



OHIO ASSOCIATION OF BLOOD BANKS



Association Officers

President

Gregg W. Witham,
MT(ASCP), SBB

President-Elect

Mary Schumacher, MS MT
(ASCP), SBB

Immediate Past President

Kathleen Nicol, MD

Secretary

Joanne Kosanke, MT
(ASCP), SBB

Treasurer

Kathy Wheeler,
MT(ASCP)SBB

From The OABB President

It was great to see many familiar faces and some new ones at our annual meeting this year. From the comments that we received, the subject matter and presentations were all very good and pertinent. Your Board works very hard to find expert speakers on topics that you request, and I want to thank all of them for their dedication and support. It was also good to see blood bank vendors present at our meeting again. Though there are fewer of them now than there were in the past, their presence seems to make our meetings even more informative. The 2008 annual meeting will be held in Columbus and your Board is already working on the agenda.

All of my messages to you over the past year have dealt with volunteerism in our organization. If you read the summary of this year's annual meeting, you will see that we continue to have trouble filling all of our Board and Committee Chair positions. As I stated at our annual business meeting, this is not presented as a doom and gloom situation, but rather an opportunity for different people to become involved in the future of our organization. I would say though that we are at a critical time in the organization. If we cannot fill vacancies we will also not be able to provide the services that we have had in the past. If, for some reason, you think that you are not qualified to participate, the only requirement we look for are people who want to contribute to our profession and can donate

a little bit of time and ideas. Please contact me at greggw@fmchealth.org, President-elect Mary Schumacher at SchumacheM@usa.redcross.org if you even think that you would like to become more involved. I am positive that we can find a spot for your talents.

In an attempt to adjust to demographic changes, all individual and institutional members will soon be receiving a proposed change to our Code of Regulations. The change involves how Board members are selected. The current code goes back to when there were only four telephone area codes in Ohio and these became the boundaries of our four regions. While we still would like representation of our membership across the state, it is not always possible to find volunteers within these boundaries. After weighing several different options, your Board feels this is the best solution at the current time. Since it is a revision to our Code, all members are entitled to vote on the change.

I hope everyone had an enjoyable summer and look forward to working with you again this year.

Sincerely,

Gregg Witham, MT(ASCP)SBB
OABB President

Inside:

- ◆ From the OABB President - Page 1
- ◆ Highlights of 2007 OABB Annual Meeting—Pages 2,3
- ◆ Continuing Education Activities—Pages 4,5
- ◆ Cold Reactive Antibodies & Cardiac Surgery—Page 6
- ◆ Reference Lab Tech 1 Job Advertisement—Page 7
- ◆ New Members—Page 8
- ◆ Proposed Change to Code of Regulations—Page 8

Highlights of 2007 OABB Annual Meeting

The 2007 Annual Meeting of the Ohio Association of Blood Banks was held on Thursday and Friday, May 3rd and 4th, 2007 at the Cleveland Airport Marriott, in Cleveland, Ohio. The President's Reception was held on Thursday night with about 25 members and speakers in attendance. The reception provided an opportunity for everyone to meet informally and discuss all types of topics in a relaxed environment.

On Friday, the meeting opened with the President's Welcome given by OABB President Gregg Witham. OABB Board member Joanne Kosanke moderated the morning session. The session started with Mary Lieb, BS, MT(ASCP)SBB discussing "Validation and Comparison Studies in a Transfusion Service." The regulations and requirements of different accrediting associations were reviewed. When preparing a validation document, the expectation of the process needs to be predetermined before validating in order to know whether it meets expectations. Validations can cover test procedures (SOP's), support systems such as phlebotomy, computer systems, facilities, equipment and personnel. Scenarios for when prospective and retrospective validations would be used were reviewed. Three approaches to validation were then discussed. Installation Qualification (IQ) is used for equipment and facilities. Operation Qualifications (OQ) is often used to demonstrate the effectiveness and reproducibility of a process. Performance Qualification (PQ) establishes process stability and that it consistently produces a product that meets all of the predetermined requirements. Sample validation plans, including implementation, execution, reviews and approvals were then discussed. Finally, the differences between validation and verification and when each can be used were discussed. Mary concluded her discussion by stating that the benefits of validation include: 1) improved customer satisfaction from fewer complaints and/or fewer recalls, 2) cost reduction from less rework and waste, 3) improved employee morale, 4) improved product quality and 5) less regulatory headaches.

The second speaker of the morning session was Timothy Hannon, MD, MBA. Dr Hannon's topic was "Perioperative Blood Management". He began his discussion by explaining that blood management is not the same as blood conservation. Blood management is an evidence-based, multidisciplinary process that is designed to promote the optimal use of blood products throughout the hospital. He displayed several published studies that showed a large variation of blood usage. The source of these variations may come from either physician practice or institutional practice. The "transfusion trigger" was discussed. A clinical trial published in the 1999 New England Journal of Medicine concluded that a restrictive strategy of red cell transfusions is at least as effective as and possibly superior to a liberal strategy in critically ill patients. A properly applied blood management program will ensure that every unit of blood transfused is appropriate. Dr. Hannon then discussed perioperative blood management strategies. This plan includes a preoperative management plan, the surgical technique and perioperative techniques. He noted that when bloodless systems are being utilized, it is important to have a pharmacist on the transfusion team. Point of care monitoring allows for real-time decision making for the proper type and amount of a component. Dr. Hannon concluded his discussion showing the reduction of blood components utilized at his institution using a blood management strategy over the last six years.

The last speaker of the morning session was Janis Lugo, BS,MT(ASCP)SBB whose topic was "Blood Product Retrievals; What is Important for the Hospital?" Janis began her discussion with a review of the testing that is required by the AABB and FDA to be performed on each unit that is received by a transfusion facility. The current list of infectious disease screening tests and their confirmation or supplemental tests methods were explained. The interpretation of these screen and confirmatory/supplemental tests determines whether the case becomes a lookback or market withdrawal. The length of time for previous donations needs to be reviewed was explained for each test. Janis explained that there are reasons other than positive tests results that a transfusion service might receive a market withdrawal or recall letter. Market withdrawals occur for minor violations that are not subject to legal action by the FDA. Examples of market withdrawals include Post Donation Information (PDI) such as travel to a malaria area or being a co-component in an adverse reaction such as TRALI. Recalls occur when the FDA considers the distributed component to be in violation of the laws it administers. Examples of recalls are collecting from a donor who previously provided information that would have deferred the donor and discovering that a test was not performed according to the package insert. Recalls are listed in FDA publications.

(continued from Page 2)

OABB Membership chairperson Cindy Condrey moderated the afternoon session. Venkata Samavedi, M.D. gave the VanDerHoven presentation titled "Role of Donor Specific Anti-HLA antibodies in the Outcome of Liver Transplantation." The Annual Meeting of the Membership followed with the Secretary, Treasurer and Committee Chairs all reporting to the membership. Vacancies at the time of meeting were: Region I Medical Representative, Region III Technical Representative, and a chairperson for the Education Committee. Additionally, a chairperson for the newsletter is being sought. President Gregg Witham encouraged the members in attendance to become more active in the organization, and to let other staff members in their facilities know about OABB. Gregg did not want the vacancies to be interpreted too negatively, but rather as an opportunity for some new blood (bankers) to become more active. The election of officers was conducted by President-elect Mary Schumacher with Suneeti Sapatnekar, MD, Cathy Fincham continuing on the Board of Directors for their third and final term. It was announced that the 2008 annual meeting will be held in Columbus and chaired by Joanne Kosanke, Kathy Nichol M.D., and Mary Schumacher.

Following the annual business meeting Lisa Walters PhD, MBA, MT(ASCP)SBB presented "FMEA: What's the Worst that can Happen?" Lisa defined FMEA as "Figure out what can go wrong and try like heck to stop it." After sharing the history of FMEA, the needed support system to implement it was described. Several methods can be used to identify all of the ways things could go wrong. These are the failure modes and the outcome of each of these must be determined. Lisa said to ask yourself: "How can process failure affect the safety, quality, identity, purity, or potency of the process or its output?" Once the effects are known, the risk needs to be established. Lisa showed how to evaluate the risk evaluating the severity, occurrence and detection of each failure mode on a 10-point scale. Multiplying the number of each of these areas will produce a Risk Priority Number or RPN. The RPN then can show you which Failure Mode to start working on first. The next step is to take corrective action by performing root cause analysis and implementing change management. The final step is to take measurements again after action has been implemented. Lisa suggested you should strive for a 50% reduction in the RPN. Lisa concluded her presentation stating the FMEA can be used during the design of a system, during the design of a process or for troubleshooting any aspect of systems or processes.

The last subject of the 2007 annual meeting was "ISBT 128, Making the Transition" presented by Suzanne H. Butch, MA, MT(ASCP)SBB. Suzanne first explained ISBT 128 as an internationally agreed upon information technology standard that includes specifications for labeling blood components and data transfer. ISBT 128 will be maintained through the International Council for Commonality in Blood Bank Automation (ICCBBA). There is no organization maintaining the current Codabar system. The advantage of ISBT 128 is process control through data identifiers, check digits and check characters, better product description, flag characters and data identifiers that can be used with RFID. The Donation Identification Number (DIN) will be longer than the Codabar unit number. The data structure of the DIN was explained. Flag characters are not part of the DIN, but used locally to convey specific information such as identifying the bag, tubes or donor record. Check characters are also not part of the DIN and also not part of the barcode; they are meant to check keyboard entries and you may want to record it in manually written records. The data structure of the Product Codes, including division/splits was explained next. A map of product codes from Codabar to ISBT 128 is available on the ICCBBAA web site (www.iccbba.org). The expiration date will be in a different location and be eye-readable as Day/Month/Year. In conclusion, Suzanne noted that with the ISBT 128 system there will be no duplicate numbers for 100 years, and with the use of Check digits and data identifiers the right information will go only in the right place. It will be important to involve and communicate to all of the stakeholders for the implementation of ISBT.

Comments from all attendees at the annual meeting were very positive. The speakers were well received and gave valuable information of pertinent topics for the whole blood banking community. Watch for announcements in the OABB Newsletter for the dates of the 2008 annual meeting and make plans to attend.

Submitted by: Gregg W. Witham MT(ASCP)SBB
Fairfield Medical Center
Lancaster, Ohio

Reagents Useful to Resolve Serologically-Difficult Samples
(0.5 CH)

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

- ◆ Identify antibody-antigen enhancement media mechanisms
- ◆ State two reagents for reducing IgG from red blood cells
- ◆ Name three antigens denatured by enzymes
- ◆ Name three antigens denatured by 0.2M Dithiothreitol (DTT)
- ◆ Name three antigens denatured by Chloroquine Diphosphate (CDP)

Today's blood banks have many reagent choices to resolve serologically difficult patient samples. This article reviews test media, reagents to reduce IgG from DAT-positive red blood cells (rbc's), and rbc modification.

There are at least four test media available for use in transfusion services: low ionic strength solution (LISS), polyethylene glycol (PEG), column agglutination technology (Gel), and solid phase.

LISS: LISS provides an environment with less sodium and chloride ions than normal saline. By having fewer ions in the test system, there are fewer charged ions to inhibit the positively-charged antibody from moving towards the negatively-charged red blood cell. The effect of a low-ionic test system is a decrease in the time necessary for the sensitization phase of the antigen-antibody reaction. As an important part of maintaining a low ionic environment, the volume of plasma added to the test must be the same as the volume of LISS reagent. Since plasma is a source of adding ions to the test system, the LISS solution is added in equal volume to keep the molar strength of the total test system low.

PEG: PEG is a water soluble polymer that replaces water molecules. When it squeezes out the water, it allows concentration of antibody and antigen, which effectively increases the chance of antibody and antigen colliding and forming bonds.

Gel: After the test rbc's and plasma incubate in the reaction chamber above the gel column, the card containing the columns is centrifuged. The sensitized cells bind with the anti-IgG in the column and form agglutinates that can not move through the gel. The stronger the reaction is, the fewer cells that can traverse the gel during the centrifugation. If cells are not agglutinated, they travel through the gel to the bottom of the column. Unlike tube testing, where even the angle at which a tech holds the dropper affects the amount of cells or serum added to a test, Gel testing uses a pipette to dispense consistent rbc and serum volumes.

When performing Gel testing, the reactions can be read immediately after centrifugation or it can be delayed, but tube testing needs to be read immediately and is dependent upon the technologist's cell button resuspension technique.

Solid Phase: In solid phase testing, wells on a plate are prepared with a single layer of red blood cells bound. The patient's sample is added to the wells, incubated to allow antibody to attach to the fixed rbc's, and then the wells are washed to remove unbound protein. An indicator cell of anti-IgG-coated rbc's is added, and the plate is centrifuged. If antibody attached to the fixed rbc's, the anti-IgG-coated cells attach to the antibody. A positive test is a diffuse pattern of cells in the well, and a negative test is a pellet of cells at the bottom.

Survey results of 35 American Red Cross Biomedical Services Immunohematology Reference Laboratories (IRL's) indicated 25 of the labs initially use two different test media for each sample investigated. There were two distinct groups for what methods were used. One group used PEG with either LISS or Gel as their second method, and the other group used LISS with ficin-treated cells as their second method.

The Indiana Association of Blood Banks reported in a 2005 AABB abstract the survey results of their state's transfusion services: 57% of the responding hospitals used Gel and 43% used tube testing.

IgG reduction from red blood cells: Two reagents well known to reduce IgG from DAT-positive rbc's are EDTA-glycine acid (EGA) and Chloroquine Diphosphate (CDP). One use of these reagents is to obtain cells for antigen typing with indirect antiglobulin (IAT) reactive antisera. Typically, antisera with the following specificities require an antiglobulin test performed with DAT-negative rbc's: S, s, Fy^a, Fy^b, Jk^a, and Jk^b. Another use of the reagents is to confirm the plasma reactivity is autoantibody. Once the patient's rbc's have IgG removed and the DAT is negative, the plasma is tested with the patient's cells. If the antibody is an autoantibody, it will react with the autologous cells.

EGA's low-acidic environment causes antigen-antibody complexes to reverse. The treatment takes only a couple minutes and the results are known quickly. CDP is a quinoline derivative which splits antigen-antibody complexes when rbc's are incubated with it for 30 minutes to 2 hours. Neither method removes complement, so testing performed with treated cells needs to be with anti-IgG.

The DAT after EGA treatment is negative about 90% of the time, and 80-90% of the time with CDP treatment. Because EGA treatment is quick and efficient, it is the preferred method to reduce IgG from DAT-positive rbc's by 28 out of 35 IRL's surveyed.

(Continued on Page 5)

(Continued from Page 4)

Modification of red blood cells: Laboratories can use enzymes, DTT, and CDP to treat test cells. Each of these reagents can provide information about the possible specificity of an antibody.

There are many enzymes, but ficin and papain are the most frequently used. Enzymes cleave protein at specific points: if the antigen has the cleavage site, the antigen is denatured. To ensure rbc's were properly treated, they are tested with antisera specificity whose corresponding antigen is denatured by enzymes. Non-reactivity with the antisera indicates successful treatment with the enzyme and the cells are ready for testing with the patient's plasma.

Common antigens denatured by enzymes include: M, N, S, s (variable), Fy^a and Fy^b. High-incidence antigens denatured by enzymes include: Ch, Rg, JMH, Yt^a, Ge2, Ge4, and In^b. When a sample has multiple antibodies to common antigens, obtaining non-reactivity with enzyme-treated cells that were previously positive with the patient's plasma alerts the technologist to a possible specificity. If the entire panel is non-reactive, an antibody to one of the high-incidence antigens can be investigated.

Another cell treatment is incubation with 0.2M DTT. If an antigen has disulfide bonds as part of its biochemistry, it is denatured by DTT.

The following are denatured or weakened by 0.2M DTT: Antigens in the Kell, Knops, Lutheran, Dombrock, YT, JMH, Indian, Scianna, and LW systems and Ge2 (not Ge3 or Ge4).

Testing DTT-treated cells with a known anti-k and obtaining non-reactivity indicates successful denaturation of antigens, and the cells are ready to test with the patient's plasma.

CDP is marketed to reduce IgG from rbc's, but it is also known to denature HLA antigens on rbc's. The three HLA antigens present on rbc's are known as Bg^a (HLA-B7), Bg^b (HLA-B17), and Bg^c (HLA-A28). Plasma with Bg antibodies may react with up to 30% of cells and appear to demonstrate no specificity. Plasma tested with CDP-treated cells can help explain random incompatibilities. Testing the CDP-treated cells and obtaining non-reactivity with a previously identified Bg antibody can assure the treatment was successful.

Summary: All of the reagents described in this article for antibody detection are acceptable methods. All staff within a laboratory should use the same enhancement method and adhere to the manufacturer's insert. The laboratory must perform parallel testing of the current method with any change in test methodology to comply

with the Clinical Laboratory Improvement Amendment (CLIA) requirement found in the Code of Federal Regulations (CFR) 493, standard 1253. When using test procedures to modify test cells to reduce IgG or denature antigens, it is important to know procedural limitations and to use proper controls to ensure interpretation of test result accuracy.

Questions:

1. The enhancement media that requires equal volumes of plasma to media to function as intended is:
 - a. Gel
 - b. LISS
 - c. PEG
 - d. Solid Phase
2. An effective reagent for removing IgG from DAT-positive cells is:
 - a. 0.2M DTT
 - b. EGA
 - c. Ficin
 - d. PEG
3. Which of the following are denatured by enzymes?
 - a. Ch, Fy^a, Knops system antigens
 - b. M, Ge2, Lutheran system antigens
 - c. M, Ch, Yt^a
 - d. S, JMH, Kell system antigens
4. Which antigen is NOT affected by 0.2M DTT?
 - a. Ch
 - b. Dombrock
 - c. K
 - d. Lu^b
5. Which antigens are denatured by CDP?
 - a. HLA
 - b. K
 - c. M
 - d. Rg

Cold Reactive Antibodies and Cardiac Surgery
Lakshmi Rajappannair, MD,
Fellow, Cleveland City-wide Program in Blood
Banking/Transfusion Medicine

Cold agglutinins are detected in the serum of almost all individuals. Mostly they react at 4 °C with titer less than 32 and thermal amplitude less than 20°C. Patients with these low titer low thermal amplitude cold antibodies do not need any precaution during surgery. Thermal range of activity is the most important factor. The higher the thermal amplitude, the greater is the clinical significance. The titer is less important than thermal amplitude. Antibodies reactive at 30°C and above are capable of causing hemolysis and special precautions need to be taken. Also special precautions are warranted when a patient has cold antibody induced autoimmune hemolytic anemia.¹

Review of literature shows that most authors identified cold agglutinins in routine preoperative testing, but few others noted unexpected agglutination during surgery. Moore and coworkers advised routine preoperative testing, but this is not widely supported.² Bracken and Dake have suggested methods for detection of cold antibodies in the cardioplegic unit.^{3, 4}

There is no need for the blood bank to routinely screen for cold reactive antibodies. Few blood banks still screen for cold reactive antibodies. If the antibodies have high thermal amplitude to cause autoimmune hemolytic anemia, they will be noticed during routine compatibility test procedures.¹

Various approaches for management of cold agglutinins during cardioplegic surgery have been described. Cardioplegic management in these patients includes warm blood cardioplegia, and use of warm and cold crystalloid cardioplegia. Plasma exchange is used as an adjunctive in some patients. This has to be performed at temperatures above the cold reactive antibodies thermal range.¹

Ordinary cold agglutinins must be distinguished from conditions associated with cold reactive proteins like cryoglobulins, Donath Landsteiner antibody, and cold agglutinin disease. These are all pathological conditions, all are rare, and a specific test is needed to diagnose each condition.

There is limited reports in literature regarding patients with cryoglobulins undergoing cardiac surgery. Of 4 reports available, one patient developed renal failure in the cold operating room, three had successful surgery.⁵

The Donath Landsteiner antibody is an IgG autoantibody that binds to red cells in the cold and fixes complement; lysis occurs when cells are warmed to 37°C. Presence of the antibody is diagnostic for paroxysmal cold haemoglobinuria. Few reports are available on cardiac surgery in patients with paroxysmal cold hemoglobinuria. Kypson et al report a successful case of mitral valve replacement in a woman with a positive Donath-Landsteiner antibody and a history of recurrent hemolysis and hemoglobinuria secondary to cold exposure.⁶

To sum up, ordinary cold reactive antibody with a low thermal amplitude in a cardioplegic surgery patient can be ignored. However, if the patient has a cold alloantibody with reactivity at 37°C and a definite specificity, antigen negative blood should be given for transfusion.

1. Immune hemolytic anemias, 2nd edition, 2003. Petz LD, Garraty G
2. Moore RA, Geller EA, Mathews ES, Botros SB, Jose AB, Clark DL. The effect of hypothermic cardiopulmonary bypass on patients with low titer, nonspecific cold agglutinins. *Ann Thorac Surg* 1984;37:233-8
3. Dake SB, Johnston MFM, Brueggeman P, Barner HB. Detection of cold hemagglutination in a blood cardioplegia unit before systemic cooling of a patient with unsuspected cold agglutinin disease. *Ann Thorac Surg* 1989;47:914-5
4. Bracken CA, Gurkowski MA, Naples JJ, et al. Cardiopulmonary bypass in two patients with previously undetected cold agglutinins. *J Cardiothorac Vasc Anesth* 1993;7:743-9
5. Surendra K. Agarwal, MCh, Probal K. Ghosh, FRCSE, Debashish Gupta, MD Cardiac Surgery and Cold-Reactive Proteins *Ann Thorac Surg* 1995;60:1143-1150
6. Alan P. Kypson, MD, John J. Warner, MD^b, Marilyn J. Telen, MD, Carmelo A. Milano, MD Paroxysmal cold hemoglobinuria and cardiopulmonary bypass *Ann Thorac Surg* 2003;75:579-581

**American Red Cross
WESTERN LAKE ERIE BLOOD SERVICES REGION**

JOB TITLE: Reference Lab Technologist I

Posted: July 5 – 15, 2007

Status: 1 Full-Time

Department: Special Services Laboratory

Hours:

Pay Rate: Commensurate with experience

DESCRIPTION:

- Perform and interpret immunohematologic procedures on donor and patient samples.
- Perform and interpret platelet antibody screening.
- Consult and communicate with hospital blood banks in the resolution of serological problems, provision of antigen negative red cell units and/or special units.
- Communicate with equipment vendors when necessary to resolve problems.
- Assist with maintenance, repair, and validation of laboratory equipment.
- Perform, review, and approve quality control on products, reagents, equipment, and various test kits.
- Maintain the required records and files.
- May assume supervisory functions such as record review, ordering supplies, and training or other duties as designated by supervisor.
- Perform additional reviews of regulated documents, logs and forms as directed.
- Participate in on-call rotation.

QUALIFICATIONS:

- Bachelor's degree in Science or Medical Technology with MT (ASCP) certification.
- Experience in immunohematology preferred.
- Minimum one year of full-time blood bank experience.
- Must be highly detailed and accurate.
- Must be able to function independently once trained.
- Must be able to use a personal computer and applicable software.
- Excellent problem-solving skills required.
- Good written and verbal communication skills.

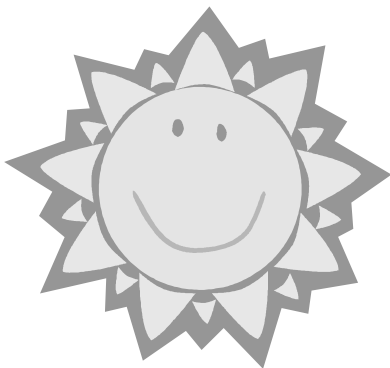
EOE M/F/V/H

WELCOME NEW MEMBERS!

Misty Jacobs, M.D.
University of Toledo Medical Center

Kenneth Spencer
Cuyahoga Community College

Tanya Combs
Cuyahoga Community College

**Attention OABB Members
Proposed Changes in our Code of
Regulations**

All members will soon receive in the mail a copy of our current version of the Code of Regulations in order to participate in a membership-wide vote of approval. Please make note of the proposed changes and then join the Board at their next meeting, September 26, 2007 @ 1pm via conference call.

Participant Instructions:

1. Dial the Reservationless Conferencing access number: 866-262-1846
2. Dial the Reservationless Conferencing room number: *2532743*
(Note: The star key must be pressed before and after your room number.)
3. Wait to be added to the conference.

**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.