



First Rapid Test for Bacterial Contamination in Platelets

FDA recently cleared for marketing the first rapid test to detect bacterial contamination in blood platelets before transfusion. The test, called the Platelet Pan Genera Detection (PGD) Test System, was developed by Verax Biomedical Inc. Bacterial contamination of platelets is the leading infectious cause of patient deaths from transfusions. To reduce the risk of transfusing contaminated platelets, blood centers typically culture samples of the platelets 24 hours after donation and then read the cultures within another 24 hours to determine if the units are contaminated. But in some cases, the number of bacteria present at the time of the culture may be so low that they cannot be detected. Using the new test, a sample can be prepared, processed and read in 30 minutes, so the platelets can be retested closer to the time they will be used. That way, if bacteria are present, they will have multiplied and be easier to detect. This provides additional assurance that the platelets are free from bacterial contamination. FDA Patient Safety News: December 2007

For more information, please see our website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=70#>