

## The Journey of a Platelet Through Manufacturing

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## Receipt into Manufacturing



- Approximately 22 donations
- Monday to Friday
- Receive in the afternoon or evening of day 0



# Day 0 - Splitting of Apheresis Platelets

- Can be made into single, double or triple product.
- Split depending on product volume
- Aim for equal amounts in each pack
- End up with approx 40 to 60 separate products





## Day 1 - Quality Monitoring



#### Check for:

- Platelet count
- White cell removal
- Volume



### Day 2 – Bacterial Screening



- Previously performed by Testing department but transferred to Manufacturing at the end of Nov 2011
- Minimum 36 hours after donation
- All apheresis and pooled platelets are tested
- 4 staff work Wed to Sun morning to sample



## **Bacterial Screening**

- 2 x 8ml sample into each BacT/ALERT bottle
- Sampled for Aerobic and Anaerobic organisms





#### Incubation

- Aim to complete all sampling before 11:00am
- BacT/ALERT bottles incubated for 6 hours 20 mins post sampling before first result is released





#### Storage of platelets



- Platelets labelled and stored in platelet agitator
- Mandatory test
- Negative result necessary for release to Validation

insert your department or title



#### Monitored until end of shelf life



- BacT/ALERT bottles are monitored to the end of shelf life
- Shelf life extended to 7 days on all screened platelets
- Any positives are recalled



#### Initial problems

- NHSBT commenced bacterial screening in February 2011 and rolled out to all centres.
- Newcastle on 10<sup>th</sup> April 2011
- Technical problems at introduction
- Resulted in a high number of initial reactives, approx 3.6%, in March 2011
- Current initial reactive rate is approximately 0.6% for apheresis platelets and 0.4% for pooled platelets



#### Investigation and recall

- All initial reactives are further investigated by the National Bacteriology Laboratory and the microorganisms isolated
- Results can only be confirmed if the platelet pack can be returned and tested



#### Why Bacterial Screen platelets?

- Bacterial contamination of platelets is a potentially life threatening hazard to transfusion
- Since 2005 the have been 9 reported incidents
- 3 fatal



#### Release platelets

- Release of platelets to Validation
- Approximately 17:30 on day 2
- Continue to monitor until the end of day
   7



### They keep coming back!

- Platelet splits
  - split into 6 small neonatal packs
- PAS platelets
  - plasma removed and platelets resuspended in platelet additive solution
    - -24 hour expiry
- All processed to order
- All need QM tested
- Normally out of hours



#### Any Questions?

insert your department or title