



OHIO ASSOCIATION OF BLOOD BANKS



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Frequently Asked Questions Bar Code Label Requirements for Blood and Blood Components

Q. Is it true that we must label blood and blood components with specific machine-readable bar code information by April 26th, 2006?

- A. Yes, under the bar code label requirements final rule of Feb 26, 2004, products subject to the rule, including blood and blood components intended for transfusion, must be in compliance by April 26, 2006. The regulation for blood and blood components is located at 21 CFR 606.121(c)(13). The final rule is entitled: Bar Code Label Requirement for Human Drug Products and Biological Products (69 Federal Register 9120, February 26, 2004).

Q. What machine-readable information is required for blood and blood components?

- A. 21 CFR 606.121(c)(13)(ii-iii) states the container label must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research.

Currently, two types of machine-readable label types are recognized by the FDA: FDA recognized the use of Codabar (a specific bar code symbology) in 1985; and the FDA accepted the use of ISBT 128, version 1.2.0, in 2000.

Each label must have at a minimum: (A) A unique facility identifier; (B) Lot number relating to the donor; (C) Product code; and, (D) ABO and Rh of the donor.

Q. We are a transfusion service and very infrequently prepare split units, pediatric units, and pooled cryoprecipitate units; do we need machine-readable labels for these units?

- A. Yes, This situation was described in the preamble to the proposed rule (68 Federal Register 12500 at 12513):

"The unit of blood or blood component label would contain the machine-readable information if the blood or blood component has any possibility of being transfused to a patient, whether or not the unit is actually transfused.

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From The OABB President

The 2006 Annual Meeting was held in Cleveland, Ohio on May 5, 2006. Based on the evaluations by the attendees, it was an excellent meeting. The Board of Directors put together a nice mix of technical, managerial, and leadership topics that was timely and extremely interesting. Special thanks to Cathy Fincham for organizing the program and making all of the hotel arrangements. We will be returning to Cleveland again next year, and the program is already being developed. Mark your calendars for May 4, 2007 in order to be able to attend.

I would like to take this opportunity to encourage all of the blood bankers in Ohio to become active members in our organization. If you are not already a member, joining is as easy as going to the OABB website at www.oabb.org and filling out the membership application. If you are already a member, there are many ways to become active. We have several committees, and I am sure at least one of them could use your talents. The Education Committee in particular would like some of you to help plan the annual Fall Workshop. I can tell you from personal experience that the friendships and professional networking that I have gained over the years are priceless.

Along this same line, I want to let the membership know that the Board is considering a Code of Regulation change to bring before the membership at our next annual meeting. Under the present system, the state is divided into four regions. The current Code of Regulations specifies that the Board be made up of one doctoral and one non-doctoral member from each region. We currently are not able to fill all of the Board positions under this arrangement and are working with one vacancy. During this next year the Board will be considering how the best way is to resolve this situation.

If you are interested in becoming more active in OABB by participating on a committee, or have suggestions about the Board makeup, please send your comments to ultimateassistant@sbcglobal.net, or to me personally at greggw@fmchealth.org.

I hope everyone has a fun and relaxing summer.

Sincerely,
Gregg Witham, MT(ASCP)SBB
OABB President

A Blood Bank Review Course

Are you a working MT or MLT (or equivalent) who feels uncomfortable about why you're doing what you're doing in the blood bank...You'd like a review of basic blood banking theory? Cuyahoga Community College (Cleveland area) is offering a distance learning opportunity for you Fall Semester (August 28-December 18, 2006). The 2 college credit course (MLT 2806 – CRN 87048) is in a web-based format...participate in the course work from any computer with internet access; no on-campus requirements and no hands-on laboratory. Participants will review the following topics: Basic immunology and genetics (applicable to blood banking), pretransfusion testing (including type and screen and DAT), problem solving concepts including antibody identification and working up a positive direct antiglobulin test (DAT), transfusion related (immunological, disease transmission and non-immunological) complications, component production and therapy.

Cost:	Cuyahoga County Residents:	\$161.08
	Other Ohio Residents:	\$212.96
	Out of State Residents:	\$436.08

Contact Sandi Gerhan (216-431-3287 or sandra.gerhan@tri-c.edu) for more information

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Additionally, the phrase, "from which the blood or blood component can be taken and transfused to a patient" would include the circumstance where blood or a blood component is extracted or aspirated with a syringe from the container of blood or blood component in order to transfuse to a patient. This technique might be used when transfusing neonates or under other medically necessitated circumstances. In this case, the blood or blood component from which the aspirate is taken must have affixed to it a label containing the required machine-readable information. This would be consistent with the pre-existing requirement at § 606.121(c)(8)(iii) that requires specific statements if a product is intended for transfusion."

- Q. I have questions about how to encode facility identifiers and product codes for pooled and aliquoted units for Codabar or ISBT 128. Where do I get information about these issues?**
- A. Please contact CBER's Manufacturers Assistance and Technical Training Branch (MATTB) at matt@cber.fda.gov for additional information. The regulation requires a unique facility identifier.
- Q. How will the FDA evaluate compliance with the rule?**
- A. Our investigators will evaluate compliance with these regulations during routine inspections of blood establishments.
- Q. May I request an exception or alternative under 21 CFR 640.120 for this requirement of the blood and blood component container label regulations?**
- A. The purpose of the bar coding rule is to reduce transfusion errors and increase patient safety. CBER will carefully review any request for exception or alternative. The bar code regulation for drug products recognizes that exemptions may be warranted when compliance would adversely affect the drug's safety, effectiveness, purity or potency or not be technologically feasible. In the preamble to the rule discussing exemptions for drug products, FDA noted that almost all drug products are capable of bearing a bar code. FDA noted that we would not consider written

requests based on reasons such as financial reasons, a claimed low rate of medication errors, or a claim that the product is unique such that medication errors do not occur or rarely occur. In assessing requests for exemptions for blood and blood components, the FDA would follow the same approach as that described in the drug regulations (21 CFR 201.25(d)).

Reference Source:

Food and Drug Administration Web Page:
www.fda.gov

U. S. Food and Drug Administration

5600 Fishers Lane, Rockville MD 20857-0001
1-888-INFO-FDA (1-888-463-6332)

WELCOME NEW MEMBERS!

Suzanne Davisson
American Red Cross

Jennifer Smith
American Red Cross

David Matthew Sulfridge
American Red Cross

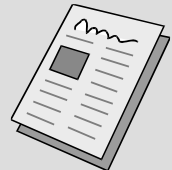
Karla S. Smith
Central Kentucky Blood Center

Ann M. VanHorn
Wilson Memorial Hospital

OABB Newsletter Submissions

Letters, articles, and announcements of upcoming events may be submitted at any time.

Classified advertisements will be accepted from any member institution and printed at no charge.



Contact:
Phylis Moder at (614) 722-5394 or via e-mail at moderp@chi.osu.edu.

Continuing Education Credit Opportunity!!!!

The OABB Board will begin offering articles for staff to use for Continuing Education. Below is the first in what we hope will be a series of such articles to be used for one-half hour credit. Answers will be found in the next edition of the newsletter.

If anyone would like to contribute, please send any articles with questions and answers to:
morderp@chi.osu.edu

Red Blood Cells

After reading this Continuing Education article, the participant shall be able to state

- ◆ the protein that causes progenitor cells to mature into red blood cells
- ◆ the standard for an approved preservative anticoagulant
- ◆ a common disease state that requires transfusion above a hemoglobin level of 7.0 g/dL
- ◆ the reason leukoreduction can decrease CMV transmission
- ◆ the reason Red Blood Cells are irradiated

Red blood cells are the vehicle that carries oxygen to all parts of the body. Hemoglobin, a molecule found inside red blood cells, binds oxygen when the red cells circulate through the lungs, and releases oxygen to other parts of the body. For the red blood cells to make hemoglobin, both iron and a protein called erythropoietin are necessary. The term anemia is used to describe the condition when a person does not have normal levels of hemoglobin.

Red blood cells, also known as erythrocytes, are made in the bone marrow. The earliest cells that will become erythrocytes are called progenitor cells. There are two types of progenitor cells: burst forming units-erythroid (BFU-E) and colony forming units-erythroid (CFU-E). For the progenitor cells to differentiate, mature, and leave the bone marrow, a protein produced by the kidney, erythropoietin is necessary. Erythropoietin is an important

messenger to tell the bone marrow to produce more red blood cells. When red blood cells are released from the bone marrow, they circulate in the body for 120 days. Each day, 1-4% of the body's red blood cells are broken down by the body and removed from circulation, and 1-4% new red blood cells leave the bone marrow and circulate through the body. The iron from the broken down cells is recycled into new red cells. Additionally, a person must have a diet with adequate sources of iron for normal levels of hemoglobin. Good sources of iron are beef, pork, eggs, clams and oysters.

Prior to collecting blood from a donor, the donor is tested for their hemoglobin level to assure units of Red Blood Cells for transfusion have optimal ability to carry oxygen and to be sure the donor can safely donate blood without jeopardizing themselves. A hemoglobin level of 12.0 g/dL is the minimum level for a person to be an acceptable donor. Normal healthy individuals have hemoglobin ranges from 12.0 g/dL to approximately 17.0 g/dL. Males tend to have higher hemoglobin levels than females. The red blood cells are collected into a special bag that has a red cell preservative-anticoagulant solution that can support the red cells to continue living and functioning in a liquid state after collection from the donor. The preservative-anticoagulant must meet specific standards for maintaining the survival and function of the red blood cells throughout storage. This standard requires that, after maximum storage, 75% of the transfused donor cells are functional in the recipient 24 hours after transfusion. The expiration of the unit of Red Blood Cells is determined from this standard. Currently there are collection bags with preservative-anticoagulant to store Red Blood Cells for as long as 42 days.

Trauma, loss of blood during surgery, and diseases such as leukemia that reduce red cell production, are conditions that may require transfusion of Red Blood Cells. Transfusion of Red Blood Cells is performed after a physician evaluates the patient for anemia and prescribes a transfusion, similar to any other medication. Generally, patients tolerate a hemoglobin level of 7.0 g/dL because of normal mechanisms

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of the body to compensate when a person has anemia. These mechanisms include an increased heart rate and breathing rate and more release of oxygen into the body's organs and tissues that require oxygen the most. When a patient has heart, lung, or cerebral vascular disease, the body cannot compensate as well, and transfusion above the level of 7.0 g/dL may be necessary. Each unit of Red Blood Cells is expected to increase the level of the patient's hemoglobin by 1.0 g/dL.

Special Red Blood Cell Components

For many years it was well known that patients who had chills and fever during transfusion of Red Blood Cells had antibodies to the white blood cells, also known as leukocytes, which are normally present in red blood cell components. Today, units of blood are filtered to remove the white cells. The filtered component is referred to as leukoreduced. It is preferable to filter the blood immediately after collection and prior to storage. If filtration occurs after storage, some white cells have already deteriorated, releasing cytokines into the component. The patient can react to the cytokines in the same way as they can react to intact white cells. Using Red Blood Cells that are leukoreduced has decreased the number of white cell related transfusion reactions.

Leukoreduction is also a method to provide blood to reduce the incidence of transmission of cytomegalovirus (CMV). Since CMV lives inside white cells, removal of white cells reduces CMV in a red blood cell component. CMV is a common virus that can cause a mild illness, and the virus occurs commonly in the general population. However, some patients with certain conditions become severely ill if CMV is transmitted through a blood transfusion. Red Blood Cells need to be provided as either CMV reduced by filtration, or selected from donors who are negative when the donor's serum is tested for evidence of exposure to CMV. Patients who should receive these CMV-safe products are those who are immunosuppressed, such as patients receiving stem cell transplants,

premature babies, and patients with HIV. The AABB (Advancing Transfusion and Cellular Therapies Worldwide, formerly American Association of Blood Banks) Standards for Blood Banks and Transfusion Services specifies a standard of less than 5×10^6 leukocytes in a component of red blood cells to be considered leukoreduced.

Irradiation of Red Blood Cells is necessary to prevent graft vs. host disease (GVHD) in patients who are immunosuppressed and in patients who receive HLA matched components or components from first degree family members. GVHD occurs when the donor's cells (the graft) responsible for a person's immune response are transfused into the patient (the host), and the transfused immune cells respond to the patient's own body as foreign. The immune cells that respond in this way are called T-cells. Irradiation prevents the T-cells from functioning and prevents their dangerous effects. Proper irradiation is important since transfusion-associated GVHD is usually fatal. Gamma irradiation delivering 2500 cGy is necessary to prevent transfusion-associated GVHD. Once a unit of Red Blood Cells is irradiated, its expiration is 28 days after irradiation, or the expiration of the original unit, whichever occurs first.

Questions:

1. What protein is responsible for differentiation and maturation of progenitor cells into red blood cells?
2. What is the required percentage of cell survival and timeframe for an approved preservative-anticoagulant?
3. What diagnosis is associated with a need to transfuse above the level of hemoglobin of 7.0 g/dL?
4. Why does removing white cells from units of Red Blood Cells reduce the incidence of CMV transmission?
5. What cell line is affected by irradiation of Red Blood Cells to prevent graft vs. host disease?