CLAIMS

~~1.~~ ~~A~~ **1.** A pathogen-inactivated cryoprecipitate composition comprising ~~a cryoprecipitate suitable~~fibrinogen for use in a therapy, wherein the pathogen-inactivated cryoprecipitate has been thawed at least 1 day prior to infusion into a subject ~~at least 1 day after thawing, wherein the cryoprecipitate is pathogen-inactivated~~.

2. The pathogen-inactivated cryoprecipitate composition for use of claim 1, wherein the cryoprecipitate is stored for at least 1 day at between 2ºC and 25ºC after thawing and prior to infusion.

3. The pathogen-inactivated cryoprecipitate composition for use of claim 1, wherein the cryoprecipitate is ~~suitable for~~ stored for at least 1 day at between 20ºC and 25ºC after thawing and prior to infusion.

~~2.~~ **4.** The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-3, wherein the cryoprecipitate has been thawed at least 3 days prior to infusion into a subject ~~at least 3 days after thawing~~.

~~3.~~ ~~The composition of claim 2, wherein the~~ **5.** The pathogen-inactivated cryoprecipitate composition ~~is suitable for~~ for use of any one of claims 1-3, wherein the cryoprecipitate has been thawed at least 5 days prior to infusion into a subject ~~at least 5 days after thawing~~.

~~The~~ **6.** The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-~~3~~5, wherein the cryoprecipitate has been thawed within 7 days prior to infusion into a subject.

7. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-6, wherein the subject suffers from bleeding.

8. The pathogen-inactivated cryoprecipitate composition for use of claim 7, wherein the bleeding is associated with fibrinogen deficiency or massive hemorrhage.

9. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-6, wherein the subject suffers from von Willebrand disease.

10. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-9, wherein the pathogen-inactivated cryoprecipitate composition comprises at least 600 mg of fibrinogen.

11. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-9, wherein the pathogen-inactivated cryoprecipitate composition comprises at least 750 mg of fibrinogen.

12. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-9, wherein the pathogen-inactivated cryoprecipitate composition comprises at least 1500 mg of fibrinogen.

13. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-12, wherein the plasma has been pathogen inactivated by photochemical inactivation.

14. The pathogen-inactivated cryoprecipitate composition for use of any one of claims 1-13, wherein the plasma has been pathogen inactivated by photochemical inactivation with a psoralen; optionally wherein the psoralen is amotosalen.

15. Use of a pathogen-inactivated cryoprecipitate composition comprising fibrinogen in the manufacture of a medicament for the treatment of a condition, wherein the pathogen-inactivated cryoprecipitate has been thawed at least 1 day prior to infusion into a subject.

16. The use of claim 15, wherein the pathogen-inactivated cryoprecipitate composition is as defined in any one of claims 1-14.

17. The use of claim 15 or claim 16, wherein the subject suffers from bleeding, optionally wherein the bleeding is associated with fibrinogen deficiency, or massive hemorrhage or von Willebrand disease.

~~4.~~ **18.** The use of any one of claims 15-17, wherein the cryoprecipitate composition comprises cryoprecipitate prepared from at least about 550 mL and less than ~~about~~ 650 mL of pathogen-inactivated plasma.

~~5.~~ **19.** The ~~composition~~use of any one of claims ~~1-3~~15-18, wherein the ~~composition comprises~~ cryoprecipitate ~~prepared from 3 units of pathogen-inactivated plasma.~~

~~6.~~ ~~The composition of any one of claims 1-3, wherein the~~ composition comprises a first cryoprecipitate prepared from at least about 550 mL and less than 650 mL of pathogen-inactivated plasma and a second cryoprecipitate prepared from at least about 550 mL and less than 650 mL of pathogen-inactivated plasma, wherein the first and the second cryoprecipitates are combined prior to ~~re-~~freezing for storage.

~~7.~~ **20.** The ~~composition of any one of claims 1-3~~use of claim 19, wherein the cryoprecipitate composition further comprises a ~~first~~third cryoprecipitate prepared from ~~3 units of pathogen-inactivated plasma and a second cryoprecipitate prepared from 3 units~~at least about 550 mL and less than 650 mL of pathogen-inactivated plasma, wherein the first, second, and ~~the second~~third cryoprecipitates are combined prior to ~~re-freezing for storage.~~infusion.

~~8.~~ **21.** The ~~composition~~use of any one of claims ~~1-7~~15-20, wherein the cryoprecipitate composition comprises cryoprecipitate prepared from plasma obtained from 2-6 donors.

~~9.~~ **22.** The ~~composition~~use of any one of claims ~~1-8~~18-21, wherein the ~~composition comprises 80-480 IU of factor VIII.~~

~~10. The composition of any one of claims 1-9, wherein the composition comprises 160-400 IU of factor VIII.~~

~~**11.** The composition of any one of claims 2-10, wherein the amount of factor VIII is determined from cryoprecipitate sampled within about 6 hours after thawing.~~

~~**12.** The composition of any one of claims 3-10, wherein the amount of factor VIII is determined from cryoprecipitate sampled about 5 days after thawing.~~

~~**13.** The composition of any one of claims 4-12, wherein the composition comprises at least 600 mg of fibrinogen.~~

~~**14.** The composition of any one of claims 4-12, wherein the composition comprises at least 750 mg of fibrinogen.~~

~~**15.** The composition of any one of claims 6-12, wherein the composition comprises at least 1500 mg of fibrinogen.~~

~~**16.** The composition of any one of claims 1-15, wherein the cryoprecipitate~~plasma has been pathogen-inactivated by photochemical inactivation.

~~**17.**~~ **23.** The ~~composition~~use of claim ~~16~~22, wherein the ~~cryoprecipitate~~plasma has been pathogen-inactivated by photochemical inactivation with a psoralen; optionally, wherein the psoralen is amotosalen.

~~**18.**~~ **24.** The ~~composition~~use of ~~claim 16 or claim 17~~any one of claims 18-23, wherein the cryoprecipitate is prepared from plasma that has been pathogen-inactivated in a first container suitable for photochemical inactivation of the plasma under sterile conditions; wherein the first container is coupled to a compound absorption device (CAD) such that the pathogen-inactivated plasma can be transferred from the first container to the CAD under sterile conditions; ~~and~~

~~wherein the cryoprecipitate is contained within one or more second containers, each of which is coupled to the CAD such that the pathogen-inactivated plasma can be transferred from the CAD to the one or more second containers under sterile conditions, and each of which is suitable for freezing the pathogen-inactivated plasma followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of the cryoprecipitate.~~

~~19.~~ ~~The composition of claim 16 or claim 17, wherein the cryoprecipitate is prepared from plasma that has been pathogen-inactivated in a first container suitable for photochemical inactivation of the plasma under sterile conditions;~~

~~wherein the first container is coupled to a compound absorption device (CAD) such that the pathogen-inactivated plasma can be transferred from the first container to the CAD under sterile conditions;~~

___wherein the CAD is coupled to one or more second containers, each of which is coupled to the CAD such that the pathogen-inactivated plasma can be transferred from the CAD to the one or more second containers under sterile conditions; and

___wherein the cryoprecipitate is contained within a third container configured to be coupled to one or more second containers, such that the pathogen-inactivated plasma can be transferred from the CAD to the one or more second containers to the third container under sterile conditions, wherein the third container is suitable for freezing the pathogen-inactivated plasma followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of the cryoprecipitate.

~~20.~~ ~~The composition of any one of claims 2-19, wherein the composition is contained within a container that further comprises a label indicating that the composition is suitable for use for at least about 3 days after thawing.~~

~~21.~~ ~~The composition of any one of claims 3-19, wherein the composition is contained within a container that further comprises a label indicating that the composition is suitable for use for at least about 5 days after thawing.~~

22. A method of preparing a cryoprecipitate for infusion into a subject comprising:

a) preparing a cryoprecipitate from pathogen-inactivated plasma;

b) freezing the cryoprecipitate; and

c) thawing the frozen cryoprecipitate, wherein the resulting cryoprecipitate of step c) is suitable for infusion into a subject at least 1 day after thawing.

23. The method of claim 22, wherein the thawed cryoprecipitate comprises at least about 600 mg of fibrinogen.

24. The method of claim 22, wherein the thawed cryoprecipitate comprises at least about 750 mg of fibrinogen.

25. The method of claim 22, wherein the thawed cryoprecipitate comprises at least about 1500 mg of fibrinogen.

26. The method of claim 22, wherein the thawed cryoprecipitate comprises 160-400 IU of factor VIII.

27. The method of any one of claims 22-26, wherein the cryoprecipitate is prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma.

28. The method of any one of claims 22-26, further comprising combining a first cryoprecipitate prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma and a second cryoprecipitate prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma, wherein the first and the second cryoprecipitates are combined prior to steps b) and c).

29. The method of any one of claims 22-26, further comprising combining a first cryprecipitate prepared from 3 units of pathogen-inactivated plasma and a second cryoprecipitate prepared from

3 units of pathogen-inactivated plasma, wherein the first and the second cryoprecipitates are combined prior to steps b) and c).

30. The method of any one of claims 22-29, wherein the resulting cryoprecipitate of step c) is suitable for infusion into a subject at least 3 days after thawing.

31. The method of claim 30, wherein the resulting cryoprecipitate of step c) is suitable for infusion into a subject at least 5 days after thawing.

32. The method of any one of claims 22-31, wherein the plasma has been pathogen-inactivated by photochemical inactivation.

33. The method of claim 32, wherein the cryoprecipitate has been pathogen-inactivated by photochemical inactivation with a psoralen.

34. The method of claim 32 or claim 33, wherein the cryoprecipitate is prepared from plasma that has been pathogen-inactivated in a first container suitable for photochemical inactivation of the plasma under sterile conditions;

wherein the first container is coupled to a compound absorption device (CAD) such that the pathogen-inactivated plasma can be transferred from the first container to the CAD under sterile conditions; and

wherein the cryoprecipitate is frozen and thawed in steps b) and c) within one or more second containers, each of which is coupled to the CAD such that the pathogen-inactivated plasma can be transferred from the CAD to the one or more second containers under sterile conditions, and each of which is suitable for freezing the pathogen-inactivated plasma followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of the cryoprecipitate.

35. The method of claim 32 or claim 33, wherein the cryoprecipitate is prepared from plasma that has been pathogen-inactivated in a first container suitable for photochemical inactivation of the plasma under sterile conditions;

wherein the first container is coupled to a compound absorption device (CAD) such that the pathogen-inactivated plasma can be transferred from the first container to the CAD under sterile conditions; and

wherein the cryoprecipitate is frozen and thawed in steps b) and c) within a third container configured to be coupled to one or more second containers, such that the pathogen-inactivated plasma can be transferred from the CAD to the one or more second containers to the third container under sterile conditions, wherein the third container is suitable for freezing the pathogen-inactivated plasma followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of the cryoprecipitate.

36. A kit comprising:

a) a container;

b) a pathogen-inactivated cryoprecipitate; and

c) instructions for using the pathogen-inactivated cryoprecipitate in an infusion into a subject, wherein the instructions indicate that the cryoprecipitate is suitable for infusion into the subject for up to about 5 days after thawing, or

c) a label indicating that the pathogen-inactivated cryoprecipitate is suitable for use for up to about 5 days after thawing.

37. Use of the composition of any one of claims 1-21 in the manufacture of a medicament for infusing a cryoprecipitate into a subject.

38. Use of a cryoprecipitate produced by the method of any one of claims 22-35 in the manufacture of a medicament for infusing the cryoprecipitate into a subject.

39. A cryoprecipitate produced by the method of any one of claims 22-35.

40. A method of preparing a pooled cryosupernatant for infusion into a subject comprising:

a) freezing at least a first pathogen-inactivated plasma and a second pathogen-inactivated plasma, wherein the first and the second pathogen-inactivated plasmas each have a volume of at least about 550 mL and less than about 650 mL;

b) thawing the first pathogen-inactivated plasma under conditions that provide for the formation of a first precipitate and a first supernatant, and thawing the second pathogen-inactivated plasma under conditions that provide for the formation of a second precipitate and a second supernatant;

c) separating the first and the second supernatants from the first and the second precipitates to form a first crosupernatant and a second cryosupernatant; and

d) combining the first and the second cryosupernatants to form a pooled cryosupernatant.

41. The method of claim 40, wherein the first and/or the second pathogen-inactivated plasmas have been pathogen-inactivated by photochemical inactivation.

42. A processing set for preparing a pathogen-inactivated cryoprecipitate, comprising

a) a first container within which one or more units of a plasma can be photochemically inactivated in the presence of a psoralen under sterile conditions;

b) a compound absorption device (CAD) coupled to the first container such that the one or more units of plasma can be transferred from the first container to the compound absorption device under sterile conditions;

c) one or more second containers, each of which is coupled to the compound absorption device such that the one or more units of plasma can be transferred from the compound absorption device to the one or more second containers under sterile conditions to provide pathogen-inactivated plasma suitable for infusion into a subject; and

d) a third container, which is configured to be coupled to the one or more second containers such that the pathogen-inactivated plasma can be transferred from the one or more second containers to the third container under sterile conditions,

wherein the third container is suitable for freezing the pathogen-inactivated plasma followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of a cryoprecipitate and a supernatant.

43. The processing set of claim 42, wherein the third container is suitable for freezing the pathogen-inactivated plasma, followed by thawing of the pathogen-inactivated plasma under conditions that provide for the formation of the cryoprecipitate and a cryosupernatant, followed by removal of all or a portion of the cryosupernatant from the third container.

44. A method of preparing a cryoprecipitate for infusion into a subject comprising:

a) preparing a cryoprecipitate from pathogen-inactivated plasma; and

b) freezing the cryoprecipitate;

wherein the cryoprecipitate is suitable for infusion into the subject for up to about 5 days after thawing.

45. The method of claim 44, wherein the cryoprecipitate is prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma.

46. The method of claim 44, further comprising combining a first cryoprecipitate prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma and a second cryoprecipitate prepared from at least about 550 mL and less than about 650 mL of pathogen-inactivated plasma, wherein the first and the second cryoprecipitates are combined prior to step b).

47. The method of claim 44, further comprising combining a first cryprecipitate prepared from 3 units of pathogen-inactivated plasma and a second cryoprecipitate prepared from 3 units of pathogen-inactivated plasma, wherein the first and the second cryoprecipitates are combined prior to step b).

48. A method of preparing a cryoprecipitate for infusion into a subject comprising:

a) preparing a cryoprecipitate from plasma; and

b) subjecting the cryoprecipitate to pathogen inactivation;

wherein the pathogen-inactivated cryoprecipitate is suitable for infusion into the subject for up to about 5 days after storage at between about 2°C and about 25°C.

49. The method of claim 48, further comprising, after step b):

c) freezing the pathogen-inactivated cryoprecipitate; and

d) thawing the frozen pathogen-inactivated cryoprecipitate;

wherein the pathogen-inactivated cryoprecipitate is suitable for infusion into the subject for up to about 5 days after thawing.

50. The method of claim 48 or claim 49, wherein the cryoprecipitate is prepared from 1 unit of plasma.

51. The method of claim 48 or claim 49, further comprising combining at least a first cryoprecipitate prepared from 1 unit of plasma and a second cryoprecipitate prepared from 1 unit of plasma, wherein the first and the second cryoprecipitates are combined prior to step b).

52. The method of claim 51, wherein combining at least a first cryoprecipitate and a second cryoprecipitate comprises combining 2-12 cryoprecipitates.