CLAIMS

1. A method for purifying an anti-kappa myeloma antigen (KMA) antibody that binds free kappa light chain not associated with heavy chain from a Chinese Hamster Ovary (CHO) cell culture comprising the anti-KMA antibody, the method comprising:

binding the antibody from the CHO cell culture to a Protein A resin of neutral pH;

washing the Protein A resin with a basic wash buffer having a pH of at least 2.5 to 5 above neutral pH to wash free kappa light chain not associated with heavy chain from the composition; and

eluting antibody bound to the Protein A resin with an elution buffer.

2. A method according to Claim 1, in which the anti-KMA antibody preferentially binds KMA over free kappa light chain not associated with heavy chain.

3. A composition comprising anti-kappa myeloma antigen (KMA) binding proteins, in which less than 20%, less than 15%, less than 10%, less than 6% of the anti-KMA binding proteins in the composition are anti-KMA binding proteins in complex with free kappa light chain not associated with heavy chain.

4. A composition according to Claim 3, in which the anti-KMA binding proteins comprise a VH region set forth in SEQ ID NO:1 and a VL region set forth in SEQ ID NO:3 or bind the same epitope of KMA as an antibody comprising a VH region set forth in SEQ ID NO:1 and a VL region set forth in SEQ ID NO:3.

5. A composition according to Claim 3 or 4, in which the binding proteins are produced by Chinese Hamster Ovary (CHO) cells, preferably in which the anti-KMA binding proteins are antibodies.

6. A composition according to Claim 3, 4 or 5, in which the anti-KMA binding proteins are purified from free kappa light chain not associated with heavy chain by a method comprising:

loading a composition comprising the anti-KMA binding proteins and free kappa light chain not associated with heavy chain onto an equilibrated affinity chromatography column of neutral pH to bind the anti-KMA binding proteins in the composition to the affinity chromatography column;

washing the affinity chromatography column with a basic wash buffer having a pH of at least 2.5 to 5 above neutral pH to wash free kappa light chain not associated with heavy chain from the composition; and

eluting the anti-KMA binding proteins bound to the affinity chromatography column with an elution buffer.

7. A composition according to Claim 6, in which the composition comprising the anti-KMA binding proteins and free kappa light chain not associated with heavy chain is cell culture fluid obtained from the cell culture of CHO cells which express the anti-KMA binding proteins.

8. A method according to Claim 1 or 2 or a composition according to Claim 6 or 7, in which the basic wash buffer has one or more of the following:

a pH of 9 to 11, or a pH of 9.5 to 10.5;

0.1M to 0.2M sodium carbonate; and

1M sodium chloride.

9. A method or composition according to any of Claims 1, 2 and 6 to 8, in which washing the affinity chromatography to wash free kappa light chain not associated with heavy chain comprises washing the affinity chromatograph column twice with a basic wash buffer.

10. A method or composition according to Claim 9, in which in a first wash the basic wash buffer comprises 0.2M sodium chloride and in a second wash the basic wash buffer comprises 0.1M sodium chloride.

11. A method or composition according to Claim 10, in which the basic wash buffers have the same pH.

12. A method or composition according to any of Claims 1, 2 and 6 to 11, in which washing the affinity chromatography column comprises washing with an acidic wash buffer.

13. A method or composition according to Claim 12, in which the acidic wash buffer has a pH of 5.5 to 6.5.

14. A method or composition according to Claim 12 or 13, in which the acidic wash buffer comprises about 35 mM sodium phosphate.

15. A method or composition according to any of Claims 1, 2 and 6 to 14, in which the elution buffer is acidic, preferably in which the elution buffer has one or more of the following:

a pH lower than the acidic wash buffer;

a pH of 2.5 to 3.5; and

10 mM sodium phosphate.

16. A method or composition according to any of Claims 6 to 15, in which the affinity chromatography column is a protein A chromatography column.

17. A method or composition according to any of Claims 1, 2 and 6 to 16, in which the method further comprises one or more of the following:

a viral inactivation step;

a viral filtration step; and

a step of formulating the eluted binding protein into a pharmaceutical composition or a diagnostic composition.

18. A method or composition according to any of Claims 1, 2 and 6 to 17, in which the free kappa light chain not associated with heavy chain is a kappa light chain dimer.

19. A method or composition according to any of Claims 1, 2 and 6 to 18, in which the molecular weight of the free light chain not associated with heavy chain is between 22 and 100 kD.

20. A method or composition according to any of Claims 1, 2 and 6 to 19, in which the eluted binding proteins are subject to cation exchange chromatography to remove any potential high molecular weight species, and:

at least 75% unbound antibody relative to antibody bound to free light chain not associated with heavy chain as determined by SEC-HPLC and/or BioCore assay

at least 85% unbound binding protein relative to binding protein bound to free light chain not associated with heavy chain as determined by SEC-HPLC and/or BioCore assay

at least 90% unbound binding protein relative to binding protein bound to free light chain not associated with heavy chain as determined by SEC-HPLC and/or BioCore assay; or

between 85% and 95% unbound binding protein relative to binding protein bound to free light chain not associated with heavy chain as determined by SEC-HPLC and/or BioCore assay.