Validation of the Specificity of the PGDprime® Test for Bacteria in Platelets with Commercial Scale Lots

Lisa Shinefeld, Nancy Hornbaker, Pat Rasmusson, Nancy Best, Willa Lee, Gary Tambolleo, Michael Pelak, Johny Lisitu, Remo Vallejo

Verax Biomedical Incorporated, Marlborough, MA
Validation of the Specificity of the PGDprime® Test for Bacteria in Platelets with Commercial Scale Lots

Lisa Shinefeld, Nancy Hornbaker, Pat Rasmusson, Nancy Best, Willa Lee, Gary Tambolleo, Michael Pelak, Johny Lisitu, Remo Vallejo

Verax Biomedical Incorporated, Marlborough, MA

Background

- The PGDprime rapid test for bacteria in platelets was developed as an improvement of the PGD® test currently used as a Safety Measure for platelet transfusion.
- It was designed to provide a simpler test procedure than the current product and improved specificity through the use of intact IgG for capture and F(ab')2 fragments for detector antibodies for 5 out of 6 test lines.
- Multiple commercial scale lots have now been manufactured under cGMP and evaluated for Specificity.

Methods

- The specificity of the new test was evaluated in a multi-site study using 3 consecutive manufacturing lots of PGDprime devices and reagents. Three sites tested a total of 3802 individual in-date platelet doses.

Platelet types evaluated:
1. Leukocyte-reduced whole blood derived platelets (LR WBD)
2. Post-storage pools of LR whole blood derived platelets (LR WBPD)
3. Leukoreduced apheresis platelets in plasma (LRAP)
5. Post-storage pools of NLR whole blood derived platelets (NLR WBD)
6. Leukocyte-reduced apheresis platelets in platelet additive solution (PAS)
7. Pre-storage pools of LR platelets (PSP)

- Any platelet sample with an initially reactive (IR) result was restested in duplicate using two additional PGDprime devices. If one or both of the two restests yielded a reactive result, the sample was classified as repeat reactive (RR) by PGDprime.
- If both restests were non-reactive, the final interpretation was non-reactive (NR). All samples were tested using aerobic and anaerobic platelet culture to determine true bacterial status.
- Single repeat testing was performed for samples with initial invalid results (INV).

- Traditional agar plate culture (APC) was used to determine the true status of each sample. Units were deemed negative if no colonies were detected under either aerobic or anaerobic conditions after 3-7 days.
- Many of the LR WBD and NLR WBD units were tested as individual units and then combined into 6-member pools.
- Although some doses were sampled and tested at multiple times, only the first interpretation generated at the initial time point has been included in the specificity calculations so that all summary results are based on unique doses.

Results/Findings

- Traditional agar plate culture (APC) was used to determine the true status of each sample. Units were deemed negative if no colonies were detected under either aerobic or anaerobic conditions after 3-7 days.
- Many of the LR WBD and NLR WBD units were tested as individual units and then combined into 6-member pools.
- Although some doses were sampled and tested at multiple times, only the first interpretation generated at the initial time point has been included in the specificity calculations so that all summary results are based on unique doses.

- The estimated Specificity based on 3800 test results was 99.9%.
- Using 3 cGMP lots to test 3800 unique units of different types of platelets, PGDprime showed 5/3800 initial reactive(0.13%), 0/3800 RR (0% False Positive results), and 0% False Negative results based on culture results.

Conclusions

- The estimated Specificity based on 3800 test results was 100% with a Lower 1-sided 95% confidence limit of 99.9%.