









**ISBT 128 Blood and Blood Component Label Examples**  
**US Label Examples of Product Types Needed for FDA Review**

**1. Whole Blood with CPD**

 A9999 19 123459 ♂ <span style="border: 1px solid black; padding: 0 2px;">6</span> <b>Accurate Blood Center</b> Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100 <div style="text-align: center; font-size: 48pt; font-weight: bold;">O</div> <div style="text-align: center; font-size: 24pt; font-weight: bold;">Rh POSITIVE</div>
<b>VOLUNTEER DONOR</b>  E0019V00	 0183652359 Expiration Date
<b>WHOLE BLOOD</b> <b>LEUKOCYTES REDUCED</b>	<b>31 DEC 2018</b>
<div>Approx 450 mL plus ____ mL CPD</div> <div>Store at 1 to 6 C</div>	







**2. Whole Blood with CPDA-1**

 A9999 19 654321 ♂ <span style="border: 1px solid black; padding: 0 2px;">H</span> <b>Accurate Blood Center</b> Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100 <div style="text-align: center; font-size: 48pt; font-weight: bold;">O</div> <div style="text-align: center; font-size: 24pt; font-weight: bold;">Rh POSITIVE</div>
<b>VOLUNTEER DONOR</b>  E0063V00	 0183652359 Expiration Date
<b>WHOLE BLOOD</b> <b>LEUKOCYTES REDUCED</b>	<b>31 DEC 2018</b>
<div>Approx 450 mL plus ____ mL CPDA-1</div> <div>Store at 1 to 6 C</div>	







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#### 3. Whole Blood with CP2D

	
A9999 19 123458 8 	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E0106V00	0183652359 Expiration Date
WHOLE BLOOD	31 DEC 2018
IRRADIATED	
Approx 450 mL plus ____ mL CP2D	
Store at 1 to 6 C	






#### 4. Red Blood Cells with CPD

	
A9999 19 012346 P 	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E0167V00	0183652359 Expiration Date
RED BLOOD CELLS	31 DEC 2018
From 500 mL CPD Whole Blood	
Store at 1 to 6 C	






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#### 5. Red Blood Cells with CPDA-1

	
A9999 19 012356 8 <b>L</b>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E0195V00	0183652359 Expiration Date
RED BLOOD CELLS	31 DEC 2018
From 450 mL CPDA-1 Whole Blood	
Store at 1 to 6 C	






#### 6. Red Blood Cells with CP2D

	
A9997 19 123652 8 <b>T</b>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E0262V00	0183652359 Expiration Date
RED BLOOD CELLS	31 DEC 2018
From 500 mL CP2D Whole Blood	
Store at 1 to 6 C	






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#### 7. Red Blood Cells – Additive Solution

 A9999 19 275493 8 <span style="border: 1px solid black; padding: 0 2px;">5</span> Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100  Rh POSITIVE
VOLUNTEER DONOR	
 E0385V00	 0183652359 Expiration Date
RED BLOOD CELLS ADENINE-SALINE (AS-5) ADDED	31 DEC 2018
From 450 mL CPD Whole Blood	
Store at 1 to 6 C	






#### 8. Red Blood Cells – Frozen

 A9999 19 275492 8 <span style="border: 1px solid black; padding: 0 2px;">7</span> Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100  Rh POSITIVE
VOLUNTEER DONOR	
 E6197V00	 0280312359 Expiration Date
FROZEN RED BLOOD CELLS LEUKOCYTES REDUCED	31 JAN 2028
____ mL	
Store at -65 C or colder	






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#### 9. Red Blood Cells – Deglycerolized

	
A9999 19 275493 8 <span style="border: 1px solid black; padding: 0 2px;">5</span>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E4519V00	0183651530 Expiration Date
DEGLYCEROLIZED RED BLOOD CELLS OPEN SYSTEM LEUKOCYTES REDUCED	31 DEC 2018 15:30
___ mL	
Store at 1 to 6 C	






#### 10. Red Blood Cells – Leukocytes Reduced

	
A9999 19 318627 8 <span style="border: 1px solid black; padding: 0 2px;">F</span>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E0336V00	0183652359 Expiration Date
RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED LEUKOCYTES REDUCED	31 DEC 2018
From 500 mL CPD Whole Blood	
Store at 1 to 6 C	






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#### 11. Red Blood Cells – Irradiated

 A9999 19 853491 8 <span style="border: 1px solid black; padding: 0 2px;">H</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 Rh POSITIVE
VOLUNTEER DONOR	
 E0161V00	 0183652359
RED BLOOD CELLS IRRADIATED	Expiration Date 31 DEC 2018
From 450 mL CPD Whole Blood Store at 1 to 6 C	






#### 12. Red Blood Cells – Leukocytes Reduced and Irradiated

 A9999 19 853496 8 <span style="border: 1px solid black; padding: 0 2px;">7</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 US License Number 1234 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 Rh POSITIVE
VOLUNTEER DONOR	
 E0274V00	 0183652359
RED BLOOD CELLS IRRADIATED LEUKOCYTES REDUCED	Expiration Date 31 DEC 2018
From 500 mL CP2D Whole Blood Store at 1 to 6 C	






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#### 13. Apheresis Red Blood Cells

	
A9999 19 429815 8 <b>6</b>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E4306V00	0183652359
APHERESIS RED BLOOD CELLS	31 DEC 2018
____ mL containing approx ____ mL ACD-A	
Store at 1 to 6 C	






#### 14. Apheresis Red Blood Cells – Leukocytes Reduced

	
A9995 19 624581 8 <b>C</b>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E4379V00	0183652359
APHERESIS RED BLOOD CELLS LEUKOCYTES REDUCED	31 DEC 2018
____ mL containing approx ____ mL ACD-A	
Store at 1 to 6 C US License Number 1234	






## ISBT 128 Blood and Blood Component Label Examples

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#### 15. Fresh Frozen Plasma

 A9999 19 104362 8 <span style="border: 1px solid black; padding: 0 2px;">Z</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 <b>Rh POSITIVE</b>
VOLUNTEER DONOR	
 E0707V00	 0193652359
FRESH FROZEN PLASMA	Expiration Date <b>31 DEC 2019</b>
____ mL from CPDA-1 Whole Blood	
Store at -18 C or colder	






#### 16. Apheresis Fresh Frozen Plasma

 A9999 19 456789 8 <span style="border: 1px solid black; padding: 0 2px;">4</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 <b>Rh POSITIVE</b>
VOLUNTEER DONOR	
 E4693V00	 0193652359
APHERESIS FRESH FROZEN PLASMA	Expiration Date <b>31 DEC 2019</b>
____ mL containing approx ____ mL ACD-A	
Store at -18 C or colder 2nd Container	

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#### 17. Cryoprecipitated AHF

 A9999 19 132048 8 <b>S</b>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 <b>Rh POSITIVE</b>
VOLUNTEER DONOR	
 E5165V00	 0193652359
	Expiration Date
CRYOPRECIPITATED AHF	31 DEC 2019
Store at -18 C or colder	

#### 18. Source Leukocytes

 A9995 19 123456 8 <b>P</b>	
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567	
Collection Date	 018031 31 JAN 2018
 E3698000	
<b>SOURCE LEUKOCYTES</b>	
<b>CAUTION: FOR MANUFACTURING USE ONLY</b>	
___ mL from 450 mL CPD Whole Blood	Negative for tests for antibodies to HIV, HCV, HBc, and HTLV-I/II and nonreactive for HBsAg, HCV RNA, HIV-1 RNA, HBV DNA, and syphilis.
Store at 1 to 10 C	






#### Note:

The label must reflect the results of any tests that have been completed before shipment of the product and must also indicate any tests not completed before shipment.




See 21 CFR 610.40(g)(2) and 606.121(h).

**ISBT 128 Blood and Blood Component Label Examples**  
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**19. Platelets**

 A9999 19 210379 8 <span style="border: 1px solid black; padding: 0 2px;">M</span> <b>Accurate Blood Center</b> Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100	 <b>Rh POSITIVE</b>
<b>VOLUNTEER DONOR</b>  E2807V00	 0183652359	Expiration Date
<b>PLATELETS</b>		<b>31 DEC 2018</b>
<p>Approx 40-70 mL From 450 mL CPD Whole Blood</p> <p>Store at 20 to 24 C</p>		






**20. Platelets – Leukocytes Reduced**

 A9999 19 210379 8 <span style="border: 1px solid black; padding: 0 2px;">M</span> <b>Accurate Blood Center</b> Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 5100	 <b>Rh POSITIVE</b>
<b>VOLUNTEER DONOR</b>  E2817V00	 0183652359	Expiration Date
<b>PLATELETS LEUKOCYTES REDUCED</b>		<b>31 DEC 2018</b>
<p>Approx 40-70 mL from 450 mL CPD Whole Blood</p> <p>Store at 20 to 24 C</p>		





## ISBT 128 Blood and Blood Component Label Examples

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#### 21. Platelets – Irradiated

 A9999 19 094657 8 <span>3</span>	 5100	 <b>Rh POSITIVE</b>
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only		
VOLUNTEER DONOR		
 E2809V00	 0183652359	Expiration Date
<b>PLATELETS</b>		<b>31 DEC 2018</b>
<b>IRRADIATED</b>		
Approx 40-70 mL from 450 mL CPD Whole Blood		
Store at 20 to 24 C		





#### 22. Apheresis Platelets

 A9999 19 810497 8 <span>X</span>	 5100	 <b>Rh POSITIVE</b>
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only		
VOLUNTEER DONOR		
 E2940V00	 0183652359	Expiration Date
<b>APHERESIS</b>		<b>31 DEC 2018</b>
<b>PLATELETS</b>		
___ mL containing approx ___ mL ACD-A		
Store at 20 to 24 C		






## ISBT 128 Blood and Blood Component Label Examples

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#### 23. Apheresis Platelets – Irradiated

	
A9998 19 649257 8 <span style="border: 1px solid black; padding: 0 2px;">L</span>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E3072V00	0183652359
APHERESIS PLATELETS IRRADIATED	31 DEC 2018
____ mL containing approx ____ mL ACD-A	
Store at 20 to 24 C 2nd Container	






#### 24. Apheresis Platelets – Leukocytes Reduced

	
A9999 19 495132 8 <span style="border: 1px solid black; padding: 0 2px;">B</span>	5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	
	Rh POSITIVE
VOLUNTEER DONOR	
	
E3077V00	0183652359
APHERESIS PLATELETS LEUKOCYTES REDUCED	31 DEC 2018
____ mL containing approx ____ mL ACD-A	
Store at 20 to 24 C	





## ISBT 128 Blood and Blood Component Label Examples

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#### 25. Apheresis Platelets – Leukocytes Reduced and Irradiated

 A9999 19 537801 8 <span>S</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 Rh POSITIVE
VOLUNTEER DONOR	
 E3058V00	 0183652359
APHERESIS PLATELETS IRRADIATED LEUKOCYTES REDUCED	Expiration Date 31 DEC 2018
____ mL containing approx ____ mL ACD-A	
Store at 20 to 24 C 3rd Container	

#### 26. Source Plasma

 A9999 19 618705 8 <span>C</span>	
Accurate Blood Center Anywhere, USA FDA Registration Number 1234567890	
Collection Date	 018022 22 JAN 2018
 E1905000	 0280222359
SOURCE PLASMA CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY ____ mL	Expiration Date 22 JAN 2028
Collected from a normal donor using 50 to 120 mL 4% Na Citrate solution by an automated method. Store at -20 C or colder	Negative for tests for antibodies to HBc, HIV, HCV, and nonreactive for HBsAg, HCV RNA, HBV DNA, and HIV-1 RNA.






#### Note:

Not all Source Plasma is tested for anti-HBc. If the Source Plasma has not been tested, then the statement "Not tested for anti-HBc" or "Not tested for antibodies to HBc" must be printed on the label.






## ISBT 128 Blood and Blood Component Label Examples

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#### 27. Pathogen Reduced Apheresis Platelets

 A9999 19 537801 8 <span>S</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 Rh POSITIVE
VOLUNTEER DONOR	
 E8340V00	 0193652359
APHERESIS PLATELETS PAS-C ADDED LEUKOCYTES REDUCED PSORALEN TREATED ____ mL containing approx ____ mL ACD-A Contains approx 65% PAS/35% Plasma  Store at 20 to 24 C	Expiration Date  31 DEC 2019





#### 28. Low Yield Platelets

 A9999 20 810497 8 <span>4</span>	 5100
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 Rh POSITIVE
VOLUNTEER DONOR	
 E4647V00	 0200312359
APHERESIS PLATELETS IRRADIATED LEUKOCYTES REDUCED  ____ mL containing approx ____ mL ACD-A CONTAINS APPROX ____ E11 PLATELETS  Store at 20 to 24 C	Expiration Date  31 JAN 2020





## ISBT 128 Blood and Blood Component Label Examples

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#### 29. Pooled Platelets

 A9999 20 810497 8 <span style="border: 1px solid black; padding: 0 2px;">4</span> Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 G000 <b>POOLED ABO</b> POOLED Rh
VOLUNTEER DONOR	
 E2897V00	 0200311735 Expiration Date / Time
POOLED PLATELETS OPEN SYSTEM	31 JAN 2020 17:35
____mL Number of units in pool ____	
Anticoagulants present ____ From Whole Blood ____	
Store at 20 to 24 C	

#### 30. Pooled Cryoprecipitated AHF

 A9999 20 810497 8 <span style="border: 1px solid black; padding: 0 2px;">4</span> Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	 H000 <b>POOLED ABO</b>
VOLUNTEER DONOR	
 E3587V00	 0200312359 Expiration Date
POOLED CRYOPRECIPITATED AHF	31 JAN 2020
____mL Number of units in pool ____	
Store at -18 C or colder	