

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 87. The method of claim 1, wherein said BoNT is in a complex.
98. The method of claim 1, further comprising the step of contacting said BoNT with a test compound prior to contacting said hPS derived neuronal cells.
- 30 109. The method of claim 98, wherein said test compound is an antibody.
1140. The method of claim 109, wherein said antibody is a neutralizing antibody.
1244. The method of claim 1140, wherein said neutralizing antibody is in a sample selected
35 from the group consisting of purified antibodies, serum and antitoxins.

1312. 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

5 b) assaying said BoNT for biological activity.

1413. The method of claim 1312, wherein said BoNT has a serotype selected from the group consisting of A, B, C, E and modified variants of said BoNTs.

10 1514. The method of claim 1312, wherein said biological activity is selected from the group consisting of cleavage of SNAP-25, cleavage of VAMP2 and neurotransmitter release.

1615. The method of claim 1312, wherein said assay is qualitative.

15 1716. The method of claim 1312, wherein said assay is quantitative.

1817. The method of claim 1312, wherein said BoNT is purified.

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

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2018. The method of claim 131, wherein said BoNT is in a complex.

2149. The method of claim 1312, wherein said neutralizing antibody is in a sample selected from the group consisting of purified antibodies, serum and antitoxins.

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2220. 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

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

2321. The use of a human induced pluripotent stem (hiPS) cell derived neuronal cell for assaying a BoNT for activity.