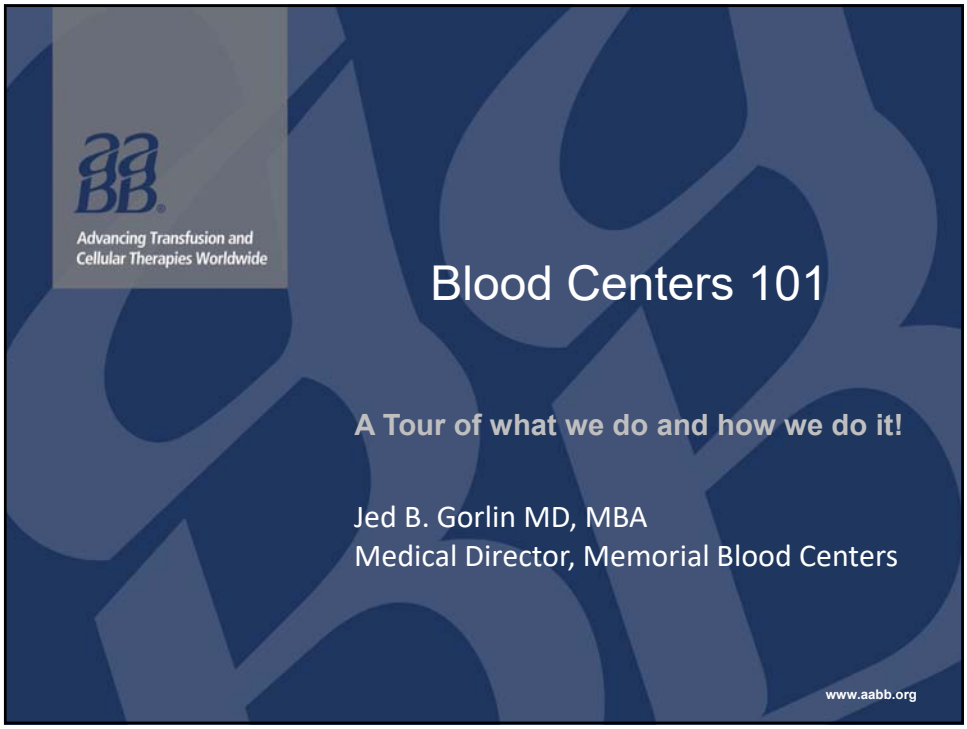


1

## Faculty Disclosure

(*In compliance with ACCME policy, AABB requires the following disclosures to the audience*)

- I am employed by Memorial Blood Centers, a division of New York Blood Center enterprises. I am also medical director of Nebraska Community Blood Bank and Community Blood Center of Greater Kansas City.
- I am also Transfusion Service Medical Director for Hennepin County Medical Center (HCMC) and Children's Hospitals and Clinics of Minnesota

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## Learning Objectives

- After viewing the participant should be able to:
  - Understand the efficiencies provided by blood centers
  - Appreciate inventory management strategies of blood centers
  - Describe the role of blood centers in recruitment of donors, collection of units, infectious disease screening, further processing and distribution of various blood components
  - Understand some of the additional roles such as Immunohematology reference laboratories, and apheresis collection programs

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# Welcome to Memorial Blood Centers, A Division of New York Blood Centers

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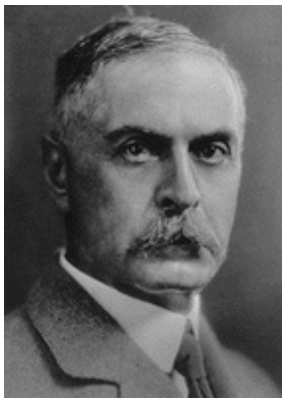
Around 1900, Karl Landsteiner discovered that there are distinct types of bloods and that mixing certain blood types causes reactions.



5

It took 10-20 years before Landsteiner's discoveries were routinely used.

**The ABO Blood System**

| Blood Type (genotype) | Type A (AA, AO) | Type B (BB, BO) | Type AB (AB) | Type O (OO) |
|---|---|---|---|---|
| Red Blood Cell Surface Proteins (phenotype) | A agglutinogens only | B agglutinogens only | A and B agglutinogens | No agglutinogens |
| Plasma Antibodies (phenotype) | b agglutinin only | a agglutinin only | NONE. No agglutinin | a and b agglutinin |

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## Historical Perspectives -
### Memorial Blood Centers

- Virtually all blood centers date their inception to shortly after WWII
- In 1947 Minnesota there was no centralized blood bank. Most hospitals were able to store blood and there was sharing of blood among hospitals, but this system proved unreliable.
- War Memorial Blood Center of Minneapolis was started by the Jaycees in 1948. Hubert Humphrey, then mayor of Minneapolis, was a major supporter. 8,823 pints were drawn, the first year.
  - Initial testing ABO, Rh(D), Syphilis

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## Memorial Blood Centers Timeline

- **1973 - Blood is collected from an all volunteer blood donor pool**
- **1985 - Name changed to Memorial Blood Centers of Minneapolis.**
- **1988 – Marrow processing**
- **1989 - NMDP National Marrow Donor Program**
- **1992 – Arrowhead Regional Blood Center established, serving hospitals in Northern MN and WI.**
- **1999 – MBC Nucleic Acid Amplification Testing (NAT)**
- **2002 – MBC purchases Eden Prairie site for collections, vans, recruiting, collection site**
- **2003 – West Nile Virus NAT implemented**

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## Things a blood center does (and some special things, our center does!)

- Recruit donors, collect, process and supply blood components for transfusion, commercial products or research
- Collect, process hematopoietic progenitors for patients and NMDP
- Infectious disease screening for donors, patients, fertility and milk bank clients
- Immunohematology reference laboratory
- Clinical trials: donor screening, collection and component modification

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## US Blood System

- Majority (>90% ) of the blood collected is by blood centers.
  - American Red Cross (ARC) collects about 43%.
  - Community Blood Centers (America's Blood Centers = ABC) collect about 49%. Memorial Blood Centers in Minnesota collects ~ 130,000 whole blood units and about 22,000 apheresis platelets.
  - Must provide to many hospitals since most hospitals don't collect for themselves.
- All donations are voluntary and non-remunerated
- FDA (Food & Drug Administration) sets the rules for blood donor screening and testing

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## Regulation of blood

- FDA (Food & Drug Administration) regulates blood as a drug
  - New tests and products for blood must be approved under IND, not IDE
  - Everything we do must be described exactly by a standard operation procedure(SOP) reviewed at least annually. We have >3000 SOPs.
  - Training and validation documentation also required
- Also subject to assessment by:
  - AABB: voluntary organization that sets standards for blood banking and transfusion, cellular therapy-*(Jed is on their board)*
  - ISCT: International Society for Cellular Therapies (FACT)
  - EU-European union: exported plasma for derivatives
    - Specific derivative manufacturers- Octapharma, ZLB/CSL regulations (AABB is deemed assessor)

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## Processes of a Donor Center

- **Recruiting donors-** Tele-recruiting and drives
- **Collection** of whole blood or apheresis products
- **Preparation** of blood products/components from the whole blood that is collected
- **Testing** of every donation every time
- **Maintain inventory** of blood products/ components
- **Distribution** of inventory to hospital blood banks in the community or in the U.S. to support transfusion management needs of patients

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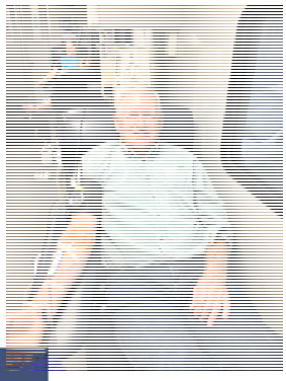
## Blood Donation

**Blood is critical for life. It is vital that the community blood center provide blood that is both safe and available when needed.**



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## Donor Eligibility

- Donor safety questions-BP, HCT
- **Must weigh at least 110 pounds** (50kg)
  (MBC requires higher weights for 16-18 yo females)
- Must be at least 17 yo or 16 with parental permission
- Recipient safety:
  - Blood born diseases: HIV, hepatitis B & C
  - Risk factors for HIV, hepatitis, malaria, NVCJD include: tattoos-piercing, drug use, travel

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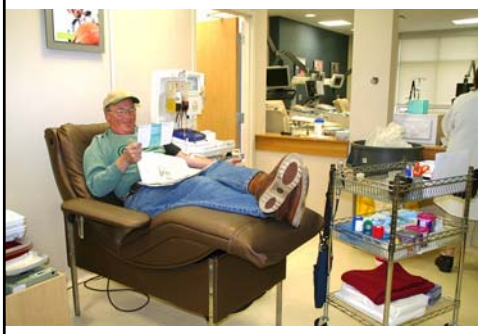
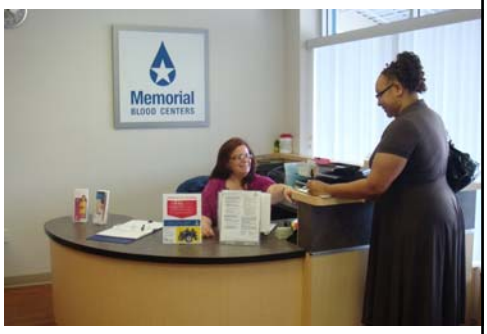
## Fixed Sites



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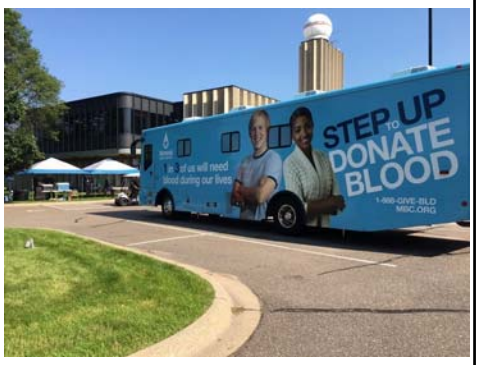
## Donor Collections: Mobile

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## Donor educational material


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## Donor Collections

- **Donor interview and physical ensure safety of the donor and unit of blood.**
- **Questions for donor and patient safety**
- **Check donor hemoglobin (≥12.5 g/dl female, ≥ 13g/dl male) BP, Pulse, Temperature**

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## Collection of Whole Blood & Other Products or Components

- **Donor Collection for Whole Blood**
  - Allogeneic healthy donor used for transfusion of someone other than the donor
    - *Routine Donor Supply (~99%)*
    - *Directed Donor for Family or Friend (<1%)*
  - Autologous- the patient gives his/her own blood
    - We discourage auto donation as up to 70% wasted
  - All donors are VOLUNTEERS
    - FDA allows paid donors (e.g. plasma donation centers) but it must be labeled as coming from a paid donor
    - Most hospitals would not accept from paid donors at this time

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## Collection of Whole Blood & Other Products or Components

**Whole Blood Collection Process**

- Donor arm prep with iodine/alcohol or chlorhexidine decontamination. (platelet donors get chlorhexidine unless sensitive)
- Volume drawn = 500 ml unless donor is <129 lbs then lower volume (~450-475ml) removed.
- Most center use rocking scales to mix blood with anticoagulant and automatically stop collection when blood volume is at goal. Most blood centers use Sample Diversion Pouches to capture the initial 30-40 ml of blood to diminish bacterial contamination.
- The samples are used for donor testing
- Donors given instructional guide

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## Collection of Whole Blood & Other Products or Components

- **Donor Collection for all Components begins as Donor Collection for Whole Blood**
- **Components are prepared in the Component Laboratory**
  - If the donor has taken medicines that contain aspirin, the Whole blood will be tagged and platelets will not be prepared from the unit.


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## Apheresis Platelets

- **Donor Collection for Platelet Apheresis**
  - Donors may donate up to 24x/year.
  - Apheresis platelets demand increased dramatically following requirement for bacterial screening.
  - MBC obtains:
    - 17% single ($3 \times 10^{11}$)
    - ~73% doubles
    - ~10% triple collections

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## Blood Unit


**How much do we collect in a donation?**
- **About one pint (500ml = 1/2 liter)**

**How often can I donate?**
- **Up to every 8 weeks (=~2 months or 6x/year)**

**How long does it take to replace the blood I donated?**
- **~6-8 weeks**

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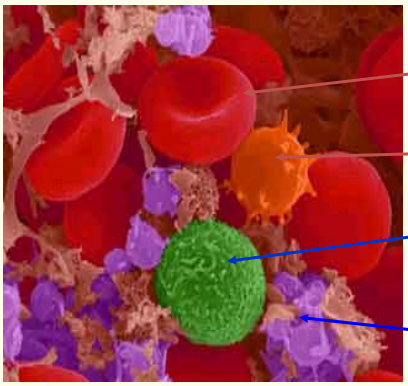
Memorial Blood Centers
MEMBER AMERICA'S BLOOD CENTERS

## *Components of Blood*




It's About *Life.*

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## Preparation of Blood Products & Components

- Time the Whole Blood was collected
- How the Whole blood was transported
  - *Transported on ice or not on ice*
- Processing schedule for EIA and NAT assays
  - *Critical for meeting inventory needs*

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## Preparation of Blood Products & Components

- **Blood shipments arrive at different times each day depending on the blood collection schedule:**
  - From fixed sites/satellite locations
  - From mobiles such as church, business, etc.
  - Blood drives
  - From blood vans that have been to shopping enters, grocery stores, etc.

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## Preparation of Blood Products & Components

**Component Preparation Process**

- Whole Blood is first centrifuged to separate it into the components
  - *Separates platelets and plasma from red blood cells*
- Expressers are used to assist in removing plasma or platelet-rich-plasma from red blood cells
- Red Cells are separated from each of the components

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## Platelet products have a short life

- Current FDA allowed expiration is 5 days
- Shortened after observation of bacterial contamination in 1970s
- Current AABB requirement to screen all platelet components for bacteria or pathogen reduction (PR)
- 7 day approval for apheresis platelet products with point of care testing or delayed large volume collection. EU allows 7 day for PR


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## Bacterial Screening of Platelets

- FDA requirement to screen platelets for ~1/2000 risk of bacterial contamination
- Current culture after 24 hours of incubation
- Point of care screening
- Final guidance 2019 requires additional testing or treatment if transfused day 4 or after, with culture at 36h (5 day) or 48 h (7 day) or Pathogen reduction

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## BacT Alert

- Used for determining bacterial contamination in platelets.
- Awaiting FDA approval for 7 day claim


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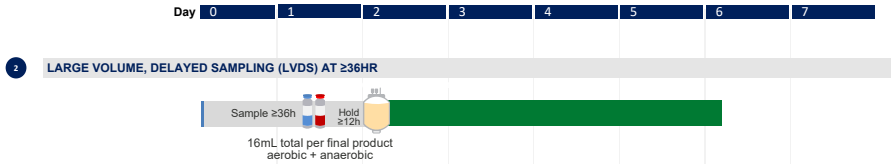
# Large Volume Delayed Sampling One Step Strategies




- All Apheresis and pre-storage pools
- Can extend to 7 days with additional bacterial sampling or rapid testing
  - Rapid testing not available for platelets in PAS


- For apheresis platelets that are approved for 7-day storage
  - Not yet available, waiting for safety claim

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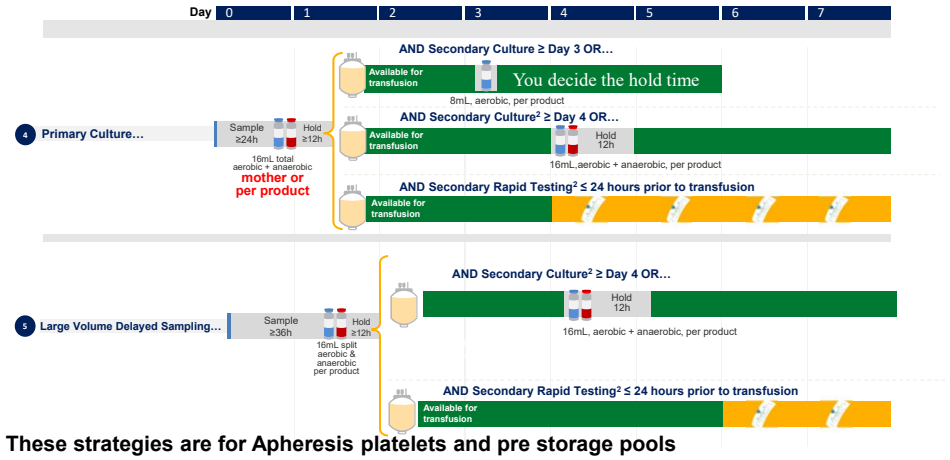
# Two Step Strategies




**These strategies are for Apheresis platelets and pre storage pools**

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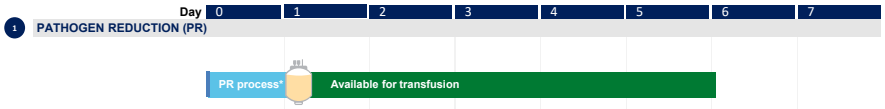
# Pathogen Reduction




- Available for Trima apheresis platelets in plasma
- Available for Amicus apheresis platelets in platelet additive solution (PAS)
- Licensed for singles and doubles only
  - May split some doubles and triples to meet acceptable guard bands
- 7-day product is not available at this time

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# Prestorage Leukoreduction

- Advantages of removing WBC before storing red cells include:
  - Diminished rates of febrile reactions.
  - Reduction of rate of platelet alloimmunization.
  - Possible other immunomodulatory effects. (Reduction of length of stay NOT documented in controlled study: Dzik-Transfusion 42:1114)
- Disadvantages of prestorage LR include:
  - additional cost for filtration
  - Loss of platelets (some bag/filters “spare” platelets)
  - Up to 15% loss of RBC mass

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## Labeling of Cleared Units for Distribution

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## Hospital Services

**Labeled Units:**
- **Stored in temperature monitored units.**

**Component Storage Temps:**
- **RBC: 2-6° C**
- **Platelets: 20-24° C**
- **Plasma (frozen): ≤ -18° C**

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## Central Receiving

- Incoming Blood Components and tubes received and sorted
- Tube Segregation
- Label with barcodes
- Accession into Computer
- Sample Centrifuge

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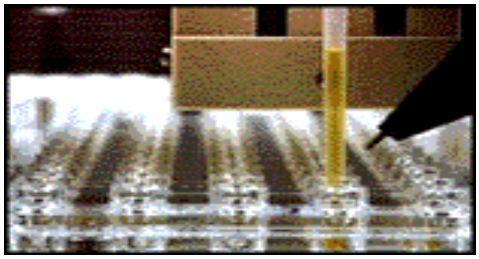
## Donor Testing Lab

➢ **Ensures the safety of the blood from Transfusion-Transmitted Diseases.**



➢ **13-14 tests on each unit of donated blood :**
**ABO, Rh(D), Antibody screen, Anti HIV-1/2, Anti-HCV(3.0), Anti-HBcore, HBSAg, Anti-HTLV I/II, Syphilis, (T. cruzi = Chagas' on first time donors), Zika and Babesia on RBC donations**

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## Blood Testing~ Donors and Patients

- **Critical factors for testing blood supply**
  - Specimens Required for Testing
  - *EDTA for Blood Grouping Instruments*
  - *EDTA or Clotted Samples for Other Instruments*
- **Parallel testing to meet component preparation and inventory needs**
  - *Blood Grouping/Antibody Screening and EIA and NAT testing usually done in parallel.*
  - *EIA and NAT usually done at night because of length of assays.*
  - *NAT runs have the longest turnaround time of 6 hours.*

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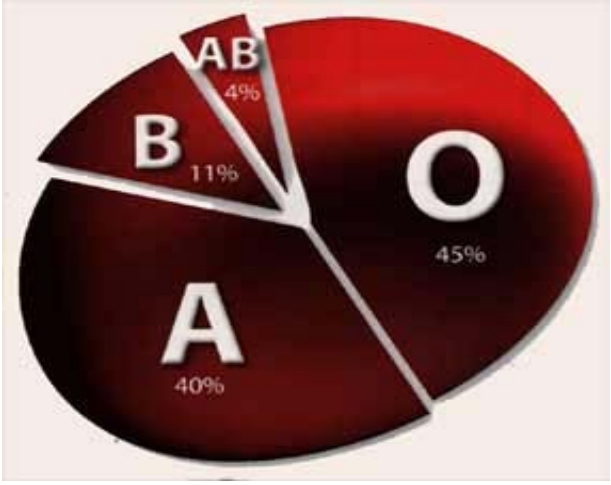
## Blood Types

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## Historical Perspective: Since 1985

- 1985: Anti-HIV-1
- 1986: ALT, Anti-HBc (Hep-B Core Ab)
- 1987: HIV-1 (conf) Western Blot licensed
- 1989: Anti-HTLV-I
- 1990: Anti-HCV1.0 (Hepatitis C Virus)
- 1992: Anti-HCV 2.0, Anti-HIV-1/HIV-2
- 1993: HCV-(conf) RIBA 2.0 blot licensed

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## ABO/Rh Screening

- Commonly used screening devices are Beckman PK 7300 and Immucor Neo/Iris (NEO upgrade)
- Both offer syphilis testing and CMV
- We also perform Rh (C,c,E,e) and K typing in addition to ABO and Rh(D) on selected 1st time donors
  - Full RBC genotyping on some repeat donors
- Antibody screening – we use the Immucor NEO


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MAJ1

## Historical Perspective: Since 1985

- 1994: FDA discusses molecular testing
- 1996: HIV-1 p24 Antigen, Anti-HCV 3.0
- 1997: HTLV-I/II
- 1999: HCV-RIBA 3.0 licensed
- 1999: HCV-NAT, HIV-NAT clinical trials licensed in 2003, 2004
- 2002: Hep. B-NAT US clinical trials
- 2003: West Nile Virus by NAT
- 2006: Chagas test licensed-
  - (Most US centers only test first time donors)
- 2015 Babesia EIA under IND
- 2016 Zika NAT research ('17 licensed)
- 2018 Babs NAT (regional approach) under IND, licensed 2019

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## Current Blood Donor Tests 2019

*CMV testing is available, but not required

**FDA requires testing on first time donors only

| Test | Methodology |
|---|---|
| ABO/Rh | Agglutination |
| Red Cell Ab screen | Agglutination |
| Syphilis | Agglutination |
| CMV* | Agglutination |
| HBsAg | EIA |
| Anti-HBc | EIA |
| Chagas** | EIA |
| Anti-HIV-1/2 + group O | EIA |
| Anti-HTLV-I/II | EIA |
| Anti-HCV | EIA |
| HBV,HIV,HCV-NAT | Pooled PCR |
| WNV-NAT | IND or Pooled PCR |
| Babesia microti | IND or Pooled PCR |
| Zika Virus | IND or Pooled PCR |

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**Slide 43**

**MAJ1** Mark A. Janzen, 11/13/2019

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## Blood Testing~ Donors and Patients

### Infectious Disease Assays by EIA

- Hepatitis C Tests
  - *Detects the antibodies response to Antibodies to HCV (Anti-HCV)*
- Hepatitis B Tests
  - *HBsAg*
  - *Antibodies to HB Core (Anti-HBc)*

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## Blood Testing~ Donors and Patients

### Infectious Disease Assays by EIA

- Two Vendors in the U.S.
  - *Abbott Diagnostics*
  - *Ortho Diagnostics*
- Two Methods
  - *Ortho Traditional Microplate*
  - *Abbott Alinity (Chemiluminescence)*

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## Blood Testing~ Donors and Patients

- **Infectious Disease Assays- Others**
  - Syphilis
  - CMV as needed for special patients
    - *Immune deficient patients*
    - *Neonates*
    - *Transplant patients*
  - Chagas (T. cruzi)
    - 1x testing prevalent after post-marketing studies show very low yield and little transmission.

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## Nucleic Acid Testing (NAT) Lab

### Using Molecular Methods

Most NAT testing in the US is performed as pooled testing, either in pools of 16 or 6.
This works well when both the assay is very sensitive and when there is a low background prevalence of the infection tested for in the tested population.
Where used in high prevalence areas, individual donor testing is better with respect to sensitivity and not having to retest.

*Cobas Hamilton STAR Pipettor*


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## Pooled Testing & Resolution Of Positive – Roche & Grifols

- Roche: Uses a pool of 6 in US. If the pool tests positive, the 6 individual samples are tested.
- Grifols: If pool of 16 is +, then each individual sample is tested
- Hence, for both platforms the secondary testing allows ruling out false positives

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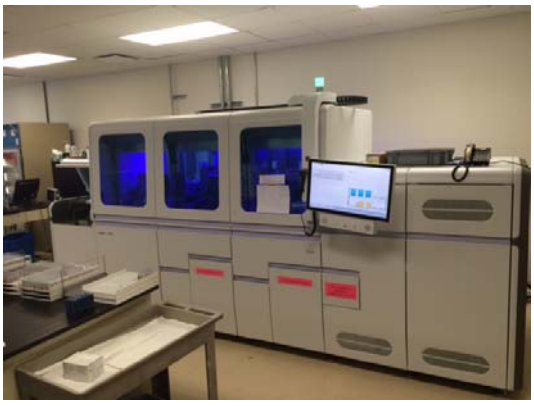
## Roche NAT Testing System

Current NAT platform performs nucleic acid extraction and PCR multiplex assays. Used to screen for HIV, Hepatitis B,C, WNV, Zika and regionally for Babesia. Generally screening performed in pools of 6 for blood donors, individually for tissue/cell therapy donors.

*Roche 8800*



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## Grifols Blood Donor Screening Assay: Babesia species

- BARCELONA, Spain, U.S. Food and Drug Administration (FDA) approved the Procleix Babesia assay, a qualitative assay for the detection of the ribosomal RNA from 4 *Babesia* species (*B. microti, B. duncani, B. divergens, B. venatorum*) in individual samples or up to 16 pooled lysed specimens from human donors.

"The assay runs on the Procleix Panther system — a fully automated platform utilizing Nucleic Acid Testing (NAT) for blood screening." Same platform is used for multiplex testing for HIV, Hep B,C and WNV and Zika.
https://www.biospace.com/article/releases/grifols-receives-fda-approval-for-procleix-babesia-assay-for-donor-screening-on-procleix-panther-system/

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## NAT Lab-
### Using nucleic acid technology to screen blood

**New tests as of 1999, HIV/HBV/HCV a multiplex assay***

- **HIV-1* (AIDS virus) ~RNA inc. group O**
- **HCV*- Hepatitis C~RNA**
- **HBV* Hepatitis B~DNA**
- **WNV-West Nile Virus**
- **Zika**
- **Babesia**

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## Risks of Transmission

- Infectious Risks
  - Viral
  - Bacterial
  - Protozoa
  - Ricketsia
  - Other
    - ?Prion-nvCJD
    - = mad cow disease
- Non-infectious risks
  - Transfusion Reaction
  - Metabolic
  - Cardiac Overload
  - Dilutional Coagulopathy
  - TAGVHD
  - Alloimmunization

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## Infectious Risks in US in NAT Era

- Infectious Agent
  - HIV (AIDS)
  - Hepatitis C Virus
  - Hepatitis B Virus
  - HTLV
  - WNV
  - Bacteria
  - Babesiosis
  - Chagas
- Risk estimate
  - <1:2,000,000
  - <1:1,600,000
  - <1:500,000
  - <1,1,000,000
  - 90% reduced by NAT
  - 1:3-5,000 platelets
  - Rare but MN is higher
  - Rare, more common in Central & South Am.

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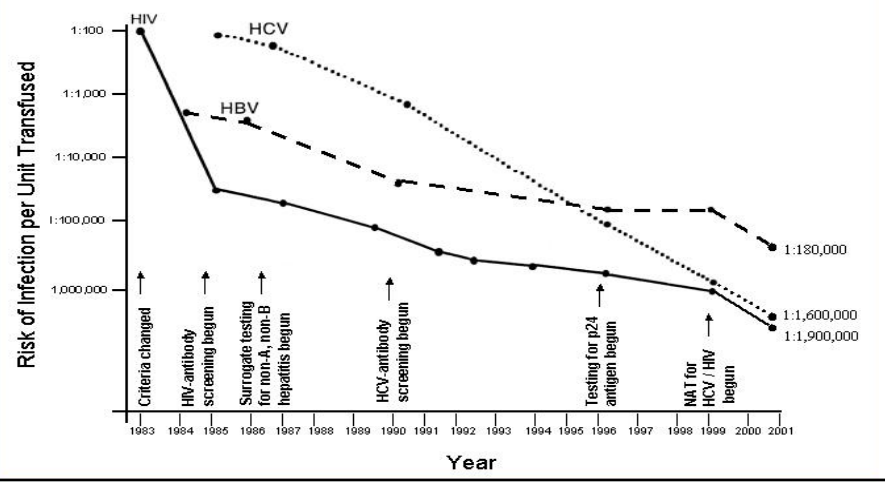
## New Test Implementation and Declining Risk of Viral Infections from Transfusion

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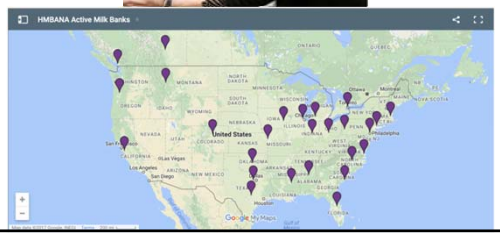
## Milk Bank testing!

We perform infectious disease testing on the donors of mother's milk.
Infants in NICUs benefit by the antibodies and other protective components of human mother's milk. Iowa and Minnesota, among other states have non-profit programs to share mother's milk.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## Immunohematology Reference Laboratory

Specialist in Blood Bank

- Identify compatible units for hospital clients across the country
  - Routine and complex antibody identification
  - Resolution of ABO discrepancies
- Perform platelet crossmatching or find HLA/HPA compatible platelet donors (donors negative for specific antibodies of patient)
- Titers
  - Of specific antibodies in pregnant females at risk of HDN
  - Of donor products, specifically- Group O donors of:
    - Whole blood anti-A (or B) titer
    - Apheresis platelets

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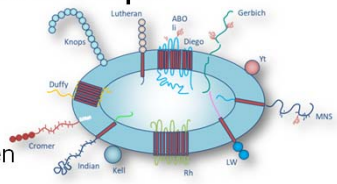
## Common Red Cell Antigen Genotyping

Thirty-seven antigens (>300 antigens on RBC surface)

- Expedite turn around time for patient workups
- Donor Screening
  - Provision of antigen negative units
    - Multiply negative units
    - Donors negative for high prevalence antigen




- American Rare Donor Program
  - To participate in rare donor registry (and request rare units), the center must commit to adding a certain number of rare donors/units to the registry annually
  - Act as access point for rare unit requests

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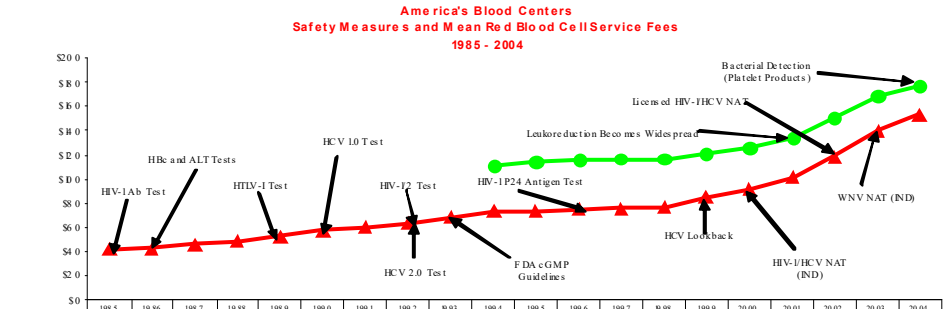
# Other Testing we do on blood donors

- TRALI mitigation: Anti HLA antibody screen: female donors with one or more prior pregnancies donating single donor platelets or plasma
- Mitigation of hemolysis from incompatible plasma: Using “low” titer anti-A (or A,B)
  - Iso A @ different cutoffs, eg whole blood, group O plts
- Hemoglobin S
  - Interferes with leukoreduction
  - Is contraindicated if being transfused into sickle cell patients or settings with low FIO2 (ECMO, NICU)

59

59




60

## Blood collection and testing in Afghanistan as of 2013

Donation through a window is typical in older Soviet era facilities!

61

## Blood collection in Afghanistan:Blood drive capacity limited to one bus and 2 mobile trucks


Well intentioned western donors tend to reproduce collection strategy. Successful locally. They do use the blood collection bus in downtown Kabul but lack of paved roads precludes use in more remote locations.

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## Maternity hospital transfusion

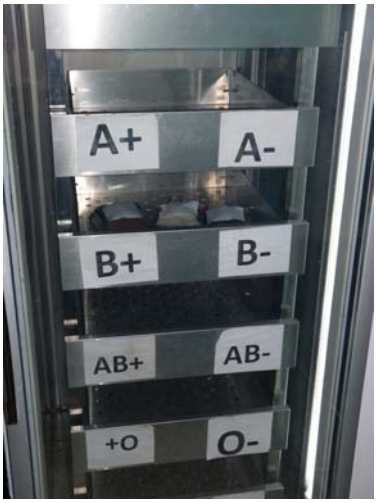
ABO/Rh typing but no Antibody screen

Whole blood is collected from family
Replacement donors

63

## Malalai maternity hospital

- Malalai hospital had exactly one O negative unit and only 3 O+ units on the shelf. They have over 120 deliveries daily!

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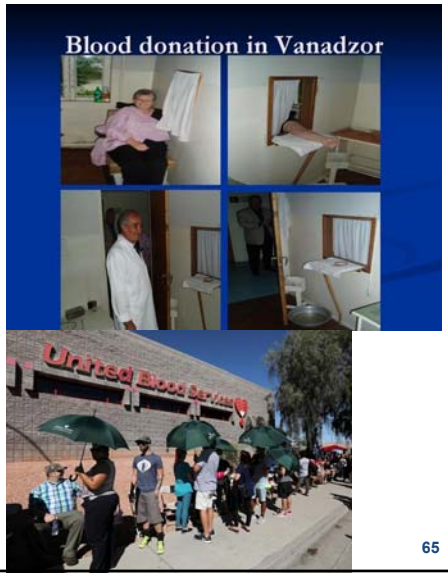
## Thanks and please encourage all eligible friends and family to donate regularly!

- Blood is available because we donate before disaster events!
- Vanadzor is site of major Armenian earthquake
- Blood donation waiting line after Las Vegas shootings October 2017

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