

Performance of the Platelet PGD[®] Test for the Detection of Bacterial Contamination of Apheresis Platelets: A Single Center Experience

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Bacterial Contamination of Platelets

- Most significant infectious risk of transfusion
- Resulted in 20 of 267 transfusion related fatalities reported to the FDA in 2005-2009.

Requirement for Detection of Bacterial Contamination

- College of American Pathologists TRM.44955
“Does the laboratory have a validated system to detect the presence of bacteria in platelet components?.”
- AABB Standard 5.1.5.1 (2004)
“The blood bank or transfusion service shall have methods to limit and detect bacterial contamination in all platelet components.”

Methods to Reduce Transfusion of Bacterial Contamination

- Reduce bacterial contamination
 - Improvements in skin disinfection¹
 - Diversion pouch²⁻⁵
 - Single arm procedures⁶
- Detect bacterial contamination
 - Bacterial culture⁶⁻⁹
 - Platelet swirl¹⁰
 - pH¹⁰
 - Glucose^{10,11}
 - PCR¹²⁻¹⁴

1. Benjamin et al. Transfusion 2011;51:531
2. deKorte et al. Transfusion 2006.;46:476
3. Benjamin et al. Transfusion 2008;48:2348
4. Robillard et al. Transfusion 2005;45:25A.
5. McDonald Transfus Med 2006;16:381.
6. Eder et al. Transfusion 2007;47:1134.
7. AuBuchon et al. Transfusion. 2002;42:855

8. Fang et al. Transfusion 2005;45:1845
9. Fuller et al. Transfusion 2009;49:2588
10. Wagner and Robinette Transfusion 1996;36:989
11. McKane et al Am J CLin Pathol 2009;131:542
12. Rood et al. J Microbiol Methods 2008;75:64
13. Stormer et al. Clin Chem 2007;53:104
14. Mohammadi et al. Transfusion 2005;45:731

Rate of Bacterial Contamination

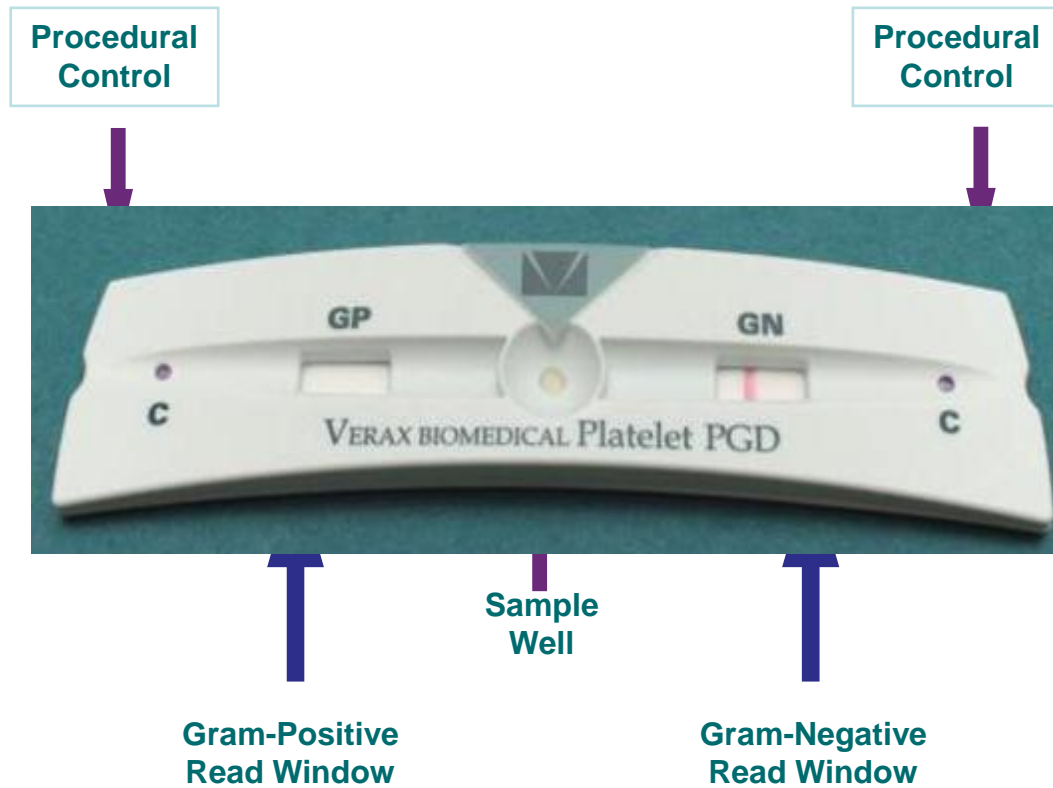
- ~1:5,000 (1:5,157-1:5856) = Rate of bacterial contamination detected by screening bacterial culture¹⁻³
- Rate of septic transfusion reactions
 - Johns Hopkins University experience⁴⁻⁵
 - 1:15,098 prior to bacterial screening
 - 1:49,625 post implementation
 - American Red Cross experience³
 - 1:74,807 post implementation of bacterial screening

1. Fang et al. Transfusion 2005;45:1845
2. Kleinman et al. Transfusion 2006;46:1787
3. Eder et al. Transfusion 2007;47:1134
4. Ness et al. Transfusion 2001;41:857
5. Fuller et al. Transfusion 2009;49:2588

Platelet PGD[®] Test

- Single-use, qualitative test for the detection of aerobic and anaerobic Gram positive and Gram negative bacteria
- PGD = pan genera detection
- Detects the presence of conserved bacterial surface cell wall antigens
 - Lipoteichoic acid = Gram positive
 - Lipopolysaccharide = Gram negative

Platelet PGD[®] Test



Study

- Study conducted 9/1/2009 – 6/30/2010
- Leukoreduced apheresis platelets
- All units were cultured by the blood center.
 - ~24 hours after collection, 8-10 mL of platelet product was inoculated into an aerobic bottle and cultured using the BacT/Alert 3D system (BioMérieux Inc., Hazelwood, MO).
 - Released for transfusion 12 hours after inoculation
- PGD testing was performed within 24 hours of issue for transfusion

Work Flow

- Platelets received multiple times/day
- 80% of Blood Bank staff trained
- Testing performed
 - All shifts
 - 135 of 304 (44%) study days
 - Average tests performed/day = 24
 - Minimum 6
 - Maximum 64

PGD Testing

Total Units Received	7,196	
PGD Tests	3,290*	(46%)
Non-reactive	3,227	(98%)
Initial results reactive	21	(0.63%)
Initial results invalid	42	(1.28%)

29 retested, all retested units were non-reactive

13 not retested

* Includes ~1% retest rate

Reactive PGD tests

Initial Test

Gram negative 11 (52%)

Gram positive 7 (33%)

Gram positive and Gram negative 3 (14%)

Repeat Reactive Test

False positive 2 (0.06%)

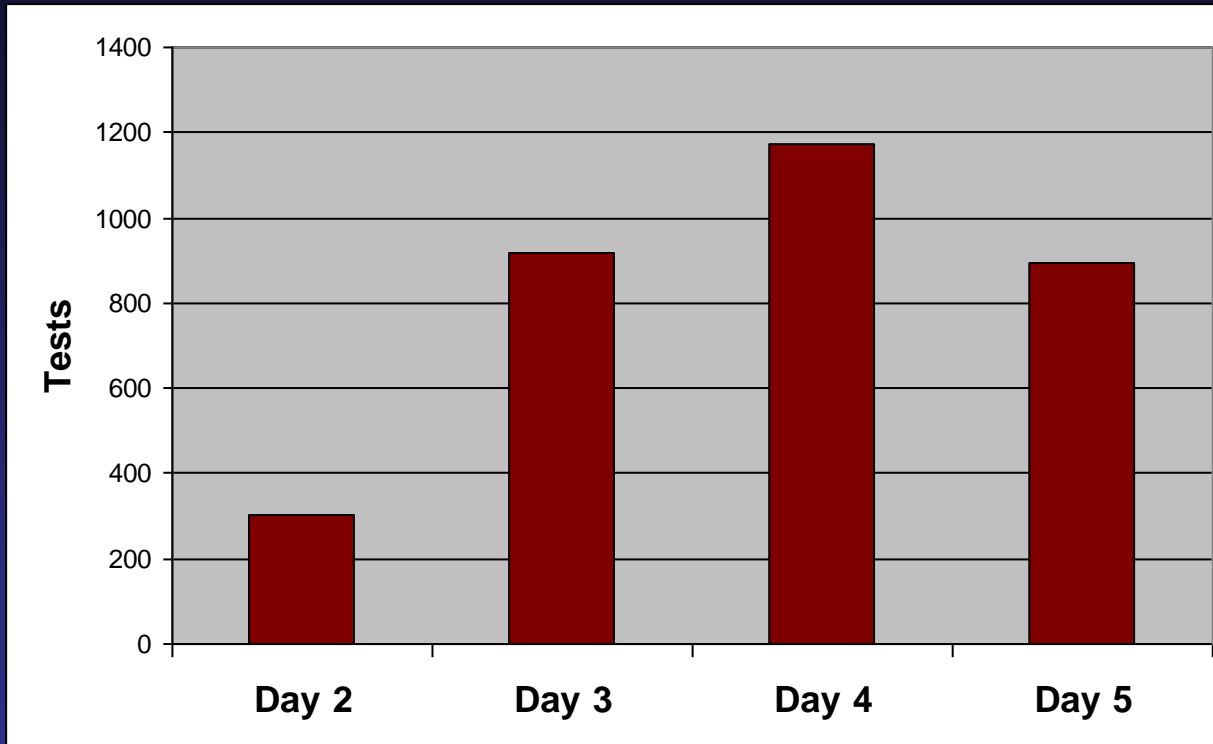
GP repeat reactive, Gram stain & culture negative

Both were tested on Day 4

True positive

Repeat reactive, Gram stain &/or culture positive 0

Platelet Age on Day of Test



	Day 2	Day 3	Day 4	Day 5
% of Tests	9	28	36	27

Passive Surveillance for Bacterial Contamination

- Detected by report of a transfusion reaction
- Two units not PGD tested prior to transfusion
 - Unit 1 transfused on day 5
 - Unit 2 transfused on day 3
- Culture negative at blood center

Passive Surveillance for Bacterial Contamination

- PGD Testing
 - Unit 1 PGD tested immediately following reaction → repeat reactive for Gram positive
 - Unit 2 - Never PGD tested
- Gram stain = Gram positive cocci
- Unit and patient culture = coagulase negative Staphylococci
- Rate of bacterial contamination ~ 1:3,600 unit

Conclusion

- The Platelet PGD[®] Test was readily incorporated in our Blood Bank workflow
- Test performance
 - False positive rate of 0.06% (~ 1:1,600)
 - Initial reactive rate of 0.63% (~ 1:150)
 - Initial invalid rate of 1.28% (~ 1:80)
 - All retested units were non-reactive
- The test was useful in assessing a septic transfusion reaction after transfusion of an untested platelet unit.
- Due to the low rate of true positive bacterially contaminated apheresis platelet units, testing would need to be performed on nearly all platelet units to significantly reduce the rate of septic transfusion reactions.

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Platelet Age of Reactive and Invalid Initial Tests

