

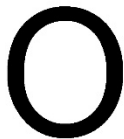






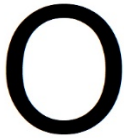


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

1. Whole Blood with CPD

	
A9999 22 123459 ♂ H	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	
	
E0019V00	0203662359
WHOLE BLOOD	Expiration Date
LEUKOCYTES REDUCED	31 DEC 2020
Approx 450 mL plus ____ mL CPD	
Store at 1 to 6 C	







2. Whole Blood with CPDA-1

	
A9999 22 654321 ♂ S	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	
	
E0063V00	0203662359
WHOLE BLOOD	Expiration Date
LEUKOCYTES REDUCED	31 DEC 2020
Approx 450 mL plus ____ mL CPDA-1	
Store at 1 to 6 C	




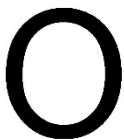


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

3. Whole Blood with CP2D

	
A9999 22 123458 	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	0203662359
WHOLE BLOOD	31 DEC 2020
IRRADIATED	
Approx 450 mL plus ____ mL CP2D	
Store at 1 to 6 C	






4. Red Blood Cells with CPD

	
A9999 22 012346 	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	0203662359
RED BLOOD CELLS	31 DEC 2020
From 500 mL CPD Whole Blood	
Store at 1 to 6 C	






ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

5. Red Blood Cells with CPDA-1

 A9999 22 012356 ♂ W 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
 E0195V00	 0203662359 Expiration Date 31 DEC 2020
RED BLOOD CELLS	
From 450 mL CPDA-1 Whole Blood	
Store at 1 to 6 C	



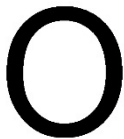


6. Red Blood Cells with CP2D

 A9997 22 123652 ♂ 3 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
 E0262V00	 0203662359 Expiration Date 31 DEC 2020
RED BLOOD CELLS	
From 500 mL CP2D Whole Blood	
Store at 1 to 6 C	



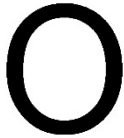


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

7. Red Blood Cells – Additive Solution

 A9999 22 275493 Ⓢ G	 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	
 E0385V00	 0203662359
RED BLOOD CELLS ADENINE-SALINE (AS-5) ADDED	Expiration Date 31 DEC 2020
From 450 mL CPD Whole Blood	
Store at 1 to 6 C	




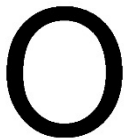


8. Red Blood Cells – Frozen

 A9999 22 275492 Ⓢ I	 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	
 E6197V00	 0300312359
FROZEN RED BLOOD CELLS LEUKOCYTES REDUCED	Expiration Date 31 JAN 2030
___ mL	
Store at -65 C or colder	




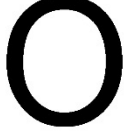


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

9. Red Blood Cells – Deglycerolized

 A9999 22 275493 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	
 E4519V00	 0203661530
DEGLYCEROLIZED RED BLOOD CELLS OPEN SYSTEM LEUKOCYTES REDUCED	Expiration Date 31 DEC 2020 15:30
___ mL	
Store at 1 to 6 C	



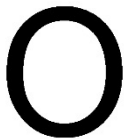


10. Red Blood Cells – Leukocytes Reduced

 A9999 22 318627 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	
 E0336V00	 0203662359
RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED LEUKOCYTES REDUCED	Expiration Date 31 DEC 2020
From 500 mL CPD Whole Blood	
Store at 1 to 6 C	



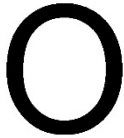


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

11. Red Blood Cells – Irradiated

 A9999 22 853491 Ⓢ 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	
 E0161V00	 0203662359 Expiration Date
RED BLOOD CELLS IRRADIATED	31 DEC 2020
From 450 mL CPD Whole Blood Store at 1 to 6 C	



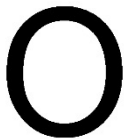


12. Red Blood Cells – Leukocytes Reduced and Irradiated

 A9999 22 853496 Ⓢ 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	 5100  Rh POSITIVE
VOLUNTEER DONOR	
 E0274V00	 0203662359 Expiration Date
RED BLOOD CELLS IRRADIATED LEUKOCYTES REDUCED	31 DEC 2020
From 500 mL CP2D Whole Blood Store at 1 to 6 C	



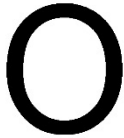


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

13. Apheresis Red Blood Cells

 A9999 22 429815 ♂ H	 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	 0203662359
APHERESIS RED BLOOD CELLS	Expiration Date 31 DEC 2020
____ mL containing approx ____ mL ACD-A	
Store at 1 to 6 C	



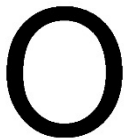


14. Apheresis Red Blood Cells – Leukocytes Reduced

 A9995 22 624581 ♂ N	 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	 0203662359
APHERESIS RED BLOOD CELLS LEUKOCYTES REDUCED	Expiration Date 31 DEC 2020
____ mL containing approx ____ mL ACD-A	
Store at 1 to 6 C US License Number 1234	



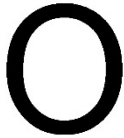


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

15. Fresh Frozen Plasma

	
A9999 22 104362 8 9	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	
	
E0707V00	0203662359
FRESH FROZEN PLASMA	31 DEC 2020
____ mL from CPDA-1 Whole Blood	
Store at -18 C or colder	



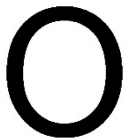


16. Apheresis Fresh Frozen Plasma

	
A9999 22 456789 8 F	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	
	
E4693V00	0203662359
APHERESIS FRESH FROZEN PLASMA	31 DEC 2020
____ mL containing approx ____ mL ACD-A	
Store at -18 C or colder 2nd Container	




ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

17. Cryoprecipitated AHF

 A9999 22 132048 8 2	 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	
 E5165V00	 0203662359
	Expiration Date
CRYOPRECIPITATED AHF	31 DEC 2020
Store at -18 C or colder	

18. Source Leukocytes

 A9995 22 123456 8 *	
Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567	
Collection Date	
 020031 31 JAN 2020	
 E3698000	
SOURCE LEUKOCYTES	
CAUTION: FOR MANUFACTURING USE ONLY	
____ 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	



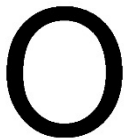


Note:

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.



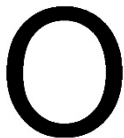


See 21 CFR 610.40(g)(2) and 606.121(h).

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

19. Platelets

 A9999 22 210379 8 <input checked="" type="checkbox"/>	 5100	 Rh POSITIVE
<p>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</p>		
<p>VOLUNTEER DONOR</p>		
 E2807V00	 0203662359	Expiration Date
<p>PLATELETS</p>		<p>31 DEC 2020</p>
<p>Approx 40-70 mL From 450 mL CPD Whole Blood</p> <p>Store at 20 to 24 C</p>		



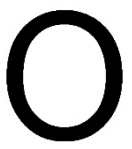


20. Platelets – Leukocytes Reduced

 A9999 22 210379 8 <input checked="" type="checkbox"/>	 5100	 Rh POSITIVE
<p>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</p>		
<p>VOLUNTEER DONOR</p>		
 E2817V00	 0203662359	Expiration Date
<p>PLATELETS LEUKOCYTES REDUCED</p>		<p>31 DEC 2020</p>
<p>Approx 40-70 mL from 450 mL CPD Whole Blood</p> <p>Store at 20 to 24 C</p>		



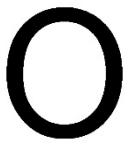


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

21. Platelets – Irradiated

 A9999 22 094657 8 E	 5100	 Rh POSITIVE
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	 0203662359	Expiration Date
PLATELETS IRRADIATED		31 DEC 2020
Approx 40-70 mL from 450 mL CPD Whole Blood Store at 20 to 24 C		



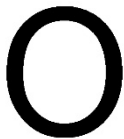


22. Apheresis Platelets

 A9999 22 810497 8 7	 5100	 Rh POSITIVE
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	 0203662359	Expiration Date
APHERESIS PLATELETS		31 DEC 2020
____ mL containing approx ____ mL ACD-A Store at 20 to 24 C		



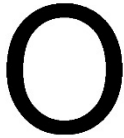


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

23. Apheresis Platelets – Irradiated

	
A9998 22 649257 ♂ W	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	0203662359
APHERESIS PLATELETS IRRADIATED	31 DEC 2020
____ mL containing approx ____ mL ACD-A	
Store at 20 to 24 C 2nd Container	



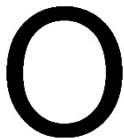


24. Apheresis Platelets – Leukocytes Reduced

	
A9999 22 495132 ♂ M	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	0203662359
APHERESIS PLATELETS LEUKOCYTES REDUCED	31 DEC 2020
____ mL containing approx ____ mL ACD-A	
Store at 20 to 24 C	





ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

25. Apheresis Platelets – Leukocytes Reduced and Irradiated

	
A9999 22 537801 S 2	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	0203662359
APHERESIS PLATELETS IRRADIATED LEUKOCYTES REDUCED	31 DEC 2020
____ mL containing approx ____ mL ACD-A	Expiration Date
Store at 20 to 24 C 3rd Container	

26. Source Plasma

	
A9999 22 618705 S N	
Accurate Blood Center Anywhere, USA FDA Registration Number 1234567890	
Collection Date	
	020022
	22 JAN 2020
	
E1905000	0300222359
SOURCE PLASMA	22 JAN 2030
CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY ____ mL	Negative for tests for antibodies to HBc, HIV, HCV, and nonreactive for HBsAg, HCV RNA, HBV DNA, and HIV-1 RNA.
Collected from a normal donor using 50 to 120 mL 4% Na Citrate solution by an automated method. Store at -20 C or colder	



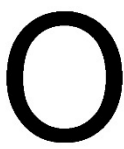


Note:

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.



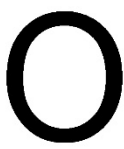


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

27. Pathogen Reduced Apheresis Platelets

 A9999 22 537801 8 2	 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	 0203662359
Expiration Date 31 DEC 2020	
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	





28. Low Yield Platelets

 A9999 22 810497 8 7	 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
Expiration Date 31 JAN 2020	
APHERESIS PLATELETS IRRADIATED LEUKOCYTES REDUCED ____ mL containing approx ____ mL ACD-A CONTAINS APPROX ____ E11 PLATELETS Store at 20 to 24 C	


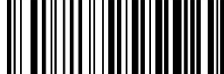


ISBT 128 Blood and Blood Component Label Examples

US Label Examples of Product Types Needed for FDA Review

29. Pooled Platelets

 A9999 22 810497 8 7 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 POOLED ABO 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 22 810497 8 7 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 POOLED ABO
VOLUNTEER DONOR	
 E3587V00	 0200312359 Expiration Date
POOLED CRYOPRECIPITATED AHF	31 JAN 2020
____mL Number of units in pool ____	
Store at -18 C or colder	