

What is claimed:

1. A lateral flow device comprising: a plurality of lateral flow regions arranged in the order:
 - a) a sample application zone (**110**) for dispensing a liquid sample thereupon wherein the sample application zone (**110**) comprises an absorbent material;
 - b) a conjugate pad (**140**) comprising an absorbent material and a plurality of pre-set gold-conjugates which include (i) a plurality of coronavirus S1 spike polypeptide-gold conjugates and (ii) a plurality of biotin-gold conjugates;
 - c) a detection zone (**150**) comprising a lateral flow membrane (**160**) comprising an absorbent material which includes a plurality of test lines and a control line, wherein the plurality of test lines includes (i) a test line (**170a**) comprising a plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents, (ii) a test line (**170b**) comprising a plurality of pre-set immobilized anti-human IgM capture antibodies, (iii) a test line (**170c**) comprising a plurality of pre-set immobilized anti-human IgG capture antibodies, and the control line (**180**) comprises a plurality of pre-set immobilized capture reagents that bind biotin; and
 - d) an absorbent pad (**190**) comprising a second absorbent material, wherein the lateral flow membrane (**160**) is in fluid communication with the absorbent pad (**190**) and wherein (i) the sample application zone (**110**) is in fluid communication with the conjugate pad (**140**) and the conjugate pad (**140**) is in fluid communication with the lateral flow membrane (**160**); or (ii) the sample pad (**130**) is in fluid communication with the lateral flow membrane (**160**).
2. A kit comprising a detectably labeled S1 spike conjugate, a detectably labeled biotin conjugate, and a lateral flow device, wherein the lateral flow device comprises a plurality of lateral flow regions arranged in the order:
 - a) a sample application zone (**110**) for dispensing a liquid sample thereupon wherein the sample application zone (**110**) comprises an absorbent material;
 - b) at least one of (i) a conjugate pad (**140**) comprising an absorbent material and a plurality of pre-set detectably labeled conjugates which include (i) a plurality of

- detectably labeled coronavirus S1 spike polypeptide conjugates and (ii) a plurality of detectably labeled biotin conjugates or (ii) a sample pad (130);
- c) a detection zone (150) comprising a lateral flow membrane (160) comprising an absorbent material which includes a plurality of test lines and a control line, wherein the plurality of test lines includes (i) a test line (170a) comprising a plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents, (ii) a test line (170b) comprising a plurality of pre-set immobilized anti-human IgM capture antibodies, (iii) a test line (170c) comprising a plurality of pre-set immobilized anti-human IgG capture antibodies, and the control line (180) comprises a plurality of pre-set immobilized capture reagents that bind biotin; and
- d) an absorbent pad (190) comprising a second absorbent material, wherein the lateral flow membrane (160) is in fluid communication with the absorbent pad (190) and wherein (i) the sample application zone (110) is in fluid communication with the conjugate pad (140) and the conjugate pad (140) is in fluid communication with the lateral flow membrane (160); or (ii) the sample pad (130) is in fluid communication with the lateral flow membrane (160).
3. The lateral flow device of claim 1 or the kit of claim 2, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates comprise coronavirus S1 spike polypeptide gold-conjugates.
4. The lateral flow device or kit of any one of the preceding claims, wherein the detectably labeled biotin conjugates comprise biotin gold-conjugates.
5. The lateral flow device or kit of any one of the preceding claims, wherein the test line (170a) comprising the plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents is the first test line, the test line (170b) comprising the plurality of pre-set immobilized anti-human IgM capture antibodies is the second test line, and the test line (170c) comprising the plurality of pre-set immobilized anti-human IgG capture antibodies is the third test line, in order of increasing distance from the sample application zone.

6. The lateral flow device or kit of any one of the preceding claims, wherein the sample application zone (110) comprises a sample pad (130) and an optional sample port (120), wherein the sample port (120) if present is in fluid communication with the sample pad (130).
7. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises S1 spike polypeptide from SARS-CoV-2 and having the amino acid sequence of SEQ ID NO:2.
8. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises a receptor binding domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line (170a).
9. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises a receptor binding domain (RBD) that binds a human anti-S1 neutralizing IgM antibody, or the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgG antibody.
10. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises a receptor binding domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents, and the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgM antibody.
11. The lateral flow device or kit of claim 10, wherein binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the human anti-S1 neutralizing IgM antibody blocks binding between the receptor binding domain (RBD) of the

coronavirus S1 spike polypeptide and the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line **(170a)**.

12. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises a receptor binding domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents, and the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgG antibody.
13. The lateral flow device or kit of claim 12, wherein binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the human anti-S1 neutralizing IgG antibody blocks binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line **(170a)**.
14. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises non-receptor binding domains that bind a human anti-S1 non-neutralizing IgM antibody.
15. The lateral flow device or kit of claim 14, wherein binding between the non-receptor binding domain of the coronavirus S1 spike polypeptide and the human anti-S1 non-neutralizing IgM antibody does not block binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line **(170a)**.
16. The lateral flow device or kit of any one of the preceding claims, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprises non-receptor binding domains that bind a human anti-S1 non-neutralizing IgG antibody.

17. The lateral flow device or kit of claim 16, wherein binding between the non-receptor binding domain of the coronavirus S1 spike polypeptide and the human anti-S1 non-neutralizing IgG antibody does not block binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line **(170a)**.
18. The lateral flow device or kit of any one of the preceding claims, wherein the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates comprise gold nanoparticles conjugated to coronavirus S1 spike polypeptides, and wherein the gold nanoparticles have a detectable color.
19. The lateral flow device or kit of any one of the preceding claims, wherein the plurality of detectably labeled biotin conjugates comprise gold nanoparticles conjugated to biotin, and wherein the gold nanoparticles have a detectable color.
20. The lateral flow device or kit of any one of the preceding claims, wherein the pre-set immobilized human ACE2 receptor polypeptide capture reagents in the test line **(170a)** comprise an epitope that binds a receptor binding domain (RBD) of an S1 spike polypeptide from SARS-CoV-2, wherein the pre-set immobilized human ACE2 receptor polypeptide comprises the amino acid sequence of SEQ ID NO:3, or a portion thereof.
21. The lateral flow device or kit of any one of the preceding claims, wherein the pre-set immobilized anti-human IgM capture antibodies in the test line (170b) bind a human anti-S1 IgM antibody (e.g., neutralizing and non-neutralizing antibodies).
22. The lateral flow device or kit of claim 21, wherein the pre-set immobilized anti-human IgM capture antibodies in the test line **(170b)** bind a plurality of a complex comprising the human anti-S1 IgM antibody bound to the detectably labeled coronavirus S1 spike polypeptide conjugate.

23. The lateral flow device or kit of any one of the preceding claims, wherein the pre-set immobilized anti-human IgG capture antibodies in the third test line (**170b**) bind a human anti-S1 IgG antibody (e.g., neutralizing and non-neutralizing antibodies).
24. The lateral flow device or kit of claim 23, wherein the pre-set immobilized anti-human IgG capture antibodies in the third test line (**170c**) bind a plurality of a complex comprising the human anti-S1 IgG antibody bound to the detectably labeled coronavirus S1 spike polypeptide conjugate.
25. The lateral flow device or kit of any one of the preceding claims, wherein the pre-set immobilized capture reagents that bind biotin at the control line (**180**) bind a plurality of detectably labeled biotin conjugates.
26. The lateral flow device or kit of any one of the preceding claims, which is disposed in a housing which includes a base, a lid, two end walls and two side walls.
27. The lateral flow device or kit of claim 26, wherein the lid of the housing includes a first cut-out region at the position of the sample port (**120**) or the sample pad (**130**) for liquid sample dispensing, and the lid includes a second cut-out region at the detection zone (**150**) for use as an observation window.
28. The lateral flow device or kit of any one of the preceding claims, wherein the capture reagents that bind biotin comprise avidin, streptavidin, NEUTRAVIDIN, EXTRAVIDIN, CAPTAVIDIN, or NEUTRALITE AVIDIN, or a truncated form thereof that retains biotin-binding activity, optionally wherein the avidin, streptavidin, NEUTRAVIDIN, EXTRAVIDIN, CAPTAVIDIN, or NEUTRALITE AVIDIN is glycosylated.
29. The lateral flow device or kit of any one of the preceding claims, wherein the lateral flow device further comprises a second plurality of lateral flow regions arranged in the order:
 - 2a) a second sample application zone for dispensing a liquid sample thereupon wherein the sample application zone comprises an absorbent material;
 - 2b) at least one of (i) a second conjugate pad comprising an absorbent material and a

plurality of pre-set detectably labeled conjugates which include (1) a plurality of detectably labeled coronavirus S1 spike polypeptide conjugates and (2) a plurality of detectably labeled biotin conjugates, or (ii) a second sample pad;

2c) a second detection zone comprising a lateral flow membrane comprising an absorbent material which includes a test line comprising a plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents and a control line comprising a plurality of pre-set immobilized capture reagents that bind biotin; and

2d) a second absorbent pad comprising an absorbent material,

wherein the lateral flow membrane is in fluid communication with the absorbent pad, and wherein (i) the sample application zone is in fluid communication with the second conjugate pad and the second conjugate pad is in fluid communication with the lateral flow membrane of the second detection zone, or (ii) the second sample pad (130) is in fluid communication with the lateral flow membrane of the second detection zone.

30. The kit of any one of claims 2-29, wherein the lateral flow device further comprises a second plurality of lateral flow regions arranged in the order:
- 2a) a second sample application zone for dispensing a liquid sample thereupon wherein the sample application zone comprises an absorbent material;
- 2b) at least one of (i) a second conjugate pad comprising an absorbent material and a plurality of pre-set detectably labeled conjugates which include (1) a plurality of detectably labeled coronavirus S1 spike polypeptide conjugates and (2) a plurality of detectably labeled biotin conjugates, or (ii) a second sample pad;
- 2c) a second detection zone comprising a lateral flow membrane comprising an absorbent material which includes a test line comprising a plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents and a control line comprising a plurality of pre-set immobilized capture reagents that bind biotin; and
- 2d) a second absorbent pad comprising an absorbent material,
- wherein the lateral flow membrane is in fluid communication with the absorbent pad, and wherein (i) the sample application zone is in fluid communication with the second conjugate pad and the second conjugate pad is in fluid communication with the lateral flow

membrane of the second detection zone, or (ii) the second sample pad (130) is in fluid communication with the lateral flow membrane of the second detection zone.

31. The lateral flow device or kit of claim 29 or the kit of claim 30, wherein the second sample application zone comprises the second sample pad and an optional sample port, wherein the optional sample port if present is in fluid communication with the second sample pad.
32. The lateral flow device or kit of any one of claims 29-31, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise S1 spike polypeptide from SARS-CoV-2 and having the amino acid sequence of SEQ ID NO:2.
33. The lateral flow device or kit of any one of claims 29-32, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise a receptor binding domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line (170d).
34. The lateral flow device or kit of any one of claims 29-33, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise a receptor binding domain (RBD) that binds a human anti-S1 neutralizing IgM antibody, or the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgG antibody.
35. The lateral flow device or kit of any one of claims 29-34, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise a receptor binding domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line (170d), and the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgM antibody.
36. The lateral flow device or kit of any one of claims 29-35, wherein the coronavirus S1 spike polypeptide in the plurality of detectably labeled coronavirus S1 spike polypeptide conjugates of the second plurality of lateral flow regions comprises a receptor binding

domain (RBD) that binds an epitope on the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line (**170d**), and the receptor binding domain (RBD) binds a human anti-S1 neutralizing IgG antibody.

37. The lateral flow device or kit of any one of claims 29-36, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise non-receptor binding domains that bind a human anti-S1 non-neutralizing IgM antibody.
38. The lateral flow device or kit of claim 37, wherein binding between the non-receptor binding domain of the coronavirus S1 spike polypeptide and the human anti-S1 non-neutralizing IgM antibody does not block binding between the receptor binding domain (RBD) of the coronavirus S1 spike polypeptide and the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line.
39. The lateral flow device or kit of any one of claims 29-38, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates in the second conjugate pad comprise non-receptor binding domains that bind a human anti-S1 non-neutralizing IgG antibody.
40. The lateral flow device or kit of any one of claims 29-39, wherein the detectably labeled coronavirus S1 spike polypeptide conjugates comprise coronavirus S1 spike polypeptide gold-conjugates.
41. The lateral flow device or kit of any one of claims 29-40, wherein the detectably labeled biotin conjugates in the second conjugate pad comprise biotin-gold conjugates.
42. The lateral flow device or kit of the immediately preceding claim, wherein the biotin-gold conjugates comprise gold nanoparticles conjugated to biotin, and wherein the gold nanoparticles have a detectable color.
43. The lateral flow device or kit of any one of claims 29-42, wherein the pre-set immobilized human ACE2 receptor polypeptide capture reagents in the test line of the second detection zone comprise an epitope that binds a receptor binding domain (RBD) of an S1 spike

polypeptide from SARS-CoV-2, wherein the pre-set immobilized human ACE2 receptor polypeptide comprises the amino acid sequence of SEQ ID NO:3, or a portion thereof.

44. The lateral flow device or kit of any one of claims 29-43, which is disposed in a housing which includes a base, a lid, two end walls and two side walls, wherein the lid of the housing includes a third cut-out region at the position of the sample port or the sample pad for liquid sample dispensing, and the lid includes a fourth cut-out region at the detection zone for use as an observation window, wherein the third and fourth cut-out regions are positioned over the second plurality of lateral flow regions.
45. A method for detecting in a liquid sample from a subject the presence or absence of anti-S1 antibody analytes of IgM and/or IgG type, the method comprising the steps of:
 - a) providing a liquid sample from the subject, wherein the liquid sample is suspected of containing human anti-S1 non-neutralizing antibody analytes of IgM and/or IgG type, and wherein the liquid sample is suspected of containing human anti-S1 neutralizing antibody analytes of IgM and/or IgG type;
 - b) dispensing the liquid sample onto the sample application zone (110) of a lateral flow device of any one of claims 1-44 (i) under a condition that is suitable for lateral flow of the liquid sample and the human anti-S1 non-neutralizing and neutralizing antibody analytes that may be contained therein, wherein the lateral flow moves the liquid sample or aliquot and the human anti-S1 non-neutralizing and neutralizing antibody analytes, if present, from the sample application zone (110) through the conjugate pad (140) through the detection zone (150) and through the absorbent pad (190), and (ii) under a condition that is suitable for lateral flow of the pre-set detectably labeled coronavirus S1 spike polypeptide conjugates and the pre-set detectably labeled biotin conjugates from the conjugate pad (140) through the detection zone (150) and through the absorbent pad (190), and (iii) under a condition that is suitable for binding of flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 non-neutralizing antibody

analytes (if present) to form at least one S1 polypeptide-non-neutralizing antibody complex, and suitable for binding of flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 neutralizing antibody analytes (if present) wherein the RBD of the S1 polypeptide binds to the neutralizing antibody to form at least one S1 polypeptide-neutralizing antibody complex, and **(iv)** under a condition that is suitable for binding flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the pre-set immobilized human ACE2 receptor polypeptide capture reagents, and is suitable for binding the detectably labeled S1 polypeptide-non-neutralizing antibody complex to the pre-set immobilized anti-human IgM and IgG capture antibodies, and is suitable for binding the S1 polypeptide-neutralizing antibody complex to the pre-set immobilized anti-human IgM and IgG capture antibodies, and is suitable for binding flowing detectably labeled biotin conjugates to the pre-set immobilized capture reagents that bind biotin;

- c) waiting a sufficient time for a color change to develop at the test line **(170a)**, the test line **(170b)**, the test line **(170c)** and the control line **(180)**, or permitting a color change to develop at one or more test and/or control lines; and
- d) detecting the color change at the test line **(170a)**, the test line **(170b)**, the test line **(170c)** and/or the control line **(180)**.

46. A method for detecting in a liquid sample from a subject the presence or absence of anti-S1 antibody analytes of IgM and/or IgG type, the method comprising the steps of:

- a) providing a liquid sample from the subject, wherein the liquid sample is suspected of containing human anti-S1 non-neutralizing antibody analytes of IgM and/or IgG type, and wherein the liquid sample is suspected of containing human anti-S1 neutralizing antibody analytes of IgM and/or IgG type, and mixing the liquid sample with a detectably labeled S1 spike conjugate and a detectably labeled biotin conjugate;
- b) dispensing the liquid sample onto the sample application pad **(130)** or the sample port **(120)** of a lateral flow device of the kit of any one of claims 2-44 **(i)** under a

- condition that is suitable for lateral flow of the liquid sample and the human anti-S1 non-neutralizing and neutralizing antibody analytes that may be contained therein, wherein the lateral flow moves the liquid sample or aliquot and the human anti-S1 non-neutralizing and neutralizing antibody analytes, if present, from the sample application pad (130) or the sample port (120) through the detection zone (150) and through the absorbent pad (190), and (ii) under a condition that is suitable for lateral flow of the detectably labeled coronavirus S1 spike polypeptide conjugates and the detectably labeled biotin conjugates from the conjugate pad (140) through the detection zone (150) and through the absorbent pad (190), and (iii) under a condition that is suitable for binding of the detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 non-neutralizing antibody analytes (if present) to form at least one S1 polypeptide-non-neutralizing antibody complex, and suitable for binding of the detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 neutralizing antibody analytes (if present) wherein the RBD of the S1 polypeptide binds to the neutralizing antibody to form at least one S1 polypeptide-neutralizing antibody complex, and (iv) under a condition that is suitable for binding flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the pre-set immobilized human ACE2 receptor polypeptide capture reagents, and is suitable for binding the detectably labeled S1 polypeptide-non-neutralizing antibody complex to the pre-set immobilized anti-human IgM and IgG capture antibodies, and is suitable for binding the S1 polypeptide-neutralizing antibody complex to the pre-set immobilized anti-human IgM and IgG capture antibodies, and is suitable for binding flowing detectably labeled biotin conjugates to the pre-set immobilized capture reagents that bind biotin;
- c) waiting a sufficient time for a color change to develop at the test line (170a), the test line (170b), the test line (170c) and the control line (180), or permitting a color change to develop at one or more test and/or control lines; and
 - d) detecting the color change at the test line (170a), the test line (170b), the test line (170c) and/or the control line (180).

47. A method for detecting in a liquid sample from a subject the presence or absence of anti-S1 antibody analytes of IgM and/or IgG type, the method comprising the steps of:
- a) providing a first liquid sample from the subject and a second liquid sample of known composition, wherein the first liquid sample is suspected of containing human anti-S1 non-neutralizing antibody analytes of IgM and/or IgG type, and wherein the first liquid sample is suspected of containing human anti-S1 neutralizing antibody analytes of IgM and/or IgG type;
 - b) dispensing the first liquid sample onto the sample application zone and dispensing the second liquid sample onto the second sample application zone of the lateral flow device of any one of claims 29-44 **(i)** under a condition that is suitable for lateral flow of the liquid samples, wherein the lateral flow moves the first liquid sample from the sample application zone through the conjugate pad, through the detection zone, and through the absorbent pad, and moves the second liquid sample from the second sample application zone through the second conjugate pad, through the second detection zone, and through the second absorbent pad, and **(ii)** under a condition that is suitable for lateral flow of the pre-set detectably labeled coronavirus S1 spike polypeptide conjugates and the pre-set detectably labeled biotin conjugates from the conjugate pad and second conjugate pad through the detection zone and second detection zone and through the absorbent pad and second absorbent pad, and **(iii)** under a condition that is suitable for binding of flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 non-neutralizing antibody analytes (if present) to form at least one S1 polypeptide-non-neutralizing antibody complex, and suitable for binding of flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 neutralizing antibody analytes (if present) wherein the RBD of the S1 polypeptide binds to the neutralizing antibody to form at least one S1 polypeptide-neutralizing antibody complex and that is suitable for binding flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line of the second detection zone, and is suitable for binding flowing detectably labeled biotin

- conjugates to the pre-set immobilized capture reagents that bind biotin at the control line of the second detection zone;
- c) waiting a sufficient time for a color change to develop at the test lines and the control lines, or permitting a color change to develop at one or more test and/or control lines; and
 - d) detecting the color change at one or more of the test lines and/or the control lines.
48. A method for detecting in a liquid sample from a subject the presence or absence of anti-S1 antibody analytes of IgM and/or IgG type, the method comprising the steps of:
- a) providing a first liquid sample from the subject and a second liquid sample of known composition, wherein the first liquid sample is suspected of containing human anti-S1 non-neutralizing antibody analytes of IgM and/or IgG type, and wherein the first liquid sample is suspected of containing human anti-S1 neutralizing antibody analytes of IgM and/or IgG type;
 - b) mixing the first liquid sample with a detectably labeled S1 spike conjugate and a detectably labeled biotin conjugate, and mixing the second liquid sample with a detectably labeled S1 spike conjugate and a detectably labeled biotin conjugate;
 - c) dispensing the first liquid sample onto the sample pad or sample port and dispensing the second liquid sample onto the second sample pad or second sample port of the lateral flow device of the kit of any one of claims 30-44 **(i)** under a condition that is suitable for lateral flow of the liquid samples, wherein the lateral flow moves the first liquid sample from the sample application zone through the detection zone, and through the absorbent pad, and moves the second liquid sample from the second sample application zone through the second detection zone, and through the second absorbent pad, and **(ii)** under a condition that is suitable for lateral flow of the detectably labeled coronavirus S1 spike polypeptide conjugates and the detectably labeled biotin conjugates through the detection zone and second detection zone and through the absorbent pad and second absorbent pad, and **(iii)** under a condition that is suitable for binding of the detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 non-neutralizing antibody

analytes (if present) to form at least one S1 polypeptide-non-neutralizing antibody complex, and suitable for binding of the detectably labeled coronavirus S1 spike polypeptide conjugates to the human anti-S1 neutralizing antibody analytes (if present) wherein the RBD of the S1 polypeptide binds to the neutralizing antibody to form at least one S1 polypeptide-neutralizing antibody complex and that is suitable for binding flowing detectably labeled coronavirus S1 spike polypeptide conjugates to the pre-set immobilized human ACE2 receptor polypeptide capture reagents at the test line of the second detection zone, and is suitable for binding flowing detectably labeled biotin conjugates to the pre-set immobilized capture reagents that bind biotin at the control line of the second detection zone;

- d) waiting a sufficient time for a color change to develop at the test lines and the control lines, or permitting a color change to develop at one or more test and/or control lines; and
 - e) detecting the color change at one or more of the test lines and/or the control lines.
49. The method of claim 47 or 48, wherein the detecting the color change at the test line (**170b**) comprising the plurality of pre-set immobilized anti-human IgM capture antibodies indicates the liquid sample contains human anti-S1 spike IgM antibodies and the subject has an active SARS-Cov-2 infection and is likely to be contagious.
50. The method of any one of claims 47-49, wherein the detecting the color change at the test line (**170c**) comprising the plurality of pre-set immobilized anti-human IgG capture antibodies indicates the liquid sample contains human anti-S1 spike IgG antibodies and the subject has been infected with SARS-CoV-2 in the past but may not currently be contagious.
51. The method of any one of the claims 47-50, wherein the detecting the color change at the test line (**170a**) comprising the plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents indicates the liquid sample does not contain detectable human anti-S1 spike IgM neutralizing antibodies and does not contain detectable human anti-S1 spike IgG neutralizing antibodies.

52. The method of any one of claims 47-51, wherein a lack of a color change at the test line (170a) comprising the plurality of pre-set immobilized human ACE2 receptor polypeptide capture reagents indicates the liquid sample contains detectable human anti-S1 spike IgM neutralizing antibodies and/or the liquid sample contains detectable human anti-S1 spike IgG neutralizing antibodies.