures have not been updated to identify the facility performing the calibration and maintenance for the [redacted] (Exhibit #T13).

The Olympus Lab has [redacted] units of [redacted] equiopment used for ABO/Rh, syphilis, CMV, and antibody testing. According to Nancy Nikolis, Assistant Manager, the calibration and maintenance for [redacted] are performed by [redacted]

The NYBC has a contract agreement with [redacted] to perform the monthly maintenance checks. The SOP maintained at the [redacted] with regards to equipment checks/maintenance has not been updated in that it does not describe the contract firm and its responsibilities.

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An FDA 483 was issued to and discussed with Jenni Lee Robins, Vice President/Responsible Head Blood Operations and other members of management on 12/20/96 pertaining to these deviations.

Attachments

1. FDA-482, dated October 29, 1996
2. FDA-482, dated November 2, 1996
3. FDA-482, dated November 22, 1996
4. FDA-483, dated December 20, 1996
5. CBER Assignment, dated December 19, 1996

Exhibits

P1. Screen print-out during demonstration of computer "off" and "on" function used to pre-read test results and fix plates.

P2. [redacted] SOP 09.0005B, 4/95, pages 4-8 - Reading Plates

P3. DI Water System, Maintenance SOP, diagram, service orders records.

P4. DI Water System Maintenance records from November 20, 1995.

P5. Validation of [redacted] upgrade to Version [redacted] installed February 26, 1996.

P6. Validation of [redacted] Version [redacted] and [redacted] Version [redacted] software/hardware upgrade installed May 28, 1996 to July 10, 1996.

P7. SOP 02.0011B - System Access, User List August 15, 1995 and October 3, 1996.

P8. Component Processing SoP for Adsol units.

P9. Labeling for [redacted] Blood Collection Bags Double, Triple, and Quad.

P10. Recovered Plasma Supply Agreement with [redacted]

P11. Example of Recovered Plasma collected into satellite bags with 100 ml. Adsol Unit #6744948, #6738174, #7629018, #6744961.

P12. Labeling for Recovered Plasma Bar Code 19501, 19601, and 19801, [redacted] Product Insert, Labeling of R. Plasma Unit #7439081.

P13. Recovered Plasma Unit #6745380, #6735715 with residual Adsol and Unit #6746332, with no Adsol.

P14. Shipment to [redacted].

P15. Statement from J.L. Robbins regarding Shipment of Recovered Plasma with Adsol.

P16. Code description for blood products, components, and collection bags.

P17. Components processed on October 30-31,1996.

P18. NYBS normal procedure to separate components from whole blood.

P19. NYBS Pedi Pac procedure to separate components from whole blood.

L1-- Lab employee signature list
L2-- Lab employee user number, group, and access level
L3-- Tech id from DMS
L4-- SafeBlood menu access by group and level
L5-- Training Tracker print-out for lab techs
L6-- Competency summary for techs
L7-- SOP for test monitoring activity
L8-- Floor plan of lab
L9-- List of monitors and their experience
L10--Section from Quality Manual concerning Internal Assessment
L11--Inspection items for QA audit of the lab
L12--Key elements and system checks for testing
L13--Examples of documented periodic audits of the lab
L14--Examples of completed QC checklists
L15--Unit audit trail in SafeBlood
L16-[redacted] non-usable test runs from 7/96 to 11/96
L17-[redacted] non-usable test runs from 10/96 to 11/96
L18--Repeat reactive rates for 1995
L19--Repeat reactive rates for Jan-Sept, 1996
L20--Prevalence rates, 1992 to 1996
L21a&b-- Floppy disks with Excel files of viral marker test cut-off values for January-July, 1996

L21c-- Floppy disk with Excel files of viral marker test cut-off values for September, 1996 and voided run information for 1996

L21d-- Floppy disk with Lotus files of reactive and confirmed rates for 1992-1996

T1-T1a-c. Copy of the firm's current NYBC/NYBS Organizational Chart.

T2. Copy of the firm's Component Lab Daily Tare and Weekly Calibration of Scales (5 pages).

T3. Firm's SOP on the daily and weekly Quality Control check for laboratory scales.

T4. Firm's daily centrifuge quality control records dated March 3, 1996, August 19, 1996, October 3, 1996, and October 18, 1996 (6 pages).

T5. Copy of the [redacted] Maintenance Contract Agreement with NYBC.

T6. Firm's copy of the preparation log for the Bi-annual cleaning of [redacted]

T7. Firm's copy of SOP 6.4, Maintenance for the [redacted]

T8. Copy of the firm's preparation log sheet October 1996.

T9. Copy of the firm's sterile connecting device work (4 pages).

T10. Copy of the [redacted] daily temperature sheets from July 1995 through March 1996 (6 pages).

T11. Copy of the firm's [redacted] for October 1995 (6 pages).

T12. Firm's SOP for the [redacted] (7 pages).

T13. Copy of the firm's SOP with regards to the calibration and maintenance for the [redacted]

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J1. Copy of the Mechanical Deficiency Report (MDR) dated 7/16/96.

J2. Copy of the Invalidation of Test Results form dated 7/18/96.

J3. Copy of the Invalidation of Test Results form dated 7/18/96.

Evelyn Taha
Investigator
New York District

Jacqueline Diaz-Albertini
Investigator
New York District

Peter Abel
Investigator
New York District

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