

Claims:

1. An anti-idiotypic antibody fused to albumin or a functional fragment of albumin.
2. The anti-idiotypic antibody albumin fusion according to claim 1, wherein the anti-idiotypic antibody is specific for an anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence
QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSTYYADSVKGRFTISRDN
SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAYWGQGTLLTVSS (SEQ ID NO: 7), and a variable light chain domain comprising the amino acid sequence
DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGNTATLTISGT
QAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (SEQ ID NO: 8).
3. The anti-idiotypic antibody albumin fusion according to any one of the preceding claims, wherein said anti-idiotypic antibody comprises a variable heavy chain comprising
an HCDR1 of the amino acid sequence YSFSNYWIS (SEQ ID NO: 18),
an HCDR2 of the amino acid sequence WMGIIDPASSKTRYSPSFQG (SEQ ID NO: 19),
an HCDR3 of the amino acid sequence SRGAGMDY (SEQ ID NO: 20), and
a variable light chain comprising
an LCDR1 of the amino acid sequence TGSSSNIGAGYDVH (SEQ ID NO: 21),
an LCDR2 of the amino acid sequence LLIYADNNRPS (SEQ ID NO: 22),
an LCDR3 of the amino acid sequence GSYDESSNSM (SEQ ID NO: 23).
4. The anti-idiotypic antibody albumin fusion according to any one of the preceding claims, wherein said anti-idiotypic antibody comprises the variable heavy chain of the amino acid sequence
QVQLVQSGAEVKKPGESLKISCKGSGYSFSNYWISWVRQMPGKGLEWMGIIDPASSKTRYSPSFQGQVTISADKS
ISTAYLQWSSLKASDTAMYCARSRGAGMDYWGQGTLLTVSS (SEQ ID NO: 16), and the variable light chain of the amino acid
sequenceDIVLTQPPSVSGAPGQRVTISCTGSSSNIGAGYDVHWYQQLPGTAPKLLIYADNNRPSGVPDRFSGSK
SGTSASLAITGLQSEADYYCGSYDESSNSMVFGGGTKLTVLGQ (SEQ ID NO: 17).

5. The anti-idiotypic antibody albumin fusion according any one of the preceding claims, wherein the heavy chain comprises the amino acid sequence

QVQLVQSGAEVKKPGESLKISCKGSGYSFSNYWISWVRQMPGKGLEWMGIIDPASSKTRYSPSFQGGQVTISADKS
ISTAYLQWSSLKASDTAMYICARSRGAGMDYWGGTGLTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYF
PEPVTVSWNSGALTSGVHTFPAVLQSSGLYSLSSVTVPSSSLGTQTYICNVNHKPSNTKVDKRVEPKSDIDAHKS
EVAHRFKDLGEENFKALVLIAFAQYLQQCPFEDHVKLNVTEFAKTCVADESAENCDKSLHTLFGDKLCTVATLR
ETYGEMADCCAKQEPERNECFLQHKDDNPPLRLVRPEVDVMCTAFHDNEETFLKKYLYEIARRHPYFYAPELLF
FAKRYKAAFTGCCQAADKAAACLLPKLDELDEGKASSAKQRLKASLQKFGERAFAKAWAVARLSQRFPKAEFAEV
SKLVTDLTKVHTECCHGDLLECADDRADLAKYICENQDSISSKLKECCEKPLLEKSHCIAEVENDEMPADLPSLAAD
FVESKDVCKNYAEAKDVFLGMFLYFYARRHPDYSVLLLLRLAKTYETTLEKCCAAADPHECYAKVFDEFKPLVEEP
QNLIKQNCLEFEQLGEYKFQNALLVRYTKKVPQVSTPTLVEVSRNLGKVGSKCKHPEAKRMPCAEDYLSVVLNQ
LCVLHEKTPVSDRVTKCTESLVNRRPCFSALEVDETYVPKEFNAETFTFHADICTLSEKERQIKKQTALVELVKHKP
KATKEQLKAVMDDFAAFVEKCKADDKETCFAEEGKKLVAASQAALGLVNSRHHHHHH (SEQ ID NO: 24), and

wherein the

light chain comprises the amino acid sequence

DIVLTQPPSVSGAPGQRVTISCTGSSSNIGAGYDVHWYQQLPGTAPKLLIYADNNRPSGVPDRFSGSKSGTSASLA
ITGLQSEDEADYYCGSYDESSNSMVFGGGTKLTVLGQPKAAPSVTLFPPSSEELQANKATLVCLISDFYPGAVTVA
WKADSSPVKAGVETTTPSKQSNNKYAASSYLSLTPEQWKSHRSYSCQVTHEGSTVEKTVAPTECS (SEQ ID NO:
25).

6. The anti-idiotypic antibody albumin fusion according any one of the preceding claims for use in evaluating a blood sample.

7. A nucleic acid encoding the anti-idiotypic antibody albumin fusion according to any one of the preceding claims.

8. A method of evaluating a blood sample obtained from a patient undergoing treatment for multiple myeloma or other gammopathy comprising

a) obtaining a blood sample from said patient,

b) incubating the blood sample with an anti-idiotypic antibody albumin fusion according to any

one of claims 1-7,

c) performing immunofixation electrophoresis (IFE), and

d) reporting the results of the IFE,

where the sample is evaluated for total M-protein levels, and

wherein the patient is undergoing treatment with the antibody

having a variable heavy domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSNTYYADSVKGRFTISRDN

SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAIWGQGTTLTVSS (SEQ ID NO: 7), and a variable light

chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGN

TATLTISGTQAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (SEQ ID NO: 8).

9. An anti-idiotypic antibody that is specific for an anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSNTYYADSVKGRFTISRDN

SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAIWGQGTTLTVSS (SEQ ID NO: 7), and a variable light

chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGN

TATLTISGTQAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (SEQ ID NO: 8).

10. A method of evaluating a blood sample obtained from a patient undergoing treatment for multiple myeloma or other gammopathy comprising

a) obtaining a blood sample from said patient,

b) incubating the blood sample with an anti-idiotypic antibody specific for the anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSNTYYADSVKGRFTISRDN

SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAIWGQGTTLTVSS (SEQ ID NO: 7), and a variable light

chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYVYVYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGNTATLTISGT

QAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (SEQ ID NO: 8),

c) performing immunofixation electrophoresis (IFE), and

d) reporting the results of the IFE,

wherein the patient is undergoing treatment with the anti-CD38 antibody having a variable heavy domain comprising the amino acid sequence

QVQLVESGGGLVQPGGSLRLSCAASGFTFSSYYMNWVRQAPGKGLEWVSGISGDPSTYYADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDLPLVYTGFAIWGQGTLVTVSS (SEQ ID NO: 7), and a variable light chain domain comprising the amino acid sequence

DIELTQPPSVSVAPGQTARISCSGDNLRHYYVYWYQQKPGQAPVLVIYGDSKRPSGIPERFSGSNSGNTATLTISGT QAEDEADYYCQTYTGASLVFGGGTKLTVLGQ (SEQ ID NO: 8),

where the sample is evaluated for total M-protein levels.

11. The antibody according to claim 9 or method according to claim 10, wherein said anti-idiotypic antibody comprises a variable heavy chain comprising

an HCDR1 of the amino acid sequence YSFSNYWIS (SEQ ID NO: 18),²⁶

an HCDR2 of the amino acid sequence WMGIIDPASSKTRYSPSFQG (SEQ ID NO: 19),

an HCDR3 of the amino acid sequence SRGAGMDY (SEQ ID NO: 20), and

a variable light chain comprising

an LCDR1 of the amino acid sequence TGSSSNIGAGYDVH (SEQ ID NO: 21),

an LCDR2 of the amino acid sequence LLIYADNNRPS (SEQ ID NO: 22),

an LCDR3 of the amino acid sequence GSYDESSNSM (SEQ ID NO: 23).