



ISBT LABELS THAT NEED TO BE SUBMITTED BY LICENSED BLOOD ESTABLISHMENTS FOR PRIOR APPROVAL

The list below is for those facilities that have had their Codabar product labels previously approved under their U.S. License. If label has not been previously approved, label must be submitted regardless of list below.

PRODUCT LABELS

1. **WHOLE BLOOD** label (for each approved anticoagulant currently in use)
2. **RED BLOOD CELLS** label (for each approved anticoagulant currently in use)
3. **RED BLOOD CELLS** label (for **one** approved additive currently in use)
4. **RED BLOOD CELLS FROZEN** (for each approved source volume, i.e. 450 ml and/or 500 mL)
5. **RED BLOOD CELLS DEGLYCEROLIZED** (for each approved source volume, i.e. 450 ml and/or 500 mL)
6. **RED BLOOD CELLS LEUKOCYTES REDUCED** label (for **one** approved anticoagulant currently in use)
7. **RED BLOOD CELLS IRRADIATED** label (for **one** approved anticoagulant currently in use)
8. **RED BLOOD CELLS LEUKOCYTES REDUCED IRRADIATED** label (for **one** approved anticoagulant currently in use)
9. **RED BLOOD CELLS BY PHERESIS** label (for **one** approved anticoagulant currently in use)
10. **RED BLOOD CELLS LEUKOCYTES REDUCED BY PHERESIS** label (for **one** approved anticoagulant currently in use)
11. **FRESH FROZEN PLASMA** label (for **one** approved anticoagulant currently in use)
12. **FRESH FROZEN PLASMA (BY APHERESIS)** label (for **one** approved anticoagulant currently in use)
13. **CRYOPRECIPITATED AHF** label
14. **SOURCE LEUKOCYTES** label (for **one** approved anticoagulant currently in use)
15. **PLATELETS** label ((for **one** approved anticoagulant currently in use)
16. **PLATELETS LEUKOCYTES REDUCED** label ((for **one** approved anticoagulant currently in use)
17. **PLATELETS IRRADIATED** label (for **one** approved anticoagulant currently in use)
18. **PLATELETS PHERESIS** label ((for **one** approved anticoagulant currently in use)
19. **PLATELETS PHERESIS IRRADIATED** label ((for **one** approved anticoagulant currently in use)

20. **PLATELETS PHERESIS LEUKOCYTES REDUCED** label (for **one** approved anticoagulant currently in use)
21. **PLATELETS PHERESIS LEUKOCYTES REDUCED IRRADIATED** label ((for **one** approved anticoagulant currently in use)
22. **SOURCE PLASMA** label (for each previously approved Codabar label currently in use)

OTHER LABELS

1. **ABO/Rh label** (one of each blood type)
2. **Donor Identification Number** (from one of your facilities)
3. **For Autologous Use Only** label with the **Intended Recipient Information** label

3/16/06