CHANNELS

Kentucky Association of Blood Banks Newsletter **Spring 2017**

Welcome to the new edition of Channels!

Channels is the official newsletter of the Kentucky Association of Blood Banks, and as such, is an area wide publication. What that means is that we would like input from all across Kentucky and surrounding areas.

Those on the newsletter committee would appreciate knowing how the newsletter could better serve you. What would you like to have included in each edition? Are there specific topics that could help you perform your daily tasks better? Would you like a question and answer forum included in each publication? Would you like to contribute an article for consideration in the next edition or have a job opening you would like to list? We would greatly appreciate your input.

The mission of this newsletter is to provide exchange of information, education and a means of collaboration among those who practice transfusion medicine. Your input helps us accomplish this mission and make the newsletter more meaningful to the reader. Please send any feedback to kalelgin@gmail.com.

FDA's Draft Guidance on Reducing Bacterial Risk for Platelets

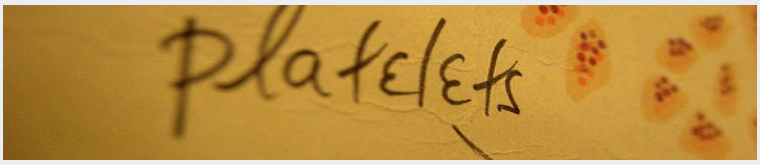
- by Debbie Bowman, MT(ASCP)SBB,CQA(ASQ)

In March of 2016, FDA published the *"Draft Guidance for Industry – Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion"*. The industry has submitted comments to FDA to be considered for the final guidance, which FDA has indicated is its top priority to finalize and publish in 2017.

What is FDA's intent? As indicated in the name of draft guidance, FDA's intent is to "*enhance the safety and availability of platelets*".

According to the draft guidance, platelets are associated with a higher risk of sepsis and related fatality than any other transfusable product, and the risk of bacterial contamination of platelets is a leading risk of infection from blood transfusion. Additionally, studies show that transfusion-associated septic reactions and related fatalities rise on days 4 and 5 of storage. The FDA is seeking to enhance the safety of platelets by the performance of additional bacterial testing on days 4 and 5, or by the use of pathogen reduction technology within 24 hours after collection of platelets. With regard to enhancing availability, the additional bacterial testing can be used to extend the shelf life of the platelets to a maximum of 7 days.

While most of us will agree with enhancing the safety and availability of platelets, the proposed options for doing so will have a significant impact on our industry.



Blood centers currently perform bacterial detection testing by culturing a sample taken at least 24 hours after collection. Products are then routinely released, although some centers hold up to an additional 24 hours prior to release. The draft guidance defines this practice as primary testing and requires secondary testing on days 4 and 5. In essence, without the secondary testing, a platelet product becomes a 3 day product.

The draft guidance indicates that in order to use platelets on day 4 or day 5, the transfusion service must perform an FDA-cleared rapid bacterial detection test, which takes at least an hour but adds 24 additional hours to the expiration date, or they must perform testing with a culture-based FDA-cleared bacterial detection device, which requires 12 hours incubation but extends the expiration date through day 5. Alternatively, the transfusion service can ship the product back to the collecting facility, if agreed upon, to perform the additional testing. Clearly, the costs and logistics required for these options are tremendous obstacles.

Continued on Page 2

FDA's Draft Guidance on Reducing Bacterial Risk for Platelets, cont.

Another option for being able to use a platelet product on day 4 or day 5 is to treat the platelet within 24 hours of collection with an FDA-cleared pathogen reduction technology. This option does not require bacterial detection testing during the 5 day period. As with the secondary testing options, increased costs are an issue. Additionally, pathogen reduction is not approved for triple platelet collections and lower collection split rates are associated with use of this technology, both of which reduce product availability.

While the intent of the FDA is to increase the safety of platelet transfusions, it is clear that options for using platelets on day 4 and day 5 will add significant costs and will reduce availability through increased outdating from logistical/cost constraints and false positives. FDA appears to seek to offset these losses by allowing the extension of platelet expiration dates to 7 days. However, the options for extending the expiration date to 7 days present additional challenges.

In order to extend the expiration date of platelets to 7 days, the platelet products will require additional bacterial detection testing, including products that were treated with pathogen reduction technology. The options defined in the guidance are:

- Perform testing using an FDA-cleared rapid bacterial detection device labeled as a "safety measure" within 24 hours prior to transfusion on day 6 or day 7.
- Perform test using a culture-based bacterial detection device labeled as a "safety measure" on day 4 or day 5 and after a negative 24 hour result, extend the expiration date for 48 hours, not to exceed 7 days.

At this time, there is only one FDA-cleared device to be used as described in option 1 and there are no FDA-cleared devices to be used as described in option 2. Also, neither of these options applies to pre-pooled platelets.

In a joint statement submitted to FDA by AABB, ABC and ARC, industry leaders have asked for several changes, including the option of delaying primary testing until 48 hours and applying a 7 day expiration date based on the 48 hour testing. They have also asked that the culture-based bacterial detection devices used for testing on 5 day platelets, be approved for use to extend dating to 7 days, without having to undergo additional designation as a "safety measure".

So where does that leave us? At this time, what we know is that FDA has indicated they consider it a top priority to publish the final version of this guidance sometime this year and when they do, we as an industry will have to implement within 12 months. What we don't know is what the final guidance will require and when it will be published. And so we wait…

For more detail, see:

Draft Guidance https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM425952.pdf

Joint Comments by AABB, ABC and ARC

http://www.aabb.org/advocacy/comments/Documents/comments160516.pdf

A patient came in through hospital ED.

She is 68 years old and complains of fatigue. Two years ago, she moved to the Florida Gulf Coast area after retiring from her teaching position in Ohio. Her history includes two pregnancies and several transfusions, but none since moving. Her current hemoglobin is 7.1 mg/dl, so two units of packed red blood cells are ordered…. *Check out our website where you will find the rest of this interesting Case Study by Doug Weaver,* MHA,BSMT(ASCP).

Interview with a Board Member…

We would like to introduce Dr. Leonard Boral in this edition of the KABB Newsletter. He is the Treasurer of KABB and is heavily involved in the planning of our KABB meetings.

Dr. Boral was born in Worcester, Massachusetts and he grew up in Brooklyn, New York. He is a seasoned Pathologist who began his residency in 1972. He holds certifications with the American Board of Pathology (Anatomic/Clinical Pathology and Transfusion Medicine) and is a member of KABB, the Kentucky Society of Pathologists, AABB, ASCP, CAP, and the Society for the Advancement of Blood Management, the American Society of Hematology and the American Society for Apheresis. In addition to his BS and MD degrees, Dr. Boral also holds a MBA.

When asked what led him to choose his profession, Dr. Boral said he aspired to be a physician from his high school years. His family expected him to have a medical career, as did his father (a Cardiologist and General Practice physician) who served as his role model and mentor in this endeavor. But he almost decided to become an Economist when he was offered the chance to study for his PhD at Wharton School of Economics in Philadelphia. If he had not become a Pathologist, Dr. Boral said that he would have become either a Hematologist or an Economist.

To Dr. Boral, the most enjoyable part of his job is working with those around him – training, mentoring and being involved in patient care. He is never bored because each day holds a different challenge. His most difficult "opportunity" is trying to convince doctors and nurses to use less blood, and thereby improve patient outcomes. His advice for anyone who pursues a profession in medicine or medical technology is to do their best in everything they attempt, enjoy the career and be a forever student.

When asked about his family, he states, "I have a great wife, three wonderful grown children and three enjoyable grandchildren. Everyone lives in the South." Outside of the hospital Dr. Boral enjoys sailing, fishing, gardening, skiing and living life to its fullest.

Thank you Dr. Boral for sharing more about yourself with the members of KABB!

Immunohematology…what a precarious beast!

Just like with most other Medical Laboratory students, one of the most challenging aspects of my future career was the Immunohematology rotation. What a precarious but important beast! It is maybe the one Medical Laboratory department that is the most immediately deadly if exercised with little caution. And yet it's the most life-saving if practiced correctly. Let's be honest, is there a single MLT/MLS student who doesn't lose their mind at the thought of the enormous responsibility of pre-transfusion testing & emergency protocol?

But I lucked out. Within two weeks of clinical rotations I became more sure of myself. I watched the senior technologist breeze through complicated antibody workups and I was instructed on how to resolve ABO discrepancies. After about 100 patient tests as a student, writing and re-writing procedure notes, and now two years working in the lab, I can say it gets better. What advice can I give? Know the procedures you will be using in your facility. You will protect yourself and the patients you are working for by doing so. Ask more experienced techs when something is out of your ballpark, and follow all protocols; they really are there for a reason. And one day, if you keep at it, allo versus auto, direct versus indirect, warm versus cold and other intimidating concepts of the Immunohematology Laboratory will all become second nature.

Andrew Randolph MLT (ASCP)

Lake Cumberland Regional Hospital, Somerset, KY

A Review of Blood Bank Chemicals

by Lisa Elgin, BSMT(ASCP) SBB^{cm}

As busy technologists, we often work against the clock to provide blood products for transfusion. In order to do this, we must accurately perform antibody detection and identification to ensure compatible blood products that are safe for transfusion. Several common blood bank chemicals aid us in our search for safe blood products; however, many of us, though very competent at testing, have forgotten how each chemical works and why we use them. This article will provide a brief review of each one. This list is by no means all inclusive.

LISS (Low Ionic Strength Solution)

LISS affects the first stage of hemagglutination (sensitization). The red cell surface has a net negative charge, due mostly to carboxyl groups attached to GPA and GPB. The Fab portion of an antibody molecule has a net positive charge due to the NH_2 terminal. Sodium and chloride ions in red cell solutions partially neutralize the opposite charges found on antigen and antibody molecules. LISS reduces the shielding effect of the sodium and chloride ions, enhancing attraction between the oppositely charged red cell surface and antibody molecules. Thus antibody uptake is enhanced, allowing for shorter incubation times.

PEG (Polyethylene Glycol)

PEG is a water soluble high molecular weight polymer. PEG affects the sensitization phase of agglutination by removing water from the reaction, thereby concentrating antibody and promoting uptake onto red cell antigens. PEG can be used when testing eluates and in performing adsorptions. It is very good for enhancing weak antibodies and has a low rate of false positives. Of note is the fact that PEG can cause proteins to precipitate and cells to aggregate. Consequently, it is not a good additive to use for patients with abnormal proteins (multiple myeloma, etc.) and tubes should never be centrifuged before PEG has been washed from the test system. Observation for hemolysis only should be performed after 37^{o} incubation. Only anti-IgG should be used when testing with PEG.

Albumin

Albumin is available in 22% concentration and affects the second stage of hemagglutination. Red cells with their net negative charge are surrounded by cations, which are then surrounded by anions. This keeps red cells from spontaneously agglutinating while in circulation. The difference in the electrical potential between the red cell surface and the outer layer of anions is called the zeta potential. Albumin reduces this zeta potential, enabling cells to come close enough together that IgG molecules can bridge the gap between specific antigens on cell surfaces and form a lattice, leading to visible agglutination. Albumin does not enhance antibody uptake onto the red cells, so incubation times are not shortened.

Enzymes

Enzymes are proteins that react with specific substrates. Enzyme specificity is due to the 3D shape of the enzyme reaction site in relation to the corresponding shape of the substrate reaction site. In the blood bank, the substrates are specific amino acids that provide antigen structure. The most commonly used enzymes are the proteolytic enzymes ficin and papain. Noncovalent bonds form between the enzyme and substrate (specific amino acids). This causes changes in covalent bonds within the substrate; consequently, some antigens are denatured while others are further exposed on the cell surface.

Proteases cleave sialoglycoproteins from the surface of the red cell and introduce water molecules at specific amino acid sites. With most sialic acid removed, the net negative charge of the cell surface is reduced, as is the zeta potential, allowing cells to come closer together. Some think that the removal of glycoproteins from the cell surface also reduces the amount of water surrounding the cells, again allowing cells to come closer together. There may also be steric changes in the red cell membrane that make some antigens more accessible to corresponding antibodies. Enzymes affect the second stage of agglutination.

Enzymes are never the sole method of antibody identification since some antigens are denatured by each enzyme, making their corresponding antibodies impossible to detect.

Neutralizing Substances

Certain substances in the body and nature are very similar in structure to specific blood group antigens. These substances can be used to inhibit reactivity of the corresponding antibodies in a patient specimen. The most common of these are Lewis, P1, Sd^{a}, Chido and Rodgers substances. When a specific antibody is suspected, neutralization of that antibody by incubation with the specific blood group substance can confirm identification and reveal underlying antibodies that may be present. Incubation of blood group substance and plasma (test dilution) must be accompanied by incubation of a diluent and plasma (dilution control) in the same ratio. Both dilutions must be tested in parallel in order to prove that lack of reactivity in the "test" plasma is due to neutralization of the antibody and not dilution of the antibody. For the test to be valid, the dilution control MUST give positive reactions.

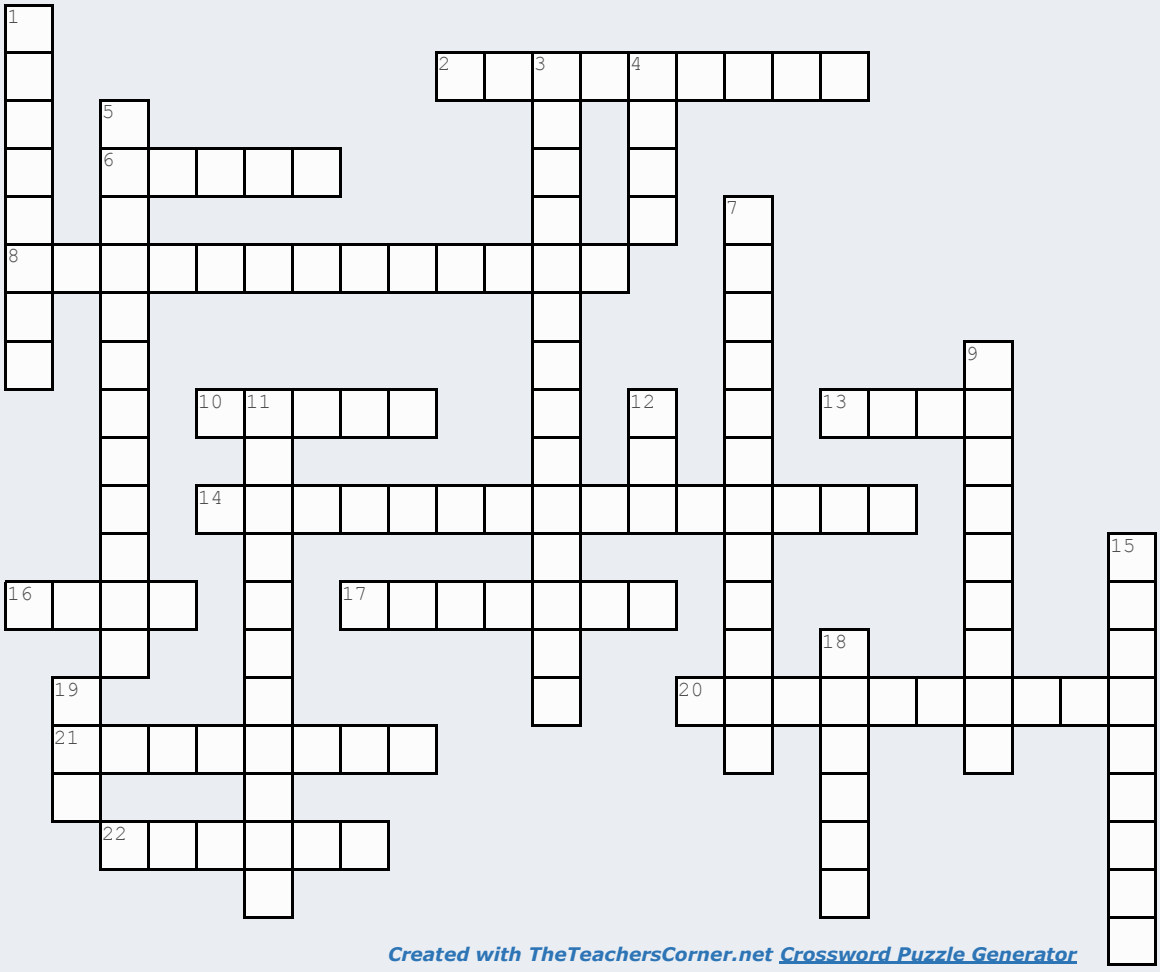
Thiol (Sulfhydryl) Reagents

Thiol reagents include Dithiothreitol (DTT), 2-mercaptoethanol (2-ME) and 2-amino-ethylisothiouronium (AET). DTT is the most commonly used in the blood bank. These chemicals reduce disulfide bonds. The IgM molecule structure is disrupted by treatment with a thiol reagent because the disulfide bonds that hold the five subunits together are broken, leaving five monomers. IgG and IgA molecules are not as easily affected by such treatment. This is the basis for treating plasma with a thiol reagent to remove IgM antibody activity, and for treating cells that are sensitized with an IgM antibody. By use of one of these chemicals, we can decide if an antibody in a prenatal patient could possibly cause HDFN, and we can resolve some ABO discrepancies.

Thiol reagents also disrupt disulfide bonds that give certain blood group antigens their tertiary structure, especially those that have extracellular cysteine residues. Hence, cells can be made null phenotype for these blood group antigens by treatment with a thiol reagent. Because of this characteristic, it is extremely important to recognize that cells incubated with such a reagent, not be used to identify the corresponding antibody to any of these denatured antigens.

Submit your completed crossword puzzle to KABB for a chance to win free registration to the Annual Meeting in August!

Name: _____ Phone:_____



Across

2. Terminal sugar of the B antigen

6. Antigens in this system are not well developed at birth

8. The biochemical changes that occur during storage of red cell units

10. An enzyme that denatures the M antigen

13. Antigens in this system are denatured by .2M DTT

14. A source of fibrinogen for patients in DIC

16. Antibodies to antigens in this system are notorious for waning in titer and causing DHTRs

17. The process of removing antibodies from the surface of cells

20. The process of removing antibodies from serum using cells of known phenotype

21. Determined by molecular testing

22. Terminal sugar of the H antigen

Down

1. An enzyme that cleaves the large multimers of vWF

3. This process makes blood products CMV safe

4. Found in large amounts on myeloma cells

5. An antibody formed in response to exposure to foreign blood group antigens

7. An antibody formed to the patient's own antigens

9. Transfusion of this product is generally contraindicated in patients who suffer TTP

11. Helps prevent GVHD due to transfusion

12. A source of multiple coagulation factors when no factor concentrates are available

15. Determined by testing patient cells with known antisera

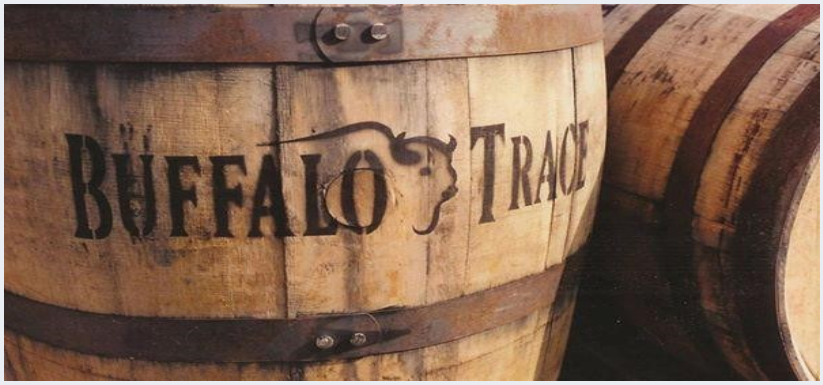
18. What we call the phenotype of a person who lacks all ABH antigens

19. Patients may receive washed red cell units if they have antibodies to this

KABB Annual Meeting Friday, August 18, 2017 at Buffalo Trace Distillery

Featuring Jay Menitove, MD

Consultant, Transfusion Medicine Kansas City, MO



REGISTRATION FORM

ALL participants must register.

SELECT ONE:

☐	KABB Member Membership	$35 with lunch $15
☐	Non-Member Technologists and Physicians	$65 with lunch
☐	Students - MT, MLT, Residents, Fellows Membership	Complimentary $5
☐	KABB Officers, Board, Committee Members	Complimentary

Register for Distillery Tour and Tasting

☐	Distillery Tour 4:30 — 5:30 P.M.	Complimentary, must register for event

Please type or print clearly.

First Name: MI: Last Name:

Credentials (MT, MLT, SBB, MD, DO, RN):

Home Address:

City: State: Zip:

Business Affiliation:

Daytime Phone: Email Address:

Mail completed form and payment by **Friday, August 4, 2017.**
(Checks only, payable to "The Kentucky Association of Blood Banks")
Leonard Boral, MD
University of Kentucky Medical Center
Dept. of Pathology and Lab Medicine, 800 Rose Street, MS117
Lexington, KY 40536

Friday, Aug. 18, 2017

8:00 — 8:40 A.M.
Registration and Coffee / Exhibits

8:40 — 8:50 A.M.
Welcoming Address
Elpidio Pena, MD *President of KABB*

8:50 — 9:10 A.M.
Septic Transfusion Reactions
Claire E. Meena-Leist, M.D., Louisville, KY
Chief Medical Officer Central Blood Services American Red Cross

9:10 - 9:30 A.M.
Pathogen Reduction
Elpidio Pena, MD, Louisville, KY
Director of the Blood Bank, Norton Healthcare

9:30 — 9:50 A.M.
Antibody Case Study - Gotta Catch'em All
Jacqueline Ensley, MT (ASCP) SBBcm, Lexington, KY
Reference Lab Manager, KY Blood Center

9:50 - 10:30 A.M.
BREAK/REFRESHMENTS/EXHIBITS

10:30 — 10:50A.M.
The Bleeding Patient on a Direct Oral Anticoagulant
Carolyn Burns, MD, Louisville, KY
Consultant, Patient Blood Management

10:50 A.M. — 12:00 P.M.
The Storage of Blood Debate. Is Longer Better?
JAY MENITOVE, MD, *former President/CEO and Medical Director Community Blood Center, Kansas City, MO*

12:00 — 1:10 P.M.
LUNCH/EXHIBITS

1:10 — 1:30 P.M.
How to Sucessfully Relocate a Blood Bank
Daoping Zhang, MT (ASCP) SBBcm, Lexington, KY
Chief Medical Technologist, University of KY Med. Ctr.

1:30 — 1:50 P.M.
Finding the Phenotype of Recently Transfused Warm Autoantibody Patients
Kathy Evans, MT(ASCP) BB, Lexington, KY
Master Tech, Good Samaritan Blood Bank

1:50 - 2:10
Delayed Hemolytic Transfusion Reactions
Jennifer Jenkins, MPH, MLS (ASCP)^{CM} Lexington, KY
Lead Tech, Good Samaritan Laboratory

2:10 — 2:30 P.M.
Complement, Inflammation and Coagulation Interaction
Leonard I. Boral, MD, MBA, Lexington KY
Director of Blood Bank Services, Univ. of KY Med. Ctr.

2:30 — 3:00 P.M.
BREAK/REFRESHMENTS/EXHIBITS

3:00 — 3:20 P.M.
Occurrence Management
Debbie Bowman, MT(ASCP)SBB, CQA(ASQ),
Executive Director of Quality & Regulatory Affairs, KY Blood Center. Lexington, KY

3:20 - 3:40 P.M.
Advantages of anti-Xa over aPTT for heparin monitoring. Duncan C. MacIvor, MD, Lexington, KY
Assoc. Director of the Blood Bank, Univ. of KY Med Ctr, Lexington, KY

3:40 — 4:00 P.M.
What' s New in the FDA for the Blood Bank
Dennis Williams, MD, Lexington, KY
Medical Director, KY Blood Center

4:00 — 4:30 P.M.
KABB Business Meeting
Suggestions for 2018

4:30 — 5:30P.M.
Distillery Tour, pre-registration required

NOTE THAT MEETING PARTICIPANTS' NAMES AND CITY/INTITUTION ARE REQUIRED BY SOME EXHIBITORS IN ORDER FOR THEM TO PARTICIPATE AND THEREFORE KABB WILL BE PROVIDING THEM THIS INFORMATION.

TARGET AUDIENCE:
Technologists (SBBs, MTs, MLTs, and Students), Pathologists, Hematologists, Anesthesiologists, Physicians, Residents, Fellows in training, and Nurses

KABB is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E. ® Program.

KABB will host the following exhibitors:
TO FOLLOW

Contact Us

Inquiries regarding registration or course content should be directed to:
Leonard Boral, MD
Telephone: 859-323-3302
Email: LIBORA2@UKY.EDU

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kyassociationofbloodbanks.wordpress.com/

The Kentucky Association of Blood Banks (KABB) was reorganized in 2015 to form an educational network among individual transfusion medicine professionals and institutional blood banks in the state of Kentucky. We encourage all individuals and institutions who are interested in immunohematology and transfusion medicine to join.

BENEFITS OF MEMBERSHIP:

•KABB website
•Continuing Education
•Annual Meeting
•Opportunity to serve on Association Committees
•Opportunity to grow in Transfusion Medicine
•Networking
•Links to AABB

KABB 2017 Membership Form

Name and credentials (MD, SBB, MT, MLT, RN): _____

Affiliation (Hospital, Blood Center, Company): _____

Home Address: _____

_____

Phone Number: _____

Email Address: _____

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2017 Dues: $15.00 for membership

$5 Student Membership

Make checks payable to: Kentucky Association of Blood Banks

Remit payment to: Angie McCowan-Bailey
320 Southbrook Dr.
Nicholasville, KY 40356

Please indicate if you are willing to assist with additional KABB activities, such as:

- Committee Participation
- Submit small article for CHANNELS newsletter
- Hold an Office
- Help edit newsletter
- Be a Speaker

KABB membership is a great opportunity to stay up-to-date with the latest blood bank news throughout the year. For only $15.00 a year, you will be able to attend our annual meeting at a discounted rate, earn CE credits, receive the KABB newsletter, network with other blood bankers and develop professionally by serving on any one of various committees. Join us now!

Jennifer Jenkins, Membership Chair

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Elpidio Pena, MD

President Elect:
Open

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Leonard Boral, MD

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Chairperson: Jackie Ensley, MT (ASCP), SBBcm

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Louisville, KY 40202

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