CLAIMS

What is claimed is:

1. A method to determine the serotype of an adeno-associated virus (AAV) particle comprising

a) denaturing the AAV particle,

b) directly subjecting the denatured AAV particle to liquid chromatography/mass spectrometry (LC/MS) intact protein analysis, and

c) determining the masses of VP1, VP2 and VP3 of the AAV particle;

wherein the specific combination of masses of VP1, VP2 and VP3 are indicative of the AAV serotype,

and wherein the method is performed in the absence of a gel separation step.

2. A method to determine the serotype of a viral particle comprising

a) denaturing the viral particle,

b) directly subjecting the denatured viral particle to liquid chromatography/mass spectrometry (LC/MS) intact protein analysis, and

c) determining the masses of one or more capsid proteins of the viral particle;

wherein the specific combination of masses of the one or more capsid proteins are indicative of the virus serotype,

and wherein the method is performed in the absence of a gel separation step.

3. The method of claim 1, wherein the calculated masses of VP1, VP2 and VP3 are compared to the theoretical masses of VP1, VP2 and VP3 of one or more AAV serotypes.

4. The method of claim 1, wherein the AAV particle is denatured with acetic acid, guanidine hydrochloride, and/or an organic solvent.

5. The method of claim 1, wherein the liquid chromatography is reverse phase liquid chromatography, size exclusion chromatography, hydrophilic interaction liquid chromatography, or cation exchange chromatography.

6. The method of claim 1, wherein the liquid chromatography is reverse phase chromatography.

7. The method of claim 6, wherein the reverse phase chromatography is a C4 or C8 reverse chromatography.

8. The method of claim 1, wherein the liquid chromatography is ultra-performance liquid chromatography (UPLC).

9. The method of claim 1, wherein the mass spectrometry comprises assisted calibration.

10. The method of claim 9, wherein sodium iodide is used as a calibrant.

11. The method of claim 1, wherein the AAV particle is a recombinant AAV (rAAV) particle.

12. The method of claim 1, wherein the AAV particle comprises an AAV1 capsid, an AAV2 capsid, an AAV3 capsid, an AAV4 capsid, an AAV5 capsid, an AAV6 capsid, an AAV7 capsid, an AAV8 capsid, an AAVrh8 capsid, an AAV9 capsid, an AAV10 capsid, an AAVrh10 capsid, an AAV11 capsid, an AAV12 capsid, an AAV LK03 capsid, an AAV2R471A capsid, an AAV2/2-7m8 capsid, an AAV DJ capsid, an AAV DJ8 capsid, an AAV2 N587A capsid, an AAV2 E548A capsid, an AAV2 N708A capsid, an AAV V708K capsid, a goat AAV capsid, an AAV1/AAV2 chimeric capsid, a bovine AAV capsid, a mouse AAV capsid rAAV2/HBoV1 (chimeric AAV / human bocavirus virus 1), an AAV2HBKO capsid, an AAVPHP.B capsid or an AAVPHP.eB capsid.

13. The method of claim 2, wherein the calculated masses of the one or more capsid proteins are compared to the theoretical masses of the one or more capsid proteins of one or more virus serotypes.

14. The method of claim 2, wherein the liquid chromatography is reverse phase liquid chromatography, size exclusion chromatography, hydrophilic interaction liquid chromatography, or cation exchange chromatography.

15. The method of claim 2, wherein the liquid chromatography is reverse phase chromatography.

16. The method of claim 15, wherein the reverse phase chromatography is a C4 or C8 reverse chromatography.

17. The method of claim 2, wherein the liquid chromatography is ultra-performance liquid chromatography (UPLC).

18. The method of claim 2, wherein the mass spectrometry comprises assisted calibration.

19. The method of claim 18, wherein sodium iodide is used as a calibrant.

20. The method of claim 2, wherein the viral particle comprises a viral vector encoding a heterologous transgene.