Lab Focus

February 2004 *– monthly insert to* 'Scope *from Fairview Clinical Laboratories*

Sound bites. . . .

Technical Approaches for Bacterial Detection

The American Association of Blood Banks provided this list of possible options for bacterial detection in platelets in their Association Bulletin #03-12. Only those with an asterisk currently meet AABB standards; estimated sensitivity is indicated in parentheses.

Metabolic substrate/products in suspending plasma

- *Glucose (10^7 CFU/mL)
- Lactic acid
- Carbon Dioxide
- *pH (10^7 CFU/mL)
- Bicarbonate
- Oxygen

Cell Growth (culture)

- *CO2 generation ($\leq 10^2$ CFU/mL)
- *%Oxygen reduction ($\leq 10^2$ CFU/mL)

Cell Markers

- Clumping/color (RBCs)
  - Swirling(10^7 CFU/mL)
  - *Gram's Stain (10^6 CFU/mL)
- *Wright stain (10^6 CFU/mL)
- *Acridine orange stain (10^6 CFU/mL)
- Antibiotic probes
- Antibody probes
- Epifluorescence microscopy

Molecular Biology

- PCR
- Ribosomal RNA

New Molecular Pathology Textbook

"Principles of Molecular Pathology," authored by Anthony Killeen, MD, PhD, was recently published by Humana Press, Totowa, NJ, 2004. It is an introductory book to the field of molecular pathology for residents, pathologists, and clinical lab scientists.

GFR Reference Range to Change Based on Physician Feedback

In response to clinician feedback we have revised the reference range for GFR to be >60 mL/min/1.73m^2 instead of >80 mL/min/1.73m^2.

We welcome additional comments about the new estimated GFR reporting. As we gain more experience, we may continue to refine our criteria and ability to provide estimates at higher levels of GFR. Because this is a screening program, it's better to err on the side of false positives than miss people who might benefit from early detection.

Numerical results are reported for patients 16 years and older when the computed (estimated) GFR is less than 80 mL/min/1.73m^2. The National Kidney Disease Education Program (NKDEP) (www.nkdep.nih.gov) recommends a reportable range for estimated GFR as less than 60 mL/min/1.73m^2. NKDEP selected 60 mL/min/1.73m^2 because the MDRD study had few patients without at least a modest decrease in renal function, and more importantly, because of the significant laboratory to laboratory bias in creatinine analytical measurement. We have confirmed our clinical laboratory method's accuracy against the MDRD study laboratory and feel comfortable in reporting values as high as 80 mL/min/1.73m^2; however, we have modified the reference range flag as noted above.

We suggest greater than 80 mL/min/1.73m^2 as compatible with normal renal function. Values less than 60 mL/min/1.73m^2 may indicate impaired renal function, with values between 60 to 80 mL/min/1.73m^2 as borderline. However, all values should be interpreted with respect to the patient's clinical status and age.

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New Bacterial Testing of Platelet Components Begins March 1

New standards from the American Association of Blood Banks (AABB) require that the blood bank and transfusion service shall implement methods to limit and detect bacterial contamination in all platelet components by March 1, 2004.

Blood suppliers are implementing bacterial detection by culture method for 100% of single donor platelet (SDP) products. Additionally changes have been made in the collection process that will limit bacterial contamination in both random and single donor platelets. These include the use of a new skin prep soap and a diversion pouch to eliminate the skin fragment that enters the needle at time of puncture. These changes were made to address the concern that skin flora may adhere to the surface keratin layer, or may reside on the surface of the inner epidermal layer or within

hair follicles and associated glands.

Fairview Northland Regional Health Care, Fairview Lakes Medical Center, Fairview Ridges Hospital, and Fairview Red Wing Hospital have decided to utilize single donor platelets exclusively due to the relatively low volume of random donor platelet transfusions performed. This decision was made based on the cost of setting up the bacterial screening in-house compared to the frequency with which it would be performed.

Fairview-University Medical Center and Fairview Southdale Hospital have decided to perform in-house testing on all random donor platelets. Based on preliminary studies, Glucose using Lifescan® meter has been selected as the preferred test for bacterial detection from the list of AABB approved testing.

Due to the volume of platelets transfused; conversion to single donor platelets would cost more than 1.5 million dollars at Fairview-University alone.

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Cystic Fibrosis Carrier Screening

Cystic fibrosis (CF) affects approximately 1 in 3,000 newborns of Caucasian or Ashkenazi Jewish descent, but is less common in other ethnic groups. CF is a serious genetic disease that is characterized by recurring lung infections, pancreatic disease, gastrointestinal abnormalities, and male infertility. It is inherited as an autosomal recessive trait.

Recent guidelines from the American College of Obstetrics and Gynecology (ACOG) and the American College of Medical Genetics (ACMG) recommend screening pregnant women and their partners to identify couples who are both carriers of CF genetic mutations, and who are therefore at risk of having a CF-affected child. Carriers of CF mutations are clinically normal, and up to 1 in 29 Caucasians or Ashkenazi Jewish individuals are CF carriers. The probability of both members of a couple being carriers is approximately 1 in 900.

Detection of carriers is made by performing DNA analysis that looks for the more common CF mutations. Over 1,000 CF mutations have been identified, but the most frequent 25 account for over 80 percent of all mutations. ACOG/ACMG guidelines recommend a specific panel of 25 mutations be included in a screening program. For high risk populations, a negative test result reduces the probability of being a CF carrier from 1 in 29 to approximately 1 in 140.

Testing that meets the ACOG/ACMG guidelines is now being performed within the UMPhysicians Molecular Diagnostics Laboratory. Sample requirements for the CF Mutation Screen are 5-10 mL of EDTA or ACD-anticoagulated blood. Results include any identified mutation, a revised risk of being a carrier (if no mutation is identified), and recommendations for further follow-up.

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