



Blood Matters is a quarterly news outlet with important medical information for you, our customers and colleagues, from Carter BloodCare. We hope you will share it with others interested in the work we do together.

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HOT TOPICS**What Do You Mean – My Platelets Have Bacteria?****Geeta Paranjape, MD**

Carter BloodCare used to perform quality control of apheresis platelets for bacteria by using a test called eBDS. This test allowed us to have a Pass/Fail (acceptable/not acceptable) result on day two and we only sent bacterially negative, or acceptable, products out to our hospitals. There was no need to call and notify hospitals about any change to test results once distributed.

As of December 2017, the eBDS methodology is no longer supported. Therefore, Carter BloodCare has implemented the use of BACT/ALERT® for bacterial detection in apheresis platelets. There is a change to the process with this new methodology.

The component must be held for 24 hours post collection and prior to inoculation; then incubated for an additional 24 hours prior to distribution to your hospital. The inoculated bottle remains incubated until the expiration of the component, which is 5 days post collection. It is possible that a positive result is detected after the platelet has been accepted by your hospital (or already transfused to a patient). If a positive alert is identified, we will call and notify the transfusion service to quarantine the component. This will prevent the relevant component from being transfused to a patient while we continue to investigate the initial positive result. Culture studies, including a gram stain, will be performed at our contracted microbiology lab. We will update the transfusion service of any preliminary and final results as they become available.

We encourage your transfusion service to notify you, the treating physician, of all results so a decision can be made either to monitor the patient more closely or give antibiotics as may be appropriate for a patient who may have been transfused. Remember, our Medical Directors are available for consultation 24/7 to answer questions or concerns associated with quarantine or recall notice of a platelet component.

Since Carter BloodCare went live with BACT/ALERT® we have tested approximately 5,000 samples and had a total of four positives, one of which was a true positive (skin contaminant) at our Bedford location. Our Tyler location has tested approximately 400 samples and has had zero positives.

It is common for most positive alerts to either be a false positive (gram stain negative or no growth) or grow a skin contaminant culture. Most donors are feeling well and healthy when they donate so the chances of having a pathogenic organism contaminating a platelet is quite slim.

If you have any questions about this methodology, or would like to consult with one of our medical directors, please call 817-412-5104 and ask to speak to a medical director.

What topic do you want included in the next issue of Blood Matters?

- A)** Flow Cytometry **B)** Red Cell Molecular Testing **C)** Cellular Therapy **D)** Other

Click [here](#) to submit your choice. If you answered **D (Other)**, remember to include your topic.



Lookbacks, Recalls, Quarantines, and Market Withdrawals – a Primer

Laurie J Sutor, MD, MBA

Confusion frequently arises over the different notifications received from the blood center regarding blood components under suspicion. This article will attempt to clarify the differences between the different categories of notification.

- 1. Quarantines.** Quarantine notifications are a preliminary notification, often while additional investigation or testing is underway. They may ultimately be released as acceptable again. The intent is to prevent components from being transfused while it is determined if the component is actually safe to use or not. An example might be quarantine of co-components collected at the same donation as a product that is preliminarily identified in a suspected septic transfusion reaction. If the final workup of the transfused component in the septic patient is negative, the co-components can be released back to active inventory. No recipient notification is necessary until the final conclusions are drawn, at which time another notification will be sent.
- 2. Market withdrawals and recalls** are similar, but reflect different levels of severity as far as the risk to blood product safety. Both are initiated following a deviation to procedures involving collection or processing of the blood component, or receipt of post-donation information regarding the donor history, health, or behavior. The safety, purity and/or potency of the blood component may be affected.

Market withdrawals tend to be more minor infractions of procedures, whereas recalls are the removal from the consignee of a product that the Food and Drug Administration (FDA) considers to be in violation of its laws and against which the agency might actually initiate legal action under 21 CFR part 7. Recalls are divided into class I, II and III depending on their severity, with Class I as the most dangerous. The Code of Federal Regulations (21 CFR part 7) defines a Class I recall as “a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.”

Remember that blood centers are required to remove from consignee inventory any product that does not meet all FDA regulations or their own SOPs. So, if information is obtained after shipment that a component is unsuitable, the blood center must notify the consignee and ask for return of that product, either as a recall or market withdrawal. A frequent example of this is donor post-donation information. The donor may remember travel to a malarial area at the time of a subsequent donation. This makes the previous donation not in compliance and must be removed from inventory as a market withdrawal or recall. The unit is not likely to cause malaria in the recipient, but the blood center is mandated to do the notification. The consignee, however, may decide whether to do recipient notification based on physician, transfusion committee, or ethics committee deliberation.

- 3. Lookback.** Lookback is a term that should be reserved for notification of consignees about receipt of previous blood components from a donor that has now tested positive for either HIV, hepatitis C, or Chagas’ disease antibody. The previous units of blood tested negative (or were untested, in the case of Chagas’ testing) but the donor could have been in the serological “window period” at the time of donation and theoretically could have infected the recipient despite the negative tests.

FDA has strict rules about HIV and HCV lookback which are outlined in the Code of Federal Regulations (21 CFR 610.46 and 21 CFR 610.47) which both the blood center and transfusing facility must follow. Guidelines about Chagas’ disease lookback are in a document posted on the FDA website (<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM528600.pdf>).

Recipients must be notified within 12 weeks and offered counseling and testing for the appropriate infection. Consignees often initially get a quarantine notice for any “in date” components following the reactive screening test on the donor. If subsequent testing is also positive and lookback is warranted, then an official lookback notice is also sent.

PHYSICIAN RESOURCES

Download three free issues of Blood Bulletin from America’s Blood Centers.

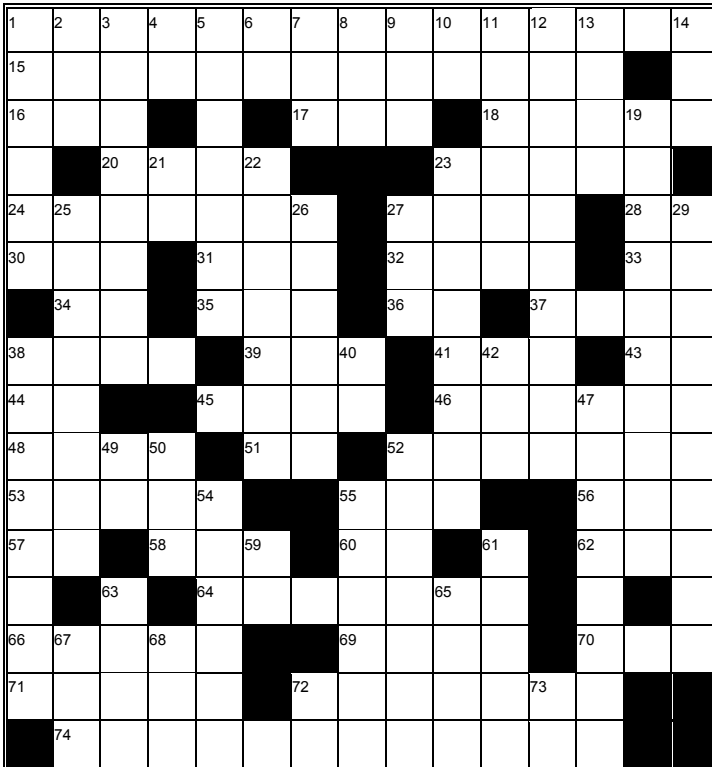
- [Platelet Transfusions for Patients with Consumptive Thrombocytopenias](#)
- [Granulocyte Transfusions For Patients With Neutropenia: Current Status](#)
- [Clinical Practice Guidelines from the AABB: Red Blood Cell Transfusion Thresholds and Storage](#)



Blood Matters

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CROSSWORD PUZZLE - Created by Dr. Laurie Sutor



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- Click [here](#) download the answer key.

Across

- Frozen blood component
- Surgeon's realm (2 wds)
- Hall of Fame hockey player Bobby
- Film director Lee
- RBC blood group with receptor for P. vivax
- Lab "how to" manuals (abbr)
- Terra ____ (earth)
- Great ____: vCJD risk area
- University important in the development of CAR-T cell therapy
- Antigen expressed more strongly on D positive RBCs
- First degree relative
- Energy provider in the Lone Star state
- "Three" in German
- Replacement given during intensive apheresis procedures (abbr)
- Hawkeye school (abbr)
- Summer in France
- Walmart corporate HQ state (abbr)
- Give up
- One with pica might eat this
- Apheresis treatment for cutaneous T-cell lymphoma (abbr)
- Chit
- Thrombus lodged in the lung (abbr)
- Memo subject line header
- Important ingredient in mosquito repellent (abbr)
- ____ eminence: bump at the base of the thumb
- Transfusion professional group founded in 1947 in Dallas
- Isotonic crystalloid (abbr)
- Bother
- German sausage
- Counterpart of yang
- Medical school on island of Nevis (abbr)
- American Horror Story network
- Antithrombin ____ (old name)
- Electrical and safety rating code (abbr)
- Hematopoietic progenitor cell recipient procedure (abbr)
- Shoulder blade
- Packages of printer paper
- Lowly worker
- 911 response team (abbr)
- Blood group antigen associated with MNSs
- Crystalloid containing calcium: ____ lactate
- Assays for fetal hemoglobin (2 wds)

Down

- Eponym for antiglobulin test
- Syphilis screening test (abbr)
- ____ enterocolitica, RBC contaminant
- Where surgeons may transfuse (abbr)
- To examine by touching
- Temperature requirement for immediate spin crossmatch test (abbr)
- Common type of donor screening test (abbr)
- Anderson Cooper's network (abbr)
- Molecule commonly detected in 1 down
- Media department (abbr)
- Ingredient in some arm scrub materials
- Device used to distend vein before venipuncture
- Old car radio type
- Ron ____, Tarzan star
- Most dangerous species of malaria
- Staff may get paid time and a half for this (abbr)
- The minimum blood donation age in many states
- Test for iron stores
- Test tube RBC phenomenon seen with high protein levels
- Corpus Christi TX county
- Kissing in public, for example (abbr)
- Places to thaw plasma or cryo (2 words)
- Eponym for Rh43
- Interlaboratory comparison subscription (abbr)
- Exclamations
- Symptom of citrate toxicity, periorally
- Chemical symbol for the element with atomic number 35
- Very large, mostly western U.S. blood center (abbr)
- A reagent to weaken a sample
- Something regulated under 21 CFR 1271
- An 80s term for a young urban professional
- Performer of song "Flashdance" (init)
- Waxes and ____
- A Spanish luo
- Private theater box
- Where blood donor hemoglobin sampling used to be done, from the lobe
- SBBs tend to be these first (abbr)
- Not left (abbr)
- A type of offensive lineman (abbr)