PLATELETS

Psoralen Treated-Pathogen Reduced (PR)

Large Volume Delayed Sampling (LVDS 36)

Large Volume Delayed Sampling (LVDS 48)

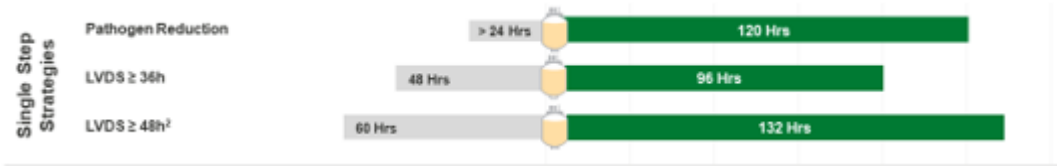
Effective June 1st,2021

FOOD AND DRUG ADMINISTRATION(FDA) PLATELET BACTERIAL GUIDANCE

- FDA has established regulations to address the control of bacterial contamination of platelets. Under 21 CFR 606.145(a), blood establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices, or other adequate and appropriate methods found acceptable for this purpose by FDA. **Implementation by 2021**
- https://www.fda.gov/media/123448/download
- Recommendations to control the risk of bacterial contamination applies to:
  - Room temperature stored platelets intended for transfusion
  - Apheresis and Whole Blood derived platelets
  - Single Donor Platelets and Acrodose pools
  - Platelets in plasma and preservative

BLOOD SUPPLIERS TESTING STRATEGIES

- Single Step Strategies implemented to meet FDA guidance
  1. Large Volume, Delayed Sampling (LVDS) ≥36 hours
  2. Large Volume, Delayed Sampling (LVDS) ≥48 hours
  3. Pathogen Reduction
- Shelf Life- 5 to 7 days, hours in green indicate potential shelf life in TSL upon release from blood supplier



LARGE VOLUME DELAYED SAMPLING (LVDS) LVDS 36 (NO SOONER THAN 36 HOURS)

- **Single culture sampled no sooner than 36 hours after collection**
  - Single-step strategy
  - Inoculate both aerobic and anaerobic cultures
  - Minimum sample volume 16 mL
  - Sample each apheresis unit
    - Each split from a unit should be sampled
  - Minimum incubation 12 hours prior to release
  - **5 day** product expiration (48 hour hold time at blood supplier prior to release to TSL)
    - Can be extended beyond 5 days with verax PGD testing to day 6 and day 7 on non pas platelets

LARGE VOLUME DELAYED SAMPLING (LVDS) LVDS 36 (NO SOONER THAN 36 HOURS)

Advantages:

- Does not hold product as long as LVDS 48
- Secondary testing (Verax) can be applied to non PAS
- Lower Cost than Pathogen Reduction

Disadvantages:

- Impact to available inventory
  - Holds product longer than Pathogen Reduction
  - Shelf life in TSL shorter than current state due to delayed release

LARGE VOLUME DELAYED SAMPLING LVDS 48 (NO SOONER THAN 48 HOURS)

- **Single culture sampled no sooner than <u>48 hours</u> after collection**
  - Single-step strategy
  - Inoculate both aerobic and anaerobic cultures
  - Minimum sample volume 16 mL
  - Sample each apheresis platelet
    - Each split from a unit should be sampled
  - Minimum incubation 12 hours prior to release
  - 7 day product expiration (60 hour hold time at blood supplier prior to release to TSL)
  - Cannot extend beyond 7 days

LARGE VOLUME DELAYED SAMPLING LVDS 48 (NO SOONER THAN 48 HOURS)

Advantages:

- More likely to detect infectious agent with additional growth time
- Lower Cost than Pathogen Reduction
- 7-Day Product

Disadvantages:

- Impact to available inventory
  - Holds product longer than Pathogen Reduction
- PAS platelets not eligible

PATHOGEN REDUCTION (PR)
PSORALEN TREATED/UVA LIGHT TREATMENT

- Targets DNA & RNA to prevent proliferation of pathogens
- Replacement for primary and secondary bacterial culture screening
- Approved alternative to Gamma Irradiation to prevent transfusion associated graft vs. host disease
- Apheresis platelets
- Currently **5 day** expiration
- Do **not centrifuge** platelet in storage container, transfer contents to transfer pack for volume reduction. The PR platelet bags have a higher incidence of breakage that can occur during centrifugation
- Pathogen Reduced and PAS do not mean the same and are not interchangeable in their use

PATHOGEN REDUCTION (PR)
PSORALEN TREATED/UVA LIGHT TREATMENT

Advantages:

- Product Availability – Early Release, Optimal Shelf-Life
- **Replaces Irradiation**
- Replaces CMV testing

Disadvantages:

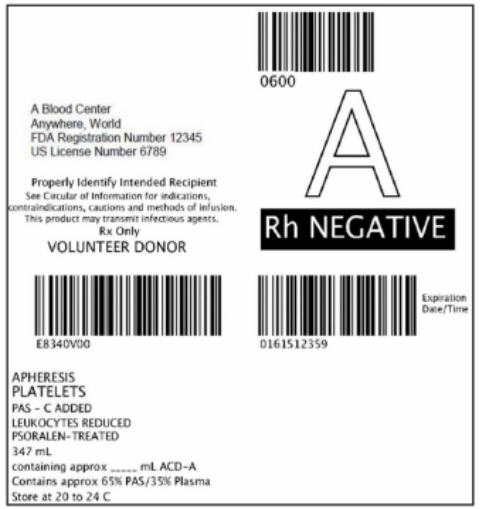
- 5 Day expiration
- Higher Cost

AMERICAN RED CROSS

IMPLEMENTATION JUNE 1ST, 2021

- American Red Cross will supply the following
  - PAS Psoralen Treated (PAS PR) platelets - *majority of ARC collections will PAS PR*
  - PAS non Psoralen Treated platelets
  - Apheresis in plasma (non PAS) platelets
  - All platelets have 5 day expiration

PR PLATELETS IN PAS-C FROM ARC



Apheresis in Platelet Additive Solution (PAS-C)
E8340 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E^{6} | Psoralen-treated
E8341 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E^{6} | 1st container | Psoralen-treated
E8342 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E^{6} | 2nd container | Psoralen-treated
E8343 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E^{6} | 3rd container | Psoralen-treated
E8344 Apheresis PLATELETS | ACD-A>PAS-C/XX/20-24C | ResLeu:<5E^{6} | <3E^{11} plts | Psoralen-treated

BLOODWORKS NORTHWEST

IMPLEMENTATION AS EARLY AS JUNE 1ST, 2021

- PAS platelets- (LVDS 36) *majority of BW supply to TSL will be PAS*
- Psoralen Treated (PR) platelets
- Apheresis in plasma (non PAS) platelets (LVDS 36 and LVDS 48)
- PAS, PR platelets will have 5 day expiration LVDS 36 have 5 day expiration – eligible to extend to day 6 and 7 with verax for non pas
- LVDS 48 have 7 day expiration

BW expects to support TSL primarily with PAS 5 day and non PAS 7 day platelets. PR and non PAS 5 day platelets will also be provided in lesser quantities. BW will also be sending all platelet components either irradiated or pathogen reduced

PAS PLATELETS LVDS 36H

5-day PAS-F LVDS Apheresis Platelets - *new* ISBT Codes		
Existing Codes	New Codes	**PAS-F Irradiated**
E7791	EA031	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial Monitoring >=36h
E7792	EA032	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial Monitoring >=36h
E7793	EA033	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial Monitoring >=36h
E7794	EA034	Apheresis PLATELETS|ACD-A>PAS-F/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial Monitoring >=36h

PR PLATELETS

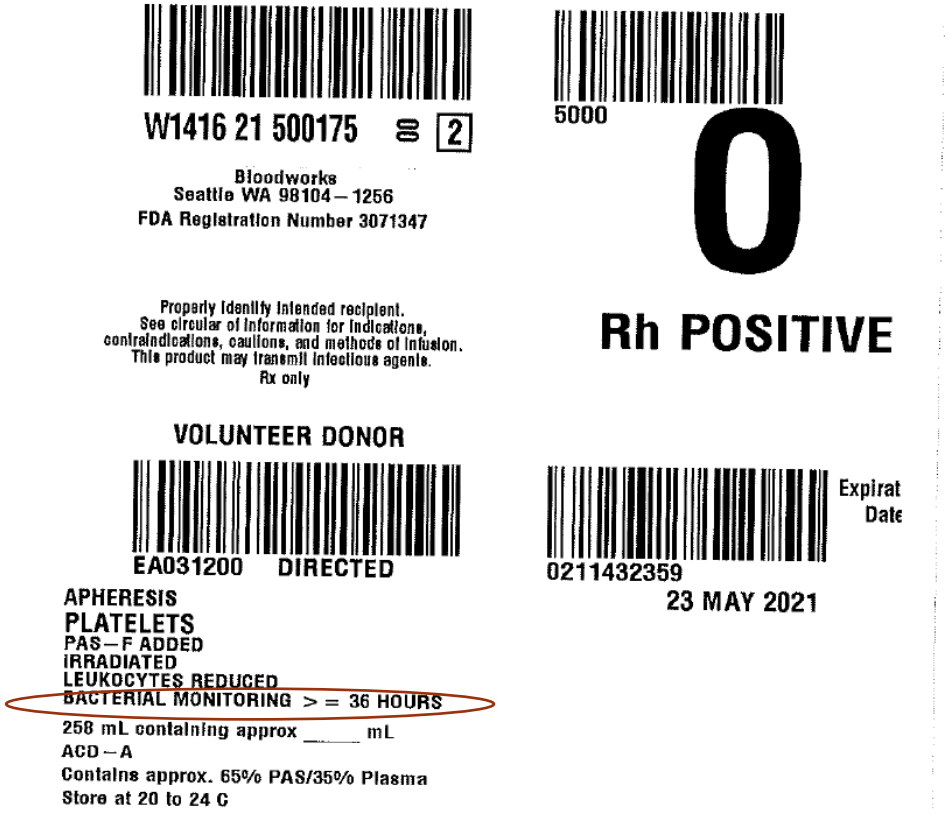
E8331	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Psoralen-treated
E8332	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|1st container|Psoralen-treated
E8333	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|2nd container|Psoralen-treated
E8334	Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|3rd container|Psoralen-treated

NON PAS PLATELETS (LVDS36 AND LVDS48)

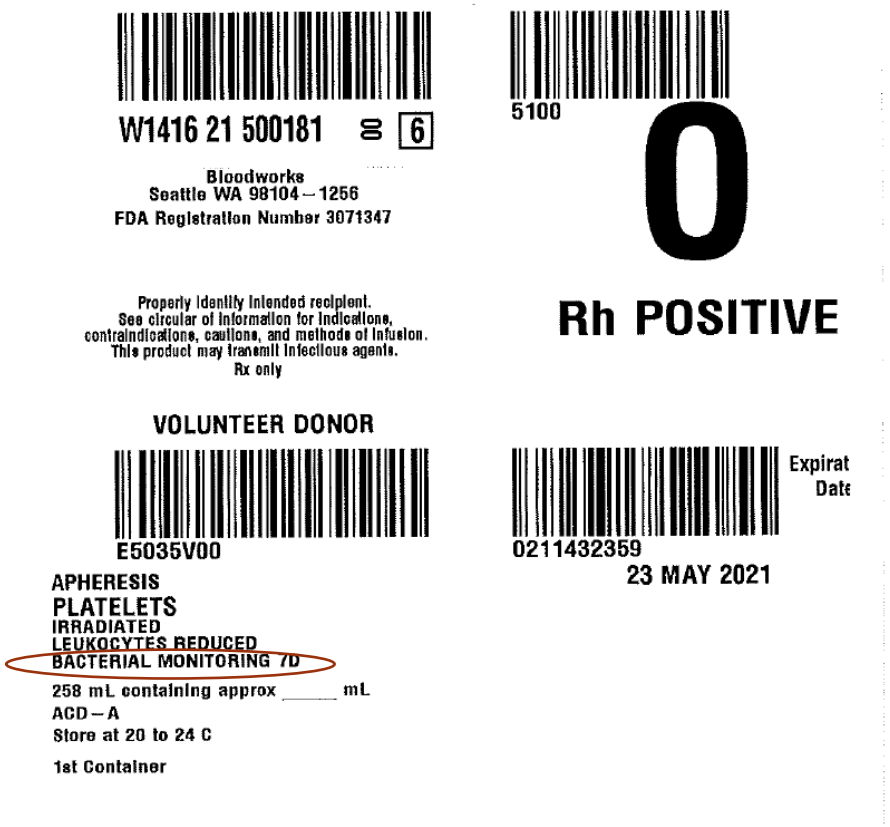
5-day LVDS Apheresis Platelets - *new* ISBT codes		
Existing Codes	New Codes	**Leukoreduced - Irradiated**
E3046	EA015	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial Monitoring >=36h
E3056	EA016	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial Monitoring >=36h
E3057	EA017	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial Monitoring >=36h
E3058	EA018	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial Monitoring >=36h

7-day LVDS Apheresis Platelets - ISBT codes unchanged	
Existing Codes	**Leukoreduced Irradiated**
E5034	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|Bacterial monitoring 7D
E5035	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|1st container|Bacterial monitoring 7D
E5036	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|2nd container|Bacterial monitoring 7D
E5037	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<5E6|3rd container|Bacterial monitoring 7D

EXAMPLE OF LVDS 36 PLATELET



EXAMPLE OF LVDS 48 PLATELET



EXAMPLE OF PATHOGEN REDUCE PLATELET

TRANSFUSION TAG COMPONENT DESCRIPTION

- *P or PPH*- PLATELET
- *PAS*- PAS PLATELET
- *HLA*- HLA PLATELET
- *W*- WASHED
- *RV*- VOLUME REDUCED
- *I*- IRRADIATED
- *L*-LEUKOREDUCED
- *PR*- PATHOGEN REDUCED (PSORALEN TREATED on label)
- EXAMPLES
  - *PPAS RV IL*- PLATELET PAS VOLUME REDUCE IRRADIATED LEUKOREDUCED
  - *PHLA1 W IL*- PLATELET HLA 1ST CONTAINER WASHED IRRADIATED LEUKOREDUCED
  - *PPH2 PASLPR*- PLATELET 2ND CONTAINER PAS LEUKOREDUCED PATHOGEN REDUCED

SUMMARY-KEY POINTS

- Pathogen reduced is Psoralen Treated. Does not require irradiation
- Psoralen treated platelet bag cannot be centrifuged. Transfer to a transfer pack prior to centrifugation during volume reduction
- PAS platelets can be pathogen reduced or non pathogen reduced.
- Patient example: Patient blood type B pos and is a BMT: RV Plt A/O or PAS, irradiated or pathogen reduced. The following platelets are acceptable examples to provide to the patient:
  - Group B pas or non pas platelet irradiated
  - Group B pas or non pas platelet psoralen treated
  - Group A platelet PAS irradiated
  - Group A platelet PAS psoralen treated
  - Group A platelet non pas psoralen treated and volume reduced