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FDA Draft Guidance on Bacterial Detection, 2016

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Draft 2: Issued March 2016

- **Follows public comment to original draft of December 2014**
- **Includes licensure of pathogen reduction technology**
- **Issued after licensure of bags approved for 7 day platelets**
- **Will be in effect by 12 months after final document is released**

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Changes for Transfusion Services

When final guidance released:

- **Use pathogen reduced platelets (apheresis only)**
- **Do a secondary test on day of transfusion for day 4 or 5 platelets**
  - Must be FDA-approved rapid test (good for 24 hours)
  - Or can re-culture
  - Includes pooled platelets not previously tested
  - No rapid test available for single whole-blood derived units

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Rapid Tests Available

Verax Platelet PGD (Fenwal)

BacTx (Immunetics)

Seven Day Platelets

To extend shelf life to 7 days:

- **Must be registered with FDA**
- **Must use approved rapid test device within 24 hours of transfusion**
- **Must change label**

Seven Day Platelets -- Cautions

- **Pathogen reduction systems not yet licensed for seven day storage**
- **Culture-based testing not licensed as "safety measure" – cannot be used for extension of shelf life**
- **Acrodose (pre-pooled platelets) not yet approved for 7 day storage**
- **Single units of whole blood derived platelets cannot be extended**

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TOTAL
ROLEX