Claims

1. An isolated antibody, or an antigen binding fragment thereof, that binds to the antigenic loop region of HBsAg and neutralizes infection with hepatitis B virus and hepatitis delta virus, wherein the antibody or the antigen binding fragment comprises CDRH1, CDRH2, and CDRH3 amino acid sequences and CDRL1, CDRL2, and CDRL3 amino acid sequences (i) according to SEQ ID NOs: 34 – 38 and 40, respectively; or (ii) according to SEQ ID NOs: 34 – 37, 39 and 40, respectively; or (iii) according to SEQ ID NOs: 34 – 38 and 58, respectively; or (iv) according to SEQ ID NOs: 34 – 37, 39 and 58, respectively; or (v) according to SEQ ID NOs: 34, 66, 36 – 38, and 40, respectively; or (vi) according to SEQ ID NOs: 34, 66, 36 – 37, 39, and 40, respectively; or (vii) according to SEQ ID NOs: 34, 66, 36 – 38, and 58, respectively; or (viii) according to SEQ ID NOs: 34, 66, 36 – 37, 39, and 58, respectively.

2. The antibody according to claim 1, or an antigen binding fragment thereof, wherein the antibody or the antigen binding fragment comprises an Fc moiety, preferably the antibody, or the antigen binding fragment thereof, is of the IgG type, more preferably of the IgG1 type.

3. The antibody according to claim 1 or 2, or an antigen binding fragment thereof, wherein the antibody or the antigen binding fragment is a monoclonal antibody or monoclonal antigen binding fragment thereof and/or a human antibody or human antigen binding fragment thereof.

4. The antibody, or the antigen binding fragment thereof, according to any one of claims 1 - 3, **characterized in that** the antibody or the antigen binding fragment comprises (i) a heavy chain variable region (VH) amino acid sequence sharing at least 95% sequence identity with SEQ ID NO: 41 or 67; and (ii) a light chain variable region (VL) amino acid sequence sharing at least 95% sequence identity with SEQ ID NO: 42, 59 or 65.

5. The antibody, or the antigen binding fragment thereof, according to claim 4, **characterized in that** the antibody or the antigen binding fragment comprises a heavy chain variable region (VH) amino acid sequence according to SEQ ID NO: 41 or 67 and a light chain variable region (VL) amino acid sequence according to SEQ ID NO: 42, 59 or 65.

6. The antibody, or the antigen binding fragment thereof, according to any of the previous claims, **characterized in that** the antibody, or the antigen binding fragment thereof, is a purified antibody, a single chain antibody, Fab, Fab', F(ab')2, Fv or scFv.

7. The antibody, or the antigen binding fragment thereof, according to any one of the previous claims, for use as a medicament, preferably for use in the prophylaxis, treatment or attenuation of hepatitis B and/or hepatitis D.

8. A nucleic acid molecule comprising a polynucleotide encoding the antibody, or the antigen binding fragment thereof, according to any one of the previous claims.

9. The nucleic acid molecule according to claim 8, wherein the polynucleotide sequence comprises or consists of a nucleic acid sequence sharing at least 80%, preferably at least 85%, more preferably at least 90%, even more preferably at least 95% and particularly preferably at least 98% or 99% sequence identity with any of SEQ ID NOs: 43 - 51, 60 - 64 and 68 - 78.

10. A vector comprising the nucleic acid molecule according to claim 8 or 9.

11. A cell expressing the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6; or comprising the vector according to claim 10.

12. A pharmaceutical composition comprising the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10 and/or the cell according to claim 11, and, optionally, a pharmaceutically acceptable excipient, diluent or carrier.

13. The antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12 for use in (i) prophylaxis, treatment or attenuation of hepatitis B and/or hepatitis D; or in (ii) *in vitro* diagnosis of hepatitis B and/or hepatitis D.

14. The antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition for use according to claim 13 in treatment or attenuation of chronic hepatitis B.

15. The antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition for use according to claim 13 in prevention of hepatitis B (re-)infection after liver transplantation in particular for hepatitis B induced liver failure.

16. The antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition for use according to claim 13 in prevention of hepatitis B in non-immunized subjects or in the newborn.

17. The antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition for use according to claim 13 in prophylaxis of hepatitis B in non-immunized subjects or in haemodialysed patients.

18. The antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition for use according to claim 13 or 14, wherein the antibody, or the antigen binding fragment thereof, the nucleic acid, the vector, the cell or the pharmaceutical composition is administered in combination with a polymerase inhibitor, an interferon and/or a checkpoint inhibitor, preferably with a polymerase inhibitor, such as lamivudine.

19. A combination of

(i) the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12; and

(i) a polymerase inhibitor, an interferon and/or a checkpoint inhibitor;

preferably for use in prophylaxis, treatment or attenuation of hepatitis B and/or hepatitis D, in particular for use in treatment or attenuation of chronic hepatitis B and/or chronic hepatitis D.

20. A kit comprising

(i) the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12; and

(ii) a polymerase inhibitor, an interferon and/or a checkpoint inhibitor.

21. Use of the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12 for monitoring the quality of anti-hepatitis-B or anti-hepatitis-D vaccines by checking *in vitro* that the antigen of said vaccine contains the specific epitope in the correct conformation.

22. Use of the antibody, or the antigen binding fragment thereof, according to any of claims 1 to 6, the nucleic acid according to claims 8 - 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12 in determining whether an isolated blood sample is infected with hepatitis B virus and/or hepatitis delta virus.

23. Use of the antibody, or the antigen binding fragment thereof, according to any of claims 1 to 6, the nucleic acid according to claims 8 – 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12 in the *in vitro* diagnosis of hepatitis B and/or hepatitis D.

24. Use of a combination of

(i) the antibody, or the antigen binding fragment thereof, according to any one of claims 1 to 6, the nucleic acid according to claim 8 or 9, the vector according to claim 10, the cell according to claim 11 or the pharmaceutical composition according to claim 12; and

(ii) a polymerase inhibitor, an interferon and/or a checkpoint inhibitor;

in the manufacture of a medicament, preferably for the prophylaxis, treatment or attenuation of hepatitis B and/or hepatitis D, in particular the treatment or attenuation of chronic hepatitis B and/or chronic hepatitis D.