CLAIMS

1. A hematology control composition comprising a red blood cell component and an isotonic suspension medium including a serum albumin component and a cholesterol component, wherein the composition is substantially free of an unesterified fatty acid component; and wherein the serum albumin component and the cholesterol component are present in amounts sufficient to provide a stable shelf life.

2. The composition of claim 1, wherein the serum albumin component and the cholesterol component are present in amounts sufficient to provide a shelf life of the composition of at least ninety-five days.

3. The composition of claim 1, wherein the shelf life of the composition is represented by a stabilization in mean cell volume, a stabilization in red blood cell distribution width, or both.

4. The composition of claim 1, wherein the red blood cell component is present in an amount sufficient to be measurable with an automated hematology instrument.

5. The composition of claim 1, wherein the serum albumin component is present at a concentration of from about 30 grams/liter to about 50 grams/liter.

6. The composition of claim 1, wherein the serum albumin component comprises a ratio of serum albumin monomer to serum albumin dimer lower than about 5:1.

7. The composition of claim 1, wherein the cholesterol component is present at a concentration of from about 400 mg/liter to about 1200 mg/liter.

8. The composition of claim 1, wherein the unesterified fatty acid component is present at a concentration less than about 4 mmol/liter.

9. The composition of claim 1, further comprising a nonionic surfactant component.

10. The composition of claim 9, wherein the nonionic surfactant component comprises a poloxamer.

11. The composition of claim 1, which further comprises a white blood cell component.

~~12. The composition of claim 11, wherein the white blood cell component simulates at least three subpopulations of white blood cells.~~

~~13. The composition of claim 12, wherein the white blood cell component simulates five subpopulations of white blood cells.~~

~~14. The composition of claim 1, which further comprises a compatible preservative component in an amount sufficient to provide fungicidal and bactericidal activity.~~

CLAIMS

1~~15~~. A hematology control composition comprising a red blood cell component and an isotonic suspension medium including a serum albumin component and a cholesterol component, wherein the composition has a free fatty acid concentration of less than ~~about~~ 4 mmol/liter; and wherein the serum albumin component ~~and the cholesterol component are present in amounts sufficient to provide a stable shelf life~~ comprises a ratio of serum albumin monomer to serum albumin dimer lower than 6:1.

2~~16~~. The composition of claim 1~~5~~, wherein the serum albumin component and the cholesterol component are present in amounts sufficient to provide a shelf life of the composition of at least ninety-five days.

3~~17~~. The composition of claim 2~~15~~, wherein the shelf life of the composition is represented by a stabilization in mean cell volume, a stabilization in red blood cell distribution width, or both.

4~~18~~. The composition of claim 1~~5~~, wherein the red blood cell component is present in an amount sufficient to be measurable with an automated hematology instrument.

5~~19~~. The composition of claim 1~~5~~, wherein the serum albumin component is present at a concentration of from ~~about~~ 30 grams/liter to ~~about~~ 50 grams/liter.

6~~20~~. The composition of claim 1~~5~~, wherein the serum albumin component comprises a ratio of serum albumin monomer to serum albumin dimer lower than ~~about~~ 5:1.

7~~21~~. The composition of claim 1~~5~~, wherein the cholesterol component is present at a concentration of from ~~about~~ 400 mg/liter to ~~about~~ 1200 mg/liter.

8~~22~~. The composition of claim 1~~5~~, further comprising a nonionic surfactant component.

923. The composition of claim 822, wherein the nonionic surfactant component comprises a poloxamer.

1024. The composition of claim 15, which further comprises a white blood cell component.

1125. The composition of claim 2410, wherein the white blood cell component simulates at least three subpopulations of white blood cells.

1226. The composition of claim 1125, wherein the white blood cell component simulates five subpopulations of white blood cells.

1327. The composition of claim 15, which further comprises a compatible preservative component in an amount sufficient to provide fungicidal and bactericidal activity.

1428. The hematology control composition of claim 15, which further comprises one or more pH adjusting agents to provide a pH in the range from about 5.8 to about 6.8.

29. A method for determine operational accuracy and reproducibility of a hematology instrument, the method comprising the steps of:

a) providing a hematology control composition comprising a blood cell component and an isotonic suspension medium including a serum albumin component and a cholesterol component, wherein the composition is substantially free of unesterified fatty acids, and wherein the composition has a known reference value for one or more blood cell parameters present in the hematology control composition;

b) determining an experimental value for the one or more blood cell parameters with a hematology instrument; and

c) comparing the experimental value for the one or more blood cell parameters obtained from step (b) with the known reference value for the one or more blood cell parameters from step (a), wherein the comparison determines the operational accuracy and reproducibility of the hematology instrument.

1530. A method for determine operational accuracy and reproducibility of a hematology instrument, the method comprising the steps of:

a) providing a hematology control composition comprising a blood cell component and an isotonic suspension medium including a serum albumin component, and a cholesterol component, wherein the composition has a free fatty acid concentration of less than ~~about~~ 4 mmol/liter, wherein the serum albumin component comprises a ratio of serum albumin monomer to serum albumin dimer lower than 6:1 and wherein the composition has a known reference value for one or more blood cell parameters present in the hematology control composition;

b) determining an experimental value for the one or more blood cell parameters with a hematology instrument; and

c) comparing the experimental value for the one or more blood cell parameters obtained from step (b) with the known reference value for the one or more blood cell parameters from step (a), wherein comparison determines the operational accuracy and reproducibility of the hematology instrument.