

The Verax Platelet PGD Test-FDA cleared indications for use and what they mean for your institution

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The Verax Platelet PGD Test has a broad range of FDA clearances to address whatever platelet types you may transfuse. In this report, we will review the specifics of each cleared indication for use and what this can mean for blood bank and transfusion service policies and procedures in your institution. The Platelet PGD Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria. The PGD test is the only technology approved or cleared as a “safety measure” by the FDA. This designation affords 7-day platelet storage in collection sets that are approved for this purpose.

The test’s current FDA cleared Indications for Use are:

The Platelet PGD Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in

• leukocyte reduced apheresis platelets (LRAP) suspended in plasma, LRAP suspended in Platelet Additive Solution C (PAS-C) and plasma, and pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets suspended in plasma, within 24 hours prior to platelet transfusion as a safety measure following testing with a growth-based quality control test cleared by FDA for platelet components

• post-storage pools (pooled within four (4) hours of transfusion) of up to six (6) units of leukocyte reduced (LR) and non-leukocyte reduced (nLR) whole blood derived platelets (WBDP) suspended in plasma and

• single units of LR and nLR WBDP suspended in plasma and tested within four (4) hours prior to platelet transfusion as individual platelet units or as components of a post-storage pool.

What do these FDA cleared indications mean to you?

- If you transfuse leukocyte-reduced apheresis platelets suspended in plasma, you can test with PGD through day 5 or extend dating through day 7 since the PGD test is cleared as a safety measure. Regardless of the outdate, PGD testing must follow early culture with a quality control test cleared by the FDA for platelet components. In practical terms, that most commonly means a blood center would culture a unit approximately 24 hours after collection and the transfusing institution would test it before transfusion with PGD. The PGD test must be performed within 24 hours prior to transfusion. This means a component need only be PGD tested once within 24 hours of transfusion, not each day that it is held in your inventory.
- If you transfuse leukocyte-reduced apheresis platelets suspended in Platelet Additive Solution C and plasma, you can test with PGD through day 5 following early culture with a quality control test cleared by the FDA for platelet components. The PGD test must be performed within 24 hours prior to transfusion. If this platelet component ever receives FDA approval for seven-day storage, the PGD test is already cleared as a safety measure to permit use through seven days.

Again, PGD does not have to be performed each day of component storage, only once on the day of transfusion.

- If you transfuse pre-storage pools of leukocyte-reduced whole blood-derived platelets (LR-WBDP) suspended in plasma (i.e. prepared with one of the Acrodose Systems, Haemonetics, Braintree, MA), you can test with PGD pools of up to six LR-WBDP suspended in plasma following early culture with a quality control test cleared by the FDA for platelet components. The PGD test must be performed within 24 hours prior to transfusion. If this platelet component ever receives FDA approval for seven-day storage, the PGD test is already cleared as a safety measure to permit use through seven days. Again, PGD does not have to be performed each day of component storage, only once on the day of transfusion.
- If you transfuse post-storage pools of LR-WBDP or non-LR-WBDP platelets suspended in plasma, you can test pools of up to six units with PGD that have been pooled within four hours of transfusion. This means, the PGD test will have been performed within four hours of transfusion of that pool.
- If you transfuse individual units of LR-WBDP or non-LR WBDP suspended in plasma (e.g. to neonates and infants), you can test with PGD within four hours prior to platelet transfusion. You can also test with PGD within four hours prior to transfusion individual units that are used as components of a post-storage pool. The latter indication refers to an instance in which you test a single unit but don't transfuse it. Tested units may be pooled and transfused without retesting if the PGD test was run within 4 hours of transfusion.

The versatility of the Verax Platelet PGD test means you can mitigate the septic risk of platelet transfusion with almost all US platelet components and be in compliance with FDA draft guidance¹ to enhance the safety and availability of platelets for transfusion. It also offers the potential to extend dating to seven days for PAS apheresis platelets and Acrodose platelets should those products ever receive FDA approval for dating extension.

Septic reactions from platelet transfusions continue to occur regularly.² The Verax PGD Test is the only technology available in the US to extend platelet expiration to seven days and can effectively detect bacterially contaminated platelets prior to transfusion without altering platelet quantity or quality.

1. US Food and Drug Administration. Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion. Available at: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM425952.pdf>
2. Fatalities reported to FDA following blood collection and transfusion. Annual Summary for Fiscal Year 2015 [Internet]. Silver Spring (MD): Food and Drug Administration; [cited 2016 Sep 1]. Available from: <http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/UCM518148.pdf>