Platelets: Always Bugging the Blood Bank

Gabriel Metzler MLS(ASCP)^{CM}SBB^{CM}
Blood Bank Supervisor
Children's Mercy Kansas City

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UMKC School of Medicine

BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT RANKED IN 10 SPECIALTIES 2017-18

MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

Objectives

- Describe the background/principle of Verax testing
- Explain why we made to the decision to move forward with testing
- Describe how we implemented testing into our workflow
- Describe what we experienced after implementation

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Verax Workstation

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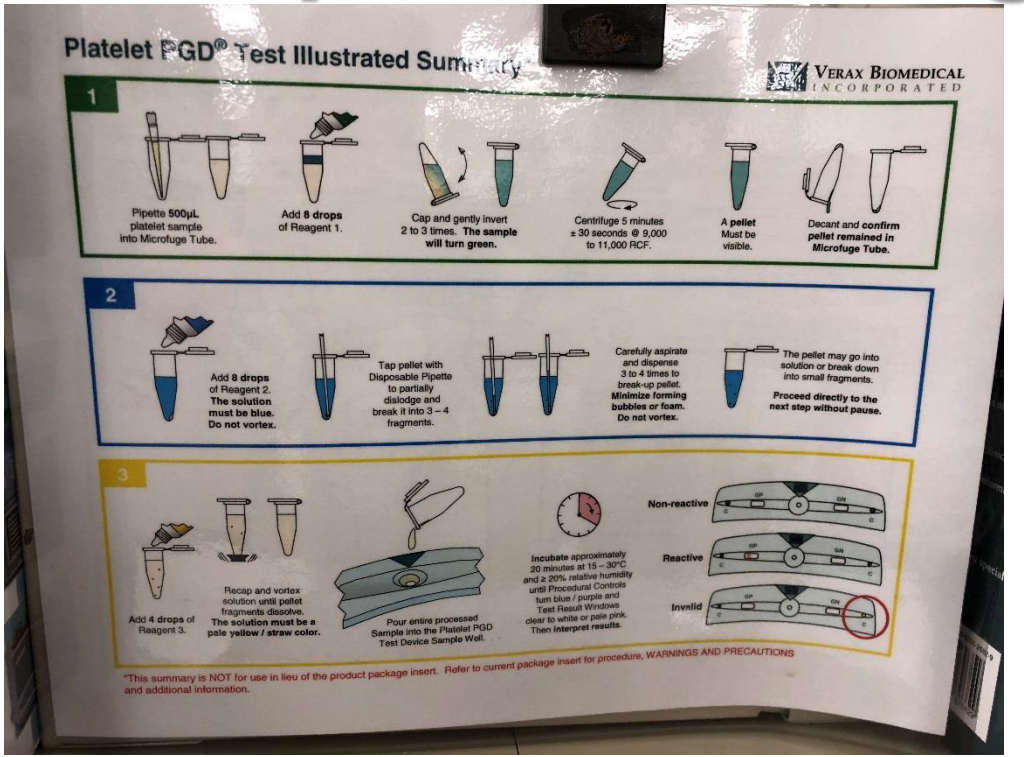
Background of Verax Platelet PGD® Test

- Rapid, qualitative immunoassay that detects the presence of bacteria in platelets for transfusion
- Detects aerobic and anaerobic Gram-positive and Gram-negative bacteria
- Platelets are tested within 24 hours of transfusion
- Must follow testing with a growth-based QC test cleared by the FDA
- Added safety measure for platelet components

Principle of Testing

- Single test device to detect both GP and GN organisms
- Tests for Lipotechoic acid (LTA) and Lipopolysaccharide (LPS) stripped from bacterial cell wall
- Detection is based on specific antibodies to LTA and LPS in a sandwich antibody-antigen-antibody reaction
- Allows for detection of the bacterial species most frequently seen in contaminated platelets

Principle of Testing



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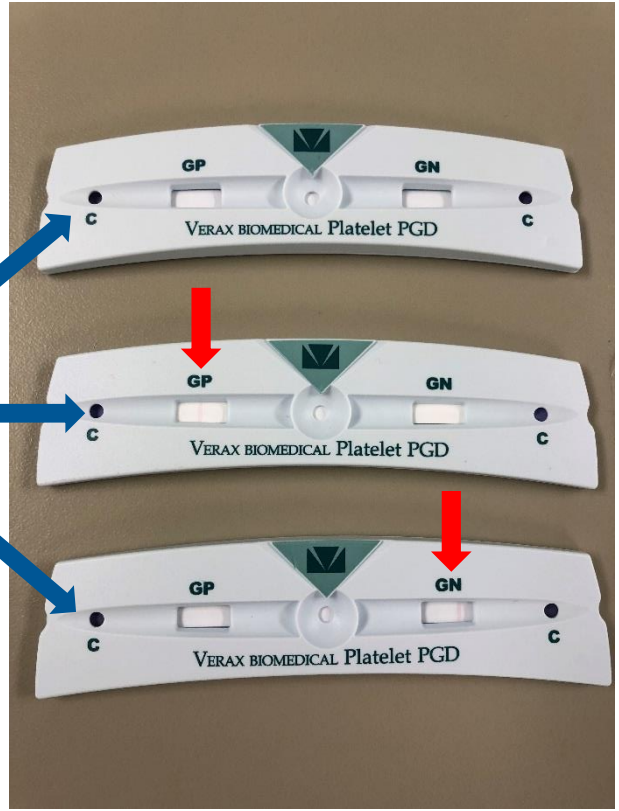
Reactions



Internal Controls

Negative

GP Reactive

GN Reactive

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Why Test?

- Approximately 1 in 100,000 transfused apheresis platelet units is implicated in transfusion associated bacterial infection
- Routine QC detects bacteria in approximately 1 in 6000 apheresis platelet donations
- Current screening methods miss detection of some bacterial contaminated apheresis platelet units due to low level of bacteria just after collection

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Fung, Mark K., Anne F. Eder, Steven L. Spitalnik, and Connie M. Westhoff. *Technical Manual*. Bethesda, MD: American Association of Blood Banks, 2017. Print.

FDA Draft Guidance

Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion

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Draft Guidance for Industry

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FDA Draft Guidance

FDA RECOMMENDATIONS FOR TESTING DAY FOUR AND DAY FIVE PLATELETS

Surveillance data on platelets stored for up to five days have shown that 95 percent of platelet transfusion-related septic reactions and 100 percent of associated fatalities have occurred with transfusion of day four and day five stored platelets, with an almost even distribution between these two days.[2]

The FDA draft guidance, in Section VII, recommends implementing secondary testing of previously cultured apheresis platelets and pre-storage pooled platelets to enhance platelet safety through day five of storage in one of two ways:

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Options

- Rapid assay to detect bacterial contamination on Day 4 and 5
- Culture of platelets on Day 4
- Pathogen Reduction

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Why Start Before Final Guidance?

- It's for the kids!!!
- Patient population:
  - Oncology
  - BMT

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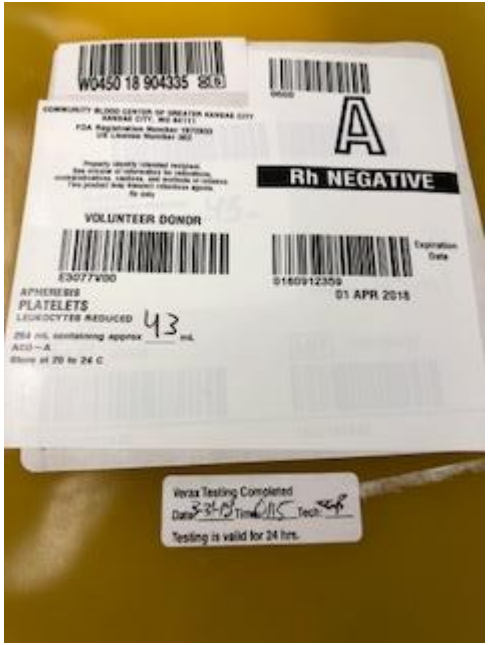
Implementation

- Plan, plan, plan!
- When?
- How many?
- Which type?
- How often?



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CMH Special Considerations

- Volume
  - Approximately 170 transfused platelets/month
  - 6% of shipped platelets are 4-5 days old
- Inventory Rotation
- CMH Platelet Requirements
- ECMO

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Our Plan

- Only test 4 and 5 day old platelets
- Batch test right after midnight including QC
- Test as needed for STATS that arrive throughout the day

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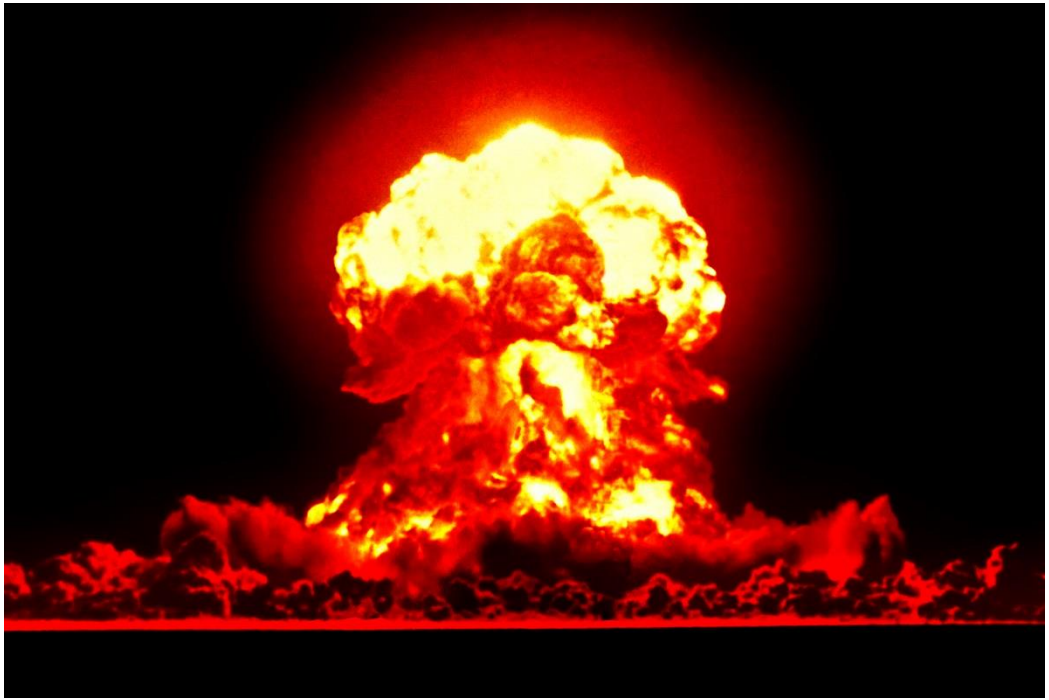
Our 1st Week



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What Did We Change?

- Moved QC to day shift
- Night shift only responsible for one batch of 6 platelets
- Group B and AB platelets will only be tested on an “As Needed” basis
- Partial platelets will only be tested on an “As Needed” basis

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All Good Now, Right?

- Improved, but still not where we want to be
- More tweaks:
  - Night shift only test 1 group A and 1 group O platelet for batch
  - When a tested platelet is used, another can be tested
  - No batch testing on weekends

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Reactive Platelets

- Three Repeat Reactive platelets
  - Two were from same donor
  - Culture negative on all three
- 0.6% false positive rate

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What's Next?

- FDA Final Guidance???
- Date extension

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Special Thanks

Robert Murzyn and Pat Rasmusson from Verax Biomedical

Community Blood Center of Greater Kansas City

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References

- Verax Biomedical Platelet PGD® Test package insert
- Fung, Mark K., Anne F. Eder, Steven L. Spitalnik, and Connie M. Westhoff. *Technical Manual*. Bethesda, MD: American Association of Blood Banks, 2017. Print.
- FDA Draft Guidance

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