Labeling of Platelets Based on Bacterial Testing – US Guidance

Use of labeling to communicate bacterial testing strategy and additional relevant information

The Americas Technical Advisory Group (ATAG) is a committee coordinated by ICCBBA that oversees the use of ISBT 128 for blood and blood components in the Americas. US Members of this group have prepared the following interim guidance to assist US based blood facilities in the selection of the correct labels for labeling platelets in the US based on the FDA Guidance: Bacterial Risk Control Strategies for Blood Collection Establishment and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (September 2019). This leaflet addresses items not covered in the United States Industry Consensus Standard for Uniform Labeling of Blood and Blood Components Using ISBT 128, Version 3.0.0 (IG-002). It is intended that this interim guidance will be incorporated into version 4.0.0 of IG-002.

Users must understand the general information in the table below to understand the guidance provided in this document.

<table>
<thead>
<tr>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>(from FDA Guidance mentioned above)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ The blood supplier is responsible for “Informing consignees of the type of storage</td>
</tr>
<tr>
<td>container the platelets are stored in, for example, whether the storage container</td>
</tr>
<tr>
<td>is approved for 5-day storage or 7-day storage.”</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ “Platelets may only be stored beyond day 5 and up to day 7 if each component is</td>
</tr>
<tr>
<td>tested using a bacterial detection device cleared by FDA and labeled for use as a</td>
</tr>
<tr>
<td>“safety measure” according to its instructions for use, and if the platelet storage</td>
</tr>
<tr>
<td>container has been cleared or approved for 7-day storage.”</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ “The container labels must include the expiration date and time, if applicable, of</td>
</tr>
<tr>
<td>the product based on bacterial detection testing (21 CFR 606.121(c)(4)(i)).”</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ “Bacterial detection testing, pathogen reduction, and storage in platelet containers</td>
</tr>
<tr>
<td>must be conducted consistent with the instructions for use of the device (21 CFR 606</td>
</tr>
<tr>
<td>65(e)).”</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ “If dating is extended beyond 5 days, the blood establishment or transfusion service</td>
</tr>
<tr>
<td>that performed the secondary testing must update the container label to reflect the</td>
</tr>
<tr>
<td>new expiration date (21 CFR 606.121(c)(4)(i)).”</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ “In the United States (U.S.), the current maximum dating period for platelets with</td>
</tr>
<tr>
<td>a storage temperature between 20 and 24 degrees Celsius is up to 7 days in the FDA-</td>
</tr>
<tr>
<td>cleared or approved storage containers.”</td>
</tr>
</tbody>
</table>
### Bacterial Testing and Monitoring Attributes

<table>
<thead>
<tr>
<th>Common Name</th>
<th>ISBT 128 Database Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Default</td>
<td>Default: Not specified</td>
<td>No monitoring is specified.</td>
</tr>
<tr>
<td>Bacterial monitoring</td>
<td>Bacterial monitoring</td>
<td>A product subjected to on-going bacterial monitoring meeting national specifications for extension of the expiry date.</td>
</tr>
<tr>
<td>Bacterial test</td>
<td>Bacterial test</td>
<td>Tested with a point-in-time test that meets national specifications for extension of expiry date.</td>
</tr>
<tr>
<td>Bacterial monitoring &gt;=24 hours</td>
<td>Bacterial monitoring &gt;=24h</td>
<td>A product subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
<tr>
<td>Bacterial monitoring &gt;=36 hours</td>
<td>Bacterial monitoring &gt;=36h</td>
<td>A product subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
<tr>
<td>Bacterial test day 4</td>
<td>Bacterial test D4</td>
<td>The unit was bacterially tested on a sample taken 4 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
<tr>
<td>Bacterial test day 5</td>
<td>Bacterial test D5</td>
<td>The unit was bacterially tested on a sample taken 5 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
<tr>
<td>Bacterial test day 6</td>
<td>Bacterial test D6</td>
<td>The unit was bacterially tested on a sample taken 6 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
<tr>
<td>Bacterial test day 7</td>
<td>Bacterial test D7</td>
<td>The unit was bacterially tested on a sample taken 7 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.</td>
</tr>
</tbody>
</table>

At the time of publication, the table of ISBT 128 Monitoring attributes and definitions above represent the attributes available and their definitions for use in product description coding that were taken from the ISBT 128 Standard Terminology for Medical Products of Human Origin document (ST-002). Users should consult the Standard Terminology document for the latest information.
A. Strategies for Apheresis Platelets and/or Pre-Storage of WBD Platelets

1. Single-Step Strategies

   a. Large volume, delayed sampling (LVDS) no sooner than 36 hours (5-day expiry)

      Note: LVDS conducted no sooner than 36 hours may also constitute Step 1 of a 2-Step strategy to extend storage beyond 5 days. Refer to Primary culture LVDS no sooner than 36 hours (5-day expiry).

      Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=36h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. The “Bacterial monitoring >=36h” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the expiration date.

      Note: The “Bacterial monitoring >=36h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

      Label Example:

      EA009

      ![Label Example](image)

   b. LVDS no sooner than 48 hours (7-day expiry)

      Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring” are available for use. Per the definition this attribute indicates that the product meets national specifications for extension of the expiry date. In the U.S. this attribute is applied to units subjected to on-going bacterial monitoring from a sample taken at least 48 hours after collection. The “Bacterial monitoring” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. “7D” shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user’s system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.
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Note: The “Bacterial monitoring” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

E5030 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial monitoring

![Barcode and label example]

Note: The “Bacterial monitoring” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:

E5030 = Apheresis PLATELETS|ACD-A/XX/20-24C|ResLeu:<5E6|Bacterial monitoring

![Barcode and label example]

**c. Pathogen Reduction (5-day expiry)**

Note: Currently, this strategy only applies to apheresis platelets; however, the strategy could apply to other platelet products in the future if the pathogen reduction methodology is FDA cleared/approved for other products.

Labeling requirements: Pathogen reduced components should be labeled with expiration dates consistent with the instructions for use for the pathogen reduction device.

Label Example:

E8340

![Barcode and label example]
2. **Two-Step Strategies**

   a. **Primary culture performed no sooner than 24 hours (5-day expiry, but requires secondary testing >/= day 3)**

Per the FDA Guidance, “Following primary culture performed no sooner than 24 hours, apheresis and pre-storage pooled platelet components should not be transfused after day 3 unless appropriate secondary testing (culture or rapid testing) has been performed to assure that the risk of bacterial contamination has been adequately controlled.”

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=24h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. BACT MON ≥24H RETEST AFTER DAY 3 shall be printed below the Component Class in the “Attribute” Section. The user’s system assigns the expiration date.

Note: The “Bacterial monitoring >=24h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Labeling Example:

E9968

![Barcode Example]

**APHESIS PLATELETS LEUKOCYTES REDUCED BACT MON ≥24H RETEST AFTER DAY 3**

___ mL containing approx ___ mL ACD-A

Store at 20 to 24 C

2nd Container

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i. **Secondary culture performed no sooner than Day 3 (5-day expiry)**

Note: Per the FDA Guidance, “During the incubation period of the secondary culture, products remain in-date through their labeled storage period, and removal of products from inventory is not required during any portion of the labeled storage, provided you have developed procedures to 1) identify when secondary testing has been completed, and 2) maintain product control during the incubation period.”

Labeling requirements: For this scenario, the component was originally labeled with a Product Description Code that included the attribute “Bacterial monitoring >=24h”. This attribute prints the statement BACT MON ≥24H RETEST AFTER DAY 3. Following secondary culture performed no sooner than Day 3, the unit may be relabeled to omit the attribute “Bacterial
monitoring >=24h” (Default: Not specified) or the retest statement may be crossed-out. The originally assigned 5-day expiration date remains valid. If the unit is relabeled, the user’s system must ensure the expiration date does NOT exceed 5 days from the collection of the platelet product.

Note: The “Default: Not specified” attribute does NOT specify monitoring. Such information would be included in the accompanying documentation.

Label Example:

E3088

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ii. Secondary culture performed no sooner than Day 4 (up to 7-day expiry)

Note: During the incubation period of the secondary culture, products remain in-date through their storage period, and do not necessitate removal from inventory during any portion of the storage period, provided you have developed procedures to identify when secondary testing has been completed, and maintain product control during the recommended incubation period.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attribute “Bacterial monitoring” are available for use. This attribute indicates that a unit is subjected to on-going bacterial monitoring for extension of the expiration date. The “Bacterial monitoring” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. “7D” shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user’s system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.

Note: The “Bacterial monitoring” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example: Secondary bacterial monitoring (7-day expiry)

E5030
iii. Secondary rapid testing (up to 7-day expiry)

Note: Secondary rapid testing should be performed according to the bacterial testing device instructions for use. Currently, for available cleared/approved devices, platelets should be transfused within 24 hours of the most recent non-reactive test.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attributes “Bacterial test D4,” “Bacterial test D5,” “Bacterial test D6,” “Bacterial test D7” are available for use. These attributes indicate that a unit was bacterially tested on a sample taken X days after collection. For example, if a platelet product was sampled on the fourth day for bacterial testing, the “Bacterial Test D4” attribute would apply. The “Bacterial Test Day [X]” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the appropriate expiration date and time.

Note: The “Bacterial Test Day [X]” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example: Secondary rapid testing (up to 7-day expiry)

E9257
b. Primary culture LVDS no sooner than 36 hours (5-day expiry)

The storage of platelets tested by LVDS no sooner than 36 hours may be extended up to 7 days by secondary testing methods. See also Large volume, delayed sampling (LVDS) no sooner than 36 hours (5-day expiry)

i. Secondary culture performed no sooner than Day 4 (up to 7-day expiry)

Note: During the incubation period of the secondary culture, products remain in-date through their storage period, and do not necessitate removal from inventory during any portion of the storage period, provided you have developed procedures to identify when secondary testing has been completed, and maintain product control during the recommended incubation period.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attribute “Bacterial monitoring” are available for use. This attribute indicates that a unit is subjected to on-going bacterial monitoring for extension of the expiration date. The “Bacterial monitoring” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. “7D” shall be appended to the attribute name (i.e., BACTERIAL MONITORING 7D). The user’s system assigns the expiration date and must ensure the date does NOT exceed 7 days from the collection of the platelet product.

Note: The “Bacterial monitoring” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.
Label Example:
E5030

ii. Secondary rapid testing (up to 7-day expiry)

Note: Secondary rapid testing should be performed according to the bacterial testing device instructions for use. Currently, for available cleared/approved devices, platelets should be transfused within 24 hours of the most recent non-reactive test.

Labeling requirements: Products can be labeled with an expiration of up to 7 days. Product Description Codes that include the attributes “Bacterial test D4,” “Bacterial test D5,” “Bacterial test D6,” “Bacterial test D7” are available for use. These attributes indicate that a unit was bacterially tested on a sample taken X days after collection. For example, if a platelet product was sampled on the fourth day for bacterial testing, the “Bacterial test D4” attribute would apply. The “Bacterial Test Day [X]” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the appropriate expiration date and time.

Note: The “Bacterial Test Day [X]” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example: Secondary rapid testing (up to 7-day expiry)
E9257
B. Strategies for Single Units and Post-storage Pools of WBD Platelets

The recommended strategies for single units of WBD platelets and post-platelet pools of WBD platelets are single step.

1. Single Units of WBD platelets
   a. Rapid bacterial testing (5-day expiry)

Note: Testing should be performed according to the bacterial testing device instructions for use.

Labeling requirements: Product Description Codes that include the default attribute "Default: Not specified" are available for use. This attribute indicates that no monitoring is specified. Products must be labeled with no more than a 5-day expiration.

Note: The “Default: Not specified” attribute does NOT specify monitoring. Such information would be included in the accompanying documentation.

Label Example:

E2807

b. Single culture with sampling performed no sooner than 36 hours after collection (5-day expiry)

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring >=36h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. The “Bacterial monitoring >=36h” attribute shall appear in all caps in the attribute section of the lower left quadrant of the label. The user’s system assigns the expiration date.

Note: The “Bacterial monitoring >=36h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.
Label Example:
EA041

```
E A041V00
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING ≥ 36 HOURS

Approx 40–70 mL
From 450 mL CPD Whole Blood
Store at 20 to 24 C
```

c. Single culture with sampling performed no sooner than 24 hours after collection (5-day expiry, but consider secondary testing ≥ day 3)

Labeling requirements: Product Description Codes that include the attribute “Bacterial monitoring ≥24h” are available for use. This attribute indicates that a product is subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. BACT MON ≥24H RETEST AFTER DAY 3 shall be printed below the Component Class in the “Attribute” Section. Products must be labeled with no more than a 5-day expiration. If the unit is transfused after day 3 of storage, secondary rapid testing should be considered.

Note: The “Bacterial monitoring ≥24h” attribute does NOT specify a testing methodology. Such information would be included in the accompanying documentation.

Label Example:
EA000

```
E A000V00
PLATELETS
LEUKOCYTES REDUCED
BACT MON ≥24H RETEST AFTER DAY 3

Approx 40–70 mL
From 450 mL CPD Whole Blood
Store at 20 to 24 C
```
2. Post-storage Pools of previously untested WBD Platelets

   a. Rapid bacterial testing (Expiry 4 hours after pooling)

   Note: Testing should be performed according to the bacterial testing device instructions for use.

   Labeling requirements: Products expire 4 hours after pooling.

   Label Example:

   E5151
Acknowledgment

ICCBBA thanks the members of the US Platelet Labeling Subcommittee of ATAG for their contributions in the development of this document.

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AABB appreciates the efforts of ICCBBA to clarify the labeling requirements based on recommendations in FDA’s Sept 2019 Bacterial Risk Control Guidance. Following a review by AABB member experts, we support the use of this document to assist with labeling of platelets based on testing to control the risk of bacterial contamination.