

CLAIMS

1. A method of assaying a Clostridium botulinum neurotoxin (BoNT) for activity, comprising the steps of:

- 5 a) contacting a human induced pluripotent stem (hiPS) derived neuronal cell with a composition comprising a BoNT; and
b) assaying the BoNT for biological activity.

2. The method of claim 1, wherein the BoNT is selected from the group consisting of
10 BoNT serotype A, BoNT serotype B, BoNT serotype C, BoNT serotype E and modified variants thereof.

3. The method of claim 1, wherein the biological activity is selected from the group consisting of cleavage of SNAP-25, cleavage of VAMP2 and neurotransmitter release.

15 4. The method of claim 1, wherein the assay is qualitative.

5. The method of claim 1, wherein the assay is quantitative.

20 6. The method of claim 1, wherein the BoNT is purified.

7. The method of claim 1, wherein the BoNT is not in a complex.

8. The method of claim 1, wherein the BoNT is in a complex.

25 9. The method of claim 1, further comprising the step of contacting the BoNT with a test compound prior to contacting the hiPS derived neuronal cells.

10. The method of claim 9, wherein the test compound is an antibody.

30 11. The method of claim 10, wherein the antibody is a neutralizing antibody.

12. The method of claim 11, wherein the neutralizing antibody is in a sample selected from the group consisting of purified antibodies, serum and antitoxins.

13. A method of assaying a Clostridium botulinum neurotoxin (BoNT) for activity, comprising the steps of:

- (a) contacting a human induced pluripotent stem (hiPS) derived neuronal cell with a composition comprising i) a BoNT and ii) a neutralizing antibody; and
- (b) assaying the BoNT for biological activity.

14. The method of claim 13, wherein the BoNT is selected from the group consisting of BoNT serotype A, BoNT serotype B, BoNT serotype C, BoNT serotype E and modified variants thereof.

15. The method of claim 13, wherein the biological activity is selected from the group consisting of cleavage of SNAP-25, cleavage of VAMP2 and neurotransmitter release.

16. The method of claim 13, wherein the assay is qualitative.

17. The method of claim 13, wherein the assays is quantitative.

18. The method of claim 13, wherein the BoNT is purified.

19. The method of claim 13, wherein the BoNT is not in a complex.

20. The method of claim 13, wherein the BoNT is in a complex.

21. The method of claim 13, wherein the neutralizing antibody is in a sample selected from the group consisting of purified antibodies, serum and antitoxins.

22. A method for determining an amount of biologically active Clostridium botulinum neurotoxin (BoNT) in a preparation, comprising the steps of:

- (a) contacting a human induced pluripotent stem (hiPS) derived neuronal cell with a sample of a preparation comprising biologically active BoNT; and
- (b) determining the amount of biologically active BoNT present in the preparation by assaying the sample for the biological activity of BoNT.

CLAIMS

We claim:

- 5 1. A method of assaying a *Clostridium botulinum* neurotoxin (BoNT) for activity, comprising:
 - a) contacting a human induced pluripotent stem cell (hiPS) derived neuronal cell with a composition comprising a BoNT; and
 - b) assaying said BoNT for biological activity.
- 10 2. The method of claim 1, wherein said BoNT has a serotype selected from the group consisting of A, B, C, E and modified variants of said BoNTs.
3. The method of claim 1, wherein said biological activity is selected from the group
- 15 consisting of cleavage of SNAP-25, cleavage of VAMP2 and neurotransmitter release.
4. The method of claim 1, wherein said assay is qualitative.
5. The method of claim 1, wherein said assay is quantitative.
- 20 6. The method of claim 1, wherein said BoNT is purified.
7. The method of claim 1, wherein said BoNT is not in a complex.
- 25 8. The method of claim 1, wherein said BoNT is in a complex.
9. The method of claim 1, further comprising the step of contacting said BoNT with a test compound prior to contacting said hiPS derived neuronal cells.
- 30 10. The method of claim 9, wherein said test compound is an antibody.
11. The method of claim 10, wherein said antibody is a neutralizing antibody.
12. The method of claim 11, wherein said neutralizing antibody is in a sample selected
- 35 from the group consisting of purified antibodies, serum and antitoxins.

13. A method of assaying a *Clostridium botulinum* neurotoxin (BoNT) for activity, comprising:

a) contacting a human induced pluripotent stem (hiPS) cell derived neuronal cell with a composition comprising i) a BoNT; and ii) a neutralizing antibody; and

b) assaying said BoNT for biological activity.

14. The method of claim 13, wherein said BoNT has a serotype selected from the group consisting of A, B, C, E and modified variants of said BoNTs.

15. The method of claim 13, wherein said biological activity is selected from the group consisting of cleavage of SNAP-25, cleavage of VAMP2 and neurotransmitter release.

16. The method of claim 13, wherein said assay is qualitative.

17. The method of claim 13, wherein said assay is quantitative.

18. The method of claim 13, wherein said BoNT is purified.

19. The method of claim 1, wherein said BoNT is not in a complex.

20. The method of claim 13, wherein said BoNT is in a complex.

21. The method of claim 13, wherein said neutralizing antibody is in a sample selected from the group consisting of purified antibodies, serum and antitoxins.

22. A method for determining the amount of biologically active BoNT in a preparation comprising biologically active BoNT, said method comprising the steps of:

(a) contacting a hiPS cell derived neuronal cell with a sample of a preparation comprising biologically active BoNT; and

(b) determining the amount of biologically active BoNT present in the preparation by assaying said sample for the biological activity of BoNT.

23. The use of a human induced pluripotent stem (hiPS) cell derived neuronal cell for assaying a BoNT for activity.