INSTRUCTIONS FOR
BLOOD BANK INSPECTION CHECKLIST AND REPORT
CMS-282

Note to Surveyors:

This form consists of portions of the FDA-2609. These portions are the only parts of the FDA-2609 that have been approved by OMB for use by CMS for CLIA purposes. In no way do the following instructions replace or supercede the CLIA regulations and guidelines.

When using the Blood Bank Inspection Checklist and Report to document deficiencies relative to FDA requirements referenced in the CLIA regulations, use:

D4270 - for deficiencies related to the proper testing of syphilis serology;

D4277 - for deficiencies related to the proper performance of HIV testing;

D4278 - for deficiencies related to the proper performance of hepatitis testing; and

D4475 - for deficiencies related to the proper performance of all other immunohematological testing, e.g., ABO group, Rh type, antibody screen, antibody identification and compatibility testing.

1. GENERAL INFORMATION

a-i. Enter name(s) of investigator(s), dates, and total time spent inspecting the blood bank.

Registration number, Medicare number/CLIA number; U.S. license number, if applicable (and location number); legal (corporate) and "doing business as" (DBA) names of establishment; address, zip code, and telephone number of location being inspected.

j. Indicate the type of operation by checking all appropriate boxes; for example, a blood bank may also have a transfusion service.

If blood is frequently drawn on mobile units, these sites should be included as part of the inspection. During an inspection of mobile sites, emphasis should be placed on areas such as adequate supervision, blood storage, and temperature control.

l. The establishment should have a validated pink copy of Form FDA-2830, Blood Establishment Registration and Product Listing, for the current calendar year or evidence of having submitted same. If the data on the registration form is not correct, list corrections to be made in comments, and instruct the establishment to submit in writing the updated information to the Division of Product Certification (DPC) (HFB-240), 8800 Rockville Pike, Rockville, MD 20892. If changes in the name and address, Medical Director, manufacturing procedures, or products have occurred, they should be reported to DPC in order to update the Form FDA-2830. For licensed establishments, changes in name, location, responsible personnel, and important manufacturing procedures must be reported to DPC according to 2l CFR 601.12.

2. RESPONSIBLE INDIVIDUALS & PERSONS INTERVIEWED

In unlicensed hospital blood banks, as a matter of courtesy, the hospital administrator should be notified that the blood bank is to be inspected.

a. The director will usually be the physician responsible for the blood bank or perhaps for the entire laboratory. It is not necessary to record the name of the hospital administrator on the checklist; however, you should note it in case the inspection reveals problems that should be addressed in a Statement of Deficiencies.

e. Enter name of person(s) with whom the overall inspection was discussed. The discussion should include the Director, if possible.

4. OPERATIONS

This section is included in order to determine the scope of the establishment's operation. Before completing this section, the investigator should determine, if possible, the times at which specific products will be processed or functions performed so that he/she will be able to observe as many operations as possible. For example, if blood is being collected only at the time of his/her arrival, it would be prudent to proceed directly to the donor area so that donor screening and collection could be observed.

PART B - LABORATORY

B1. (a) Licensed antisera - some establishments may "otherwise meet the requirements" for ABO and Rh licensed antibodies by producing their own antisera. If so, production records that are in compliance with the requirements for the manufacture of these products specified in 21 CFR 660, Subpart C must be kept. Licensed blood banks must have CBER approval to use such antisera.

Test procedures must be performed according to the protocols described in the blood bank's SOP. Test methods used for ABO, Rh and antibody screening, which are different from the manufacturer's instructions, should not be cited as deviations if they are not prohibited by the manufacturer, have been demonstrated to be satisfactory, or have been approved for use by CBER. For example, the Microtiter plates and Groupamatic machines may be used for ABO, Rh, and antibody testing. The reagents must be tested and shown to perform adequately or satisfactorily when using these techniques.

B1. (d) Blood which tests Rho(D) negative must be confirmed by further testing (usually D^u) unless it is labeled in accordance with 21 CFR 640.5(c). Acceptable methods for further testing to confirm D negatives include use of the antiglobulin method, and use of special channel on the Kontron Groupamatic, Olympus PK700, or the Gamma STS-M automated blood groupers. Licensed blood establishments should have a letter from OBER approving their use of an automated blood grouper for D^u testing.

Not all anti-D reagents may be used for D^u testing; the package insert must include directions for D^u testing.

B1. (f) The investigator should check expiration dates for all test reagents for required tests to be certain they are in-date when used to test blood and blood products. Procedures have been approved to use reagents with the Groupamatic™ beyond the dating period, provided a proper set of controls is used. Licensed establishments should have a letter from CBER on file indicating that a protocol has been submitted and approved for this procedure. Rare reagents, e.g., anti-Jk^b, anti-Le^b, etc., are sometimes used beyond the expiration date; this is acceptable only if adequate controls are used and the reactivity and specificity of the reagents are documented.

B1. (g) The reactivity and specificity of reagents are generally confirmed by testing at least one positive and one negative control sample. The negative controls are not essential for ABO reagents because the antithetical cell and serum results provide confirmation of test accuracy. The Anti-Human Globulin (Coombs) reagent must be tested each day of use with an IgG sensitized ("Coombs" control or "check") cell. A record of all quality control tests must be kept.

B1. (i) The manufacturer's instructions specify that the storage requirement for Anti-A, Anti-B, and Anti-D reagents is between 2-8˚C; however, it is accepted practice for these reagents to stay at room temperature for the duration of the working day. This will usually not diminish the potency of the products throughout the normal period of use.

B2. Laboratory records for automated testing should include the name of the person who prepared the reagents. If the system does not provide positive sample identification, a record must be made for the loading pattern and the record must include the name of the person(s) who loaded and unloaded the sampler; if results are visually interpreted, the record must include the name of the person(s) interpreting and transferring the results.

B2. (b) If the facility used automated methods for ABO and Rh typing at the time of licensure, a separate letter of approval from CBER for automated ABO and Rh testing will not be issued to the establishment. Approval for this procedure must be obtained if a licensed facility converts from manual to automated methods.

B2. (e) Reagents used in microplate test systems should be recommended for this use by the manufacturer's package insert. If not originally licensed for the use of the microplate test system, a licensed establishment should have on file a letter from CBER approving its use. Gamma-Micro-U microtiter plates are approved for use only with the Gamma microtiter reagent unless the reagent has been evaluated and found acceptable for such use according to an established protocol.

B2. (g) Occasionally an automated blood grouping instrument is unable to interpret an ABO or Rh result. The facility should have an SOP to follow-up with further testing to obtain a result (usually by manual methods) and to up-date the testing record (data entry and verification).

B3. All units of blood must be tested by an acceptable serological test for syphilis (STS). Indicate in comments the name of test performed.

B4. (a) Each unit of blood must be tested for HBsAg by a licensed third generation test. Third generation tests include radioimmunoassay (RIA), reverse passive hemagglutination (RPHA), or enzyme-linked immunosorbent assay (ELISA or EIA). The testing must be done on a sample of blood taken at the time of donation.

Each unit must be tested for antibody to HIV-1 with a licensed test kit. As of March 1991, there are three types of licensed kits based upon different manufacturing technologies:

1) Whole viral lysates:
   Abbott Laboratories
   Cellular Products, Inc.
   Pharmacia Diagnostics, Inc. (formerly Electro-Nucleonics)
   E.I. duPont de Nemours & Co., Inc.
   Genetic Systems
   Organon Teknika Corporation
   Ortho Diagnostic Systems, Inc.

2) Recombinant DNA Technology:
   Cambridge Biotech - ELISA and Latex Agglutination (LA) Test. (The LA test is not recommended for the use in routine screening of blood donor samples. See the February 1 and August 1, 1989, memoranda "Use of the Recombigen HIV-1 LA Test" for further information.)

3) Synthetic peptides:
   United Biomedical (Olympus) - ELISA

The licensed Western blots for confirmation testing are manufactured by Biotech Research Laboratories, Inc. (U.S. license no. 1035) and distributed by E. I. duPont de Nemours & Co., Inc. (U.S. license no. 967); Epitope, Inc. (U.S. license no. 1133); and Novapath HIV-1 Immunoblot Kit by Biorad (U.S. license no. 1109).

A licensed test for the antibody to HIV-2 kit is manufactured by Genetics Systems; testing for anti-HIV-2 is recommended (see the April 23, 1992, CBER memorandum to registered blood establishments "Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products").

B5. (a) SOP's should be reviewed to assure that test procedures are performed according to the manufacturer's current specifications. Observe testing procedures and review records to determine that samples and controls are diluted properly; the time and temperature of incubation are accurate; the instrument and equipment settings (i.e., the mode of the spectrophotometer, amount delivered by the automatic dilutors) are correct; calculations are accurate (i.e., cutoff); and initially reactive results are repeated in duplicate. Refer to the following memoranda for further information: Recommendations for the Management of Donors and Units that are initially Reactive for Hepatitis B Surface Antigen (HBsAg)" dated December 2, 1987, and "Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products" dated February 9, 1990.

B5. (b) If automated testing equipment is interfaced with a computer system, determine that the equipment is designed for such use. Documentation should be available that the equipment was qualified prior to interfacing and that the system was validated. See Section K, Computerization, for further guidance.

B5. (c) In the past, the area used for HBsAg and anti-HIV testing would, by design, be in rooms separated from other blood bank activities. This is no longer considered to be important as all blood samples should be treated as capable of transmitting an infectious disease, and Biosafety Level 2 precautions should be applied in all areas where open samples are handled. However, if RIA procedures are used in the facility these areas still must be physically separated from other areas. Work areas, such as counter tops, should be constructed of non-porous materials and designed to permit excessive traffic of unauthorized personnel through viral testing areas.

B5. (e) Testing data must be reviewed by personnel (usually supervisory) to assure that results are calculated accurately, interpreted appropriately, and run failures, if occurring, are resolved. The invalidating of results or test runs by the firm must be documented, including the reason for invalidating.

B6. Most blood establishments will be participating in a proficiency testing program, either an in-house developed or an established program such as the College of American Pathologists (CAP), AABB or CDC. Review the records of the proficiency testing and determine that the facility performs appropriate corrective actions in the event unacceptable results are obtained.

A proposed rule was published in the June 6,1989, *Federal Register* to require that each establishment or laboratory responsible for performing FDA required tests for HBsAg and anti-HIV participate in an approved program to demonstrate proficiency in performing these tests. The final regulation proposed by FDA has not been published, however, the final rule proposed by CMS, which regulates all laboratories, was published in the February 28,1992, *Federal Register*. This final rule requires laboratories to have policies and procedures for an ongoing program to assure that employees are competent and maintain their competency to perform their duties.

B7. Refer to the following memoranda sent to registered blood establishments regarding recommendations for viral testing: "HTLV-l Antibody Testing," November 29, 1988, and "Testing for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)," November 29, 1990. A memorandum will be sent in the near future for recommendations of testing blood and blood components for antibody to Hepatitis B Core (anti-HBc).

B10. Records of the results of all laboratory testing, including viral testing performed on site, must be maintained.

B11. (a) The results and interpretations of all (initial and repeat) tests performed and an explanation of any symbols or phrases used in reporting results should be provided by the testing facility to the blood bank. The blood bank should have an SOP for the interpretation of the reports obtained from outside testing laboratories and written assurance that the outside testing laboratory interprets that results according to FDA requirements. The raw test data, i.e., absorbance readings from the spectrophotometer, need not be sent to the blood bank. In addition, if the blood establishment is reentering donors with previously repeatably reactive anti-HIV test results, the establishment must determine if the outside testing laboratory is performing Western blot assays with licensed test kits.

B11. (e) At this time, 21 CFR 607.65(g) exempts CLIA laboratories approved for Medicare reimbursement that perform hepatitis and anti-HIV testing on donor blood for other registered facilities from the requirement to register with the FDA. If not registered, as applicable, the testing laboratory should be asked to voluntarily register. Notify the FDA to send the testing laboratory Form FDA-2830, Blood Establishment Registration and Product Listing, in accordance with the procedures described in Field Management Directive 92. Licensed blood establishments may have viral testing performed at testing facilities which are also licensed, and only with CBER approval (see CFR 640.2(a)).

B11. (f) Except for emergencies, no units should be issued until written hepatitis and HIV antibody test results are in the possession of the blood bank.

B12. Refer to the October 26,1989, memorandum "Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors").

PART H - COMPATIBILITY TESTING AND TRANSFUSION REACTIONS

H1. Compatibility testing should be performed in an area sufficiently removed from other areas to eliminate distraction or the introduction of errors in testing.

H2. Hospitals may elect not to crossmatch blood for certain surgical procedures that usually do not require the transfusion of blood. This procedure is referred to as "type and screen" and requires: 1) determination of the patient's blood group; 2) tests of patient's serum for unexpected antibodies; and 3) availability of units of blood in case the patient does need blood during the operation.

Following a December 1981, FDA sponsored workshop, the Blood Products Advisory Committee recommended revising 21 CFR 606.151 to permit alternative methods for the antiglobulin phase of the crossmatch. (See the December 14, 1984, memorandum to blood establishments "Equivalent Methods for Compatibility Testing.") The following elements must be adhered to if an antiglobulin phase of the crossmatch is not done (these do not apply to autologous units):

1. A determination of the ABO and Rh groups of the donor and recipient using licensed blood grouping sera or their equivalent.
2. Antibody detection tests that will demonstrate significant alloantibodies active at 37°C in the serum or plasma of a previously transfused or previously pregnant donor.
3. Testing of the recipient's serum for unexpected alloantibodies by the antiglobulin technique or an equally sensitive method that will demonstrate significant antibodies reactive with the donor's cells at 37°C.
4. Procedures to expedite transfusions in life-threatening emergencies and, if applicable, procedures for testing blood for neonatal transfusions and autologous transfusions.

In addition, other methods for the compatibility testing may also be appropriate. These methods include, but, are not limited to, the use of a 72 hour old patient specimen and the use of plasma (rather than a clotted, serum specimen) for compatibility testing. SOPs should be current and reflect the procedure performed by the facility.

H4. The hospital or transfusion service need not repeat the antibody screen if it has been performed by the supplier, nor is it necessary for the hospital or transfusion service to perform a minor crossmatch since the requirements of 21 CFR 606.151(d) have been met. If the donor's blood has not been tested for irregular red blood cell antibodies, records should show that a minor crossmatch was performed using donor's serum and recipient's cells.

If retesting for ABO, Rh, unexpected antibody, etc., of Whole Blood and Red Blood Cells is performed on units obtained from outside facilities, records should be maintained.

H5. The recipient's blood sample should be identified by name and number to ensure positive identification.

Donor and recipient blood samples should be saved for at least seven days after transfusion in case there is a need for retesting.

H7. SOPs should be available to expedite testing for transfusions in a life threatening emergency. Documentation should include signature of the requesting physician. If crossmatches are not completed, sufficient documentation should be available.

H8. Records should be kept of receipt of recipient's sample and the ABO and Rh test results; lot number of reagents used for testing; and routine and emergency crossmatches and direct antiglobulin testing (if done). The vital signs of a recipient are not required to be on file at the blood bank.

H10. The blood bank's SOP manual should list and describe recipient reactions it considers to be adverse, as well as the procedures to be followed for handling and investigating these reactions. Recipient reactions usually not considered serious include low fever and chills of short duration, hives, or urticaria. Serious adverse recipient reactions usually include hemolysis, bacteremia, or septicemia.

If the blood bank acts as a transfusion service and receives blood from other sources, errors in the ABO and Rh grouping should be reported to the suppliers. Procedures should be established between the suppliers and users of blood and blood products for monitoring recipient adverse reactions which occur outside the supplying facility. If the supplier of mistyped blood is a licensed establishment, it is the responsibility of that establishment to report any errors to CBER, Office of Compliance.

PART I - STORAGE, DISTRIBUTION

I1. (b) Blood products should be stored separately from hazardous or potentially contaminating agents, but not necessarily in a different refrigerator.

I1. (c) Quarantine procedures are a very important area in the control procedures to prevent the distribution of unsuitable units. Separate storage areas should be maintained for untested units, for units which are not suitable for use (units to be retested or repeatably reactive), and for units which are suitable for distribution.

I1. (d) Units of blood intended for autologous use should be stored in an area separate from units for homologous use.

I2. Whole Blood, Red Blood Cells, and Liquid Plasma should be stored between 1 and 6˚C. Room temperature Platelets and Platelet Rich Plasma between 20 and 24˚C or 1 – 6˚C as indicated on the product label. Fresh Frozen Plasma, Plasma and Cryoprecipitated AHF should be stored at -18˚C or colder.

All required temperatures should be maintained. Fluctuations outside storage temperature limits must be documented as to the possible reason, and any action required to maintain the blood or components at the proper storage temperature must also be documented.

I3. Blood should be visually inspected at the time of issue for any abnormality, such as hemoglobin in the plasma from red cell lysis, purple tinged red cells due to bacterial contamination, or blood clots.

I4. Whole Blood and Red Blood Cells should not be shipped with any products that are contaminated and hazardous.

Fresh Frozen Plasma, Plasma and Cryoprecipitated AHF must be shipped at -18˚C or colder; Whole Blood, Red Blood Cells, Liquid Plasma at 1 – 10˚C; and room temperature Platelets and Platelet Rich Plasma as close as possible to 20 – 24˚C. Facilities should have procedures to show that shipping containers maintain products at their appropriate temperature.

I5. Reissue requirements are as follows: The container must have a tamper-proof seal which remains unbroken; and tamper-proof pilot tube or segment must be attached; records should indicate that the blood was maintained at 1 – 10˚C while outside the control of the establishment; and the unit must be inspected prior to reissue. Blood issued for transfusion to a ward or operating room and not refrigerated may be reissued if the unit is returned to the blood bank within 30 minutes (studies have shown that the unit of blood sitting at room temperature usually maintains a temperature of <=10˚C for 30 minutes).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICES
FOOD AND DRUG ADMINISTRATION

BLOOD BANK INSPECTION CHECKLIST AND REPORT

1. GENERAL INFORMATION

a. NAME OF INVESTIGATOR(S)

b. DATE(S) OF INSPECTION

c. TOTAL INSPECTION TIME IN THE BLOOD BANK

d. LEGAL NAME OF THE BLOOD BANK

e. DBA

f. ADDRESS OF ESTABLISHMENT BEING INSPECTED

g. TELEPHONE NUMBER

h. REGISTRATION NUMBER/MEDICARE NUMBER/CLIA NUMBER

i. U.S. LICENSE NUMBER AND LOCATION NUMBER

j. TYPE OF OPERATION *(Check all applicable)*

☐ BLOOD BANK ☐ TRANSFUSION SERVICE
☐ DONOR CENTER ☐ TESTING LABORATORY
☐ MOBILE SITE

k. TYPE OF INSPECTION *(Check all applicable)*

☐ SCHEDULED ☐ FOLLOW-UP
☐ PRELICENSE ☐ INVESTIGATION

l. ARE THERE CORRECTIONS TO BE MADE ON FORM FDA 2830, "BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING?"

☐ YES *(If "Yes" specify in comments)* ☐ NO

m. ARE ALL FIXED LOCATIONS REGISTERED?

☐ YES ☐ NO

n. HAS FORM FDA 483, "INSPECTION OBSERVATIONS" BEEN ISSUED?

☐ YES ☐ NO

o. HAVE DEVIATIONS CITED IN THE PREVIOUS INSPECTION BEEN CORRECTED?

☐ YES ☐ NO *(If "No" list continuing deviations in comments)*

2. RESPONSIBLE INDIVIDUALS AND PERSON(S) INTERVIEWED

a. NAME OF DIRECTOR, IF NOT LICENSED [606.20(a)]

b. NAME OF RESPONSIBLE HEAD, IF LICENSED [600.10(a)]

c. NAME OF SUPERVISOR(S)

d. NAME AND TITLE OF INDIVIDUAL(S) INTERVIEWED

e. NAME OF PERSON(S) WITH WHOM OVERALL INSPECTION WAS DISCUSSED

3. RESOURCE DATA

a. APPROXIMATELY HOW MANY UNITS OF WHOLE BLOOD ARE COLLECTED EACH YEAR?

_____

(1) HOW MANY OF THESE ARE AUTOLOGOUS? _____

(2) HOW MANY OF THESE ARE DIRECTED? _____

b. APPROXIMATELY HOW MANY UNITS OF WHOLE BLOOD AND RED BLOOD CELLS ARE RECEIVED FROM OUTSIDE SOURCES EACH YEAR?

_____

(1) HOW MANY OF THESE ARE AUTOLOGOUS? _____

(2) HOW MANY OF THESE ARE DIRECTED? _____

c. APPROXIMATELY HOW MANY UNITS OF WHOLE BLOOD AND RED BLOOD CELLS ARE TRANSFUSED EACH YEAR?

4. OPERATIONS (circle products prepared and activities conducted)

a. DONOR SUITABILITY AND COLLECTION (Whole blood)

(1) HOMOLOGOUS

(2) AUTOLOGOUS

(3) DIRECTED DONORS

(4) THERAPEUTIC

b. LABORATORY (For establishments that collect blood and/or prepare components, includes ABO & Rh and viral testing of blood components)

c. RED BLOOD CELLS

(1) ADDITIVE SOLUTIONS

(2) RED BLOOD CELLS, FROZEN

(3) RED BLOOD CELLS, DEGLYCEROLIZED

(4) REJUVENATING SOLUTIONS

(5) RED BLOOD CELLS, LEUKOCYTES REMOVED

(6) IRRADIATED BLOOD

d. PLASMA, LIQUID PLASMA, FRESH FROZEN PLASMA, AND RECOVERED PLASMA (If plasmapheresis or theraupeutic plasma exchange is performed, also complete form FDA 2722, "Plasmapheresis Checklist and Report.")

e. PLATELETS

f. CRYOPRECIPIATED AHF/POOLED (If plasmapheresis or theraupeutic plasma exchange is performed, also complete form FDA 2722, "Plasmapheresis Checklist and Report.")

g. LABELING

h. COMPATIBILITY TESTING AND TRANSFUSION REACTIONS

i. STORAGE, DISTRIBUTION

j. PLATELETS, PHERESIS

k. COMPUTERIZATON

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
B. LABORATORY				
1. ABO AND Rh TESTING:				
a. Are licensed reagents used for ABO and Rh testing?	640.5(b) & (c)			
b. Are red cells tested with Anti-A and with Anti-B, and is serum tested with known A and known B cells?	640.5(b)			
c. Are red cells tested with Anti-D?	640.5(c)			
d. Are D negatives confirmed by further testing?	640.5(c)			
e. Do test methods conform to manufacturers instructions?	606.65(e)			
f. Are reagents used within the dating period?	606.65(e)			
g. Are reagents tested as required to determine their capacity to perform as expected?	606.65(c)			
h. Are adequate quality control records maintained?	606.160 (b)(5)(i) & (ii)			
i. Are reagents stored properly as prescribed by the manufacturer(s)?	606.65(e)			
2. AUTOMATED TESTS FOR ABO AND Rh TESTING:				
a. If an automated system is used for ABO and Rh testing, write the name and model in comments.				
b. If automated or microplate testing is employed for ABO/Rh by a licensed establishment, has CBER approved?	601.12			
c. Are there procedures for accurate identification of samples?	606.100(b) 606.140(c)			
d. Are all reagents dated when put into use?	606.160(a)			
e. If the reagents have not been FDA approved or licensed for use with this instrument, have appropriate reagent evaluations been conducted?	606.140(b)			
f. If reagents are used in a dilution, has appropriate evaluation been conducted for each lot in use?	606.140(b)			
g. If the instrument is unable to determine the blood type, is there an SOP for manual ABO Rh testing which includes updating test results?	606.100(b)			
h. Is there a record documenting repairs and preventive maintenance?	606.160(b)			
3. SEROLOGICAL TEST FOR SYPHILIS:				
a. Are all units tested?	640.5(a)			
b. Do the test methods conform to manufacturer's instructions?	640.65(e)			
c. Are proper QC procedures performed each day of use?	640.65(c)			

ITEM	CFR NO.	HBsAg		Anti-HIV		COMMENTS - IDENTIFY BY NUMBER
		YES	NO	YES	NO	
4. HBsAg and ANTI-HIV TESTING						
a. Is each unit of blood tested for HBsAg by a third generation test for Anti-HIV?	610.40(a) 610.45(a)					
b. Are tests made on samples taken at the time of donation?	610.40(b) 610.5					
c. Are only licensed kits used for testing?	610.40(b) 610.45(a)					

ITEM	CFR NO.	HBsAg		Anti-HIV		COMMENTS - IDENTIFY BY NUMBER
		YES	NO	YES	NO	
B. LABORATORY *(Continued)*						
5. TESTING PERFORMED ON PREMISES: *(If testing is performed by an outside laboratory, see Item B10.)*						
a. Are tests performed in accordance with manufacturer's instructions?	606.65(e)					
b. Is automated equipment used during viral testing, operated and maintained according to manufacturer's instructions?	606.65(e)					
c. Are tests performed in an area segregated from component preparation?	600.11(e)(1) 606.40(a)(7)					
d. Are supplies and reagents used in testing properly disposed?	606.40(d)(1)					
e. Are test data reviewed before final testing results/interpretations are reported?	606.100(c)					
f. For invalid runs, are problems documented and resolved?						
6. PROFICIENCY TESTING: Is proficiency testing performed? If so,						
a. In what proficiency testing program is the laboratory participating?						
b. Are tests performed by the same personnel and on the same equipment, as routinely done?						
c. Is the performance rating acceptable?						
d. If not, is corrective action documented?						

ITEM	CFR NO.	Anti-HTLV-1		Anti-HCV		Anti-HBc							
		YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO
7. LIST ADDITIONAL TESTS PERFORMED:													
a. Name(s) of test(s). Fill in additional test name(s) in the chart.													
b. Are SOP's for test procedures available?	606.100(b)(7)												
c. Do test methods conform to manufacturer's instructions?	606.65(e)												
d. Are controls performed and interpreted correctly?	606.140												
e. Are all reagents used within the expiration date?	606.65(e)												

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
8. Are there SOPs for appropriate donor deferral (and reentry if applicable)?	606.100(b)(1)			
9. CHECK ALL THE TESTS/PROCEDURES THAT WERE OBSERVED; a. ABO and Rh Method: (1) ☐ Automated (Include name of equipment) (2) ☐ Microplate (3) ☐ Slide/Tube b. ☐ HBsAg c. ☐ HIV Antibody d. ☐ STS e. ☐ Anti-HTLV-1 f. ☐ Anti-HCV g. ☐ Anti-HBc h. ☐ Other (List in Comments Section)				
10. LABORATORY RECORDS:				
a. Are records maintained as required?	606.160(a)(1)			
b. Are manufacturer, lot number, and expiration date of reagents recorded?	606.160 (b)(7)(v)			

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
B. 10. LABORATORY RECORDS *(Continued):*				
c. Do records identify persons responsible for performing the testing procedures?	606.160(a)			
11. TESTING PERFORMED BY OUTSIDE LABORATORY:				
a. Do written test reports contain the results and interpretations of all tests performed?	606.160(a)(1) 606.160 (b)(2)(i)			
b. Does the blood bank have written assurance that the outside testing laboratory interprets test results according to FDA requirements?				
c. List laboratory(ies) performing test(s)	640.2(a)			
d. If blood bank being inspected is licensed, has CBER approved the use of this outside testing laboratory?	601.12			
e. Is (are) the laboratory(ies): ☐ (1) registered? ☐ (2) FDA licensed? ☐ (3) CLIA approved?	640.2(a)			
f. Are written test results in the possession of the collection facility before units are issued?	606.100(c) 610.1 610.40(b)(4)			
12. USE OF REACTIVE UNITS:				
a. Are HBsAg positive or Anti-HIV repeatably reactive units used in research or the manufacture of test reagents?				
b. If so, are units labeled to indicate reactive results and possible transmission?	610.40(d) 606.121(g)			
c. Was CBER notified for shipment of HBsAg positive products for further manufacture?	610.40(d)			
d. Was CBER approval obtained for shipment of Anti-HIV repeatably reactive products for further manufacture?	610.45(c)			

COMMENTS - IDENTIFY BY NUMBER

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
H. COMPATIBILITY TESTING AND TRANSFUSION REACTIONS				
1. COMPATIBILITY TESTING: Is compatibility testing performed?				
2. METHODS:				
a. Does the SOP for compatibility testing include the antiglobulin (Coombs) method or	606.151(c)			
b. An equivalent method which includes ABO/Rh groups, antibody screens, and positive identification of blood samples?				
3. SOP: Is the SOP followed?	606.100(b)			
4. ANTIBODY TESTING: If unexpected antibody testing was not performed on the donor unit, do records show that the compatibility test included a minor crossmatch; i.e., donor's serum and recipient cells, was performed?	606.151(d)			
5. RECIPIENT SAMPLE ID: Does the labeling of the recipient's blood sample insure positive identification?	606.151(a)			
6. REAGENTS:				
a. Are reagents used according to manufacturer's directions?	606.65(e)			
b. Are reagents used for required tests in-date?	606.65(e)			
c. Are reagent performance checks done each date of use?	606.65(c)			
d. Are reagents stored as prescribed by the manufacturer(s)?	606.65(e)			
7. EMERGENCY TRANSFUSIONS:				
a. Are procedures available for life-threatening emergencies?	606.151(e)			
b. Are records maintained of units issued before completion of cross-matches?	606.151(e) 606.160(b) (3)(v)			
c. Do records show subsequent completion of cross-matches?	606.160 (b)(4)(i)			
d. Do records include documentation of need for emergency procedures signed by requesting physicians?	606.151(e) 606.160(b) (3)(v)			
8. COMPATIBILITY TEST RECORDS:				
a. Are records maintained as required?	606.160(a)(1)			
b. Do records include results of compatibility tests, testing of patient samples, antibody screening, and identification?	606.160 (b)(4)(i)			
c. Do records include results of ABO and Rh confirmatory testing?	606.160 (b)(4)(ii)			
d. Do records indicate date of receipt of recipient's sample?	606.160(b)(4)			
9. TEST PROCEDURES: Were the following test procedures observed by the investigator? (Check all applicable): ☐ ABO and Rh? ☐ Cross-matching? ☐ Antibody screen?				

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
H. COMPATIBILITY TESTING AND TRANSFUSION REACTIONS *(Continued)*				
10. RECIPIENT ADVERSE REACTIONS:				
a. Are records kept of reports of suspected adverse transfusion reactions?	606.160(b)(6) 606.170(a)			
b. Does the blood bank have an SOP for investigating suspected adverse transfusion reactions?	606.100(b)(9)			
c. Are suspected adverse transfusion reactions reviewed by appropriate personnel?	606.170(a)			
d. When an adverse transfusion reaction results from a faulty product, do records indicate the manufacturer or collecting facility was notified, if applicable?	606.170(a)			
11. PLASMA DERIVATIVES: If plasma derivatives, e.g., Rh immune globulin, Factors VIII and IX, Albumin, etc., are distributed by the blood bank, do the records identify lot numbers and recipients?	606.160 (b)(3)(i)			

ITEM	CFR NO.	YES	NO	COMMENTS - IDENTIFY BY NUMBER
I. STORAGE, DISTRIBUTION				
1. PHYSICAL STORAGE:				
a. Are blood products stored on premises?				
b. Are units stored separately from hazardous or contaminated items?	606.40(a)(7)			
c. Do quarantine areas provide for storage of blood or components:	606.40(a)(7)			
(1) Prior to completion of tests?	606.40 (a)(3) & (4)			
(2) Not suitable for use?	606.40(a)(6)			
d. Are autologous units segregated?	606.40(a)			
2. STORAGE TEMPERATURES AND RECORDS:				
a. Is there an explanation for temperature deviations?	606.160(b)(3)			
b. Is a temperature recorder used? If yes,				
(1) Is it compared daily against the thermometer?	606.40(b)			
(2) Are blood bank temperature recorder charts changed at proper intervals?				
(3) Are charts retained (dated and initialed)?	606.160 (b)(3)(iii) 606.160(d)			
c. If remote storage refrigerators, e.g., ICU, are used, are storage temperatures monitored?	606.160(b) (3)(iii)			
d. Do all observed temperatures and temperature records meet standards?	610.53			
e. Are alarms checked on a regularly scheduled basis?	606.60(a)			
3. INSPECTION:				
a. Are blood and blood components visually inspected at the time of issue?	640.5(e) 640.11(b)			
b. Is a record of such inspections maintained?	606.160(b) (3)(ii)			
4. SHIPPING:				
a. Are blood products distributed to outside facilities? If so,				
b. Are they shipped in such a manner as to assure maintenance of proper temperature?	600.15			
c. Does the establishment use shipping containers that have been shown to maintain proper temperature in transit?	606.160(b) (5)(iv)			
5. REISSUE: If blood is reissued, are all requirements met?	640.2(e) 606.160(b) (3)(iv)			
6. LOOKBACK POLICY:				
a. Is there a retrospective review of records of prior donations for donors found to be anti-HIV positive?				
b. Does this review determine:				
(1) All components prepared?				
(2) The disposition of each component?				
c. Are consignees promptly notified of all indate products?				
d. Is there a procedure for notifying consignees of previous products prepared from positive donors within the past six months?				