What is claimed is:

1. A method for characterization of a protein in at least one visible or sub-visible particle in a sample, comprising:

isolating and capturing the at least one visible or sub-visible particle;

analyzing the at least one visible or sub-visible particle to identify a presence of a protein using Raman spectroscopy;

subjecting the at least one visible or sub-visible particle to a separation step to produce a separated protein; and

subjecting the separated protein to mass spectrometry analysis to characterize the protein.

2. The method of claim 1, wherein the at least one visible or sub-visible particle has a size of at least about 100 μm.

3. The method of claim 1, wherein the at least one visible or sub-visible particle is an inherent impurity.

4. The method of claim 1, further comprising capturing the at least one visible or sub-visible particle on a gold-coated polycarbonate membrane.

5. The method of claim 4, wherein a pore size of the gold-coated polycarbonate membrane is about 5 μm.

6. The method of claim 1, further comprising dissolving the sample in urea after analyzing the at least one visible or sub-visible particle.

7. The method of claim 6, wherein the concentration of urea is about 8 M.

8. The method of claim 1, further comprising digesting the sample under denaturing conditions after analyzing the at least one visible or sub-visible particle.

9. The method of claim 1, wherein the sample further comprises a protein of interest.

10. The method of claim 9, wherein the protein of interest is an antibody.

11. The method of claim 9, wherein the protein of interest is a therapeutic antibody.

12. The method of claim 1, wherein said separation step comprises subjecting the at least one visible or sub-visible particle to liquid chromatography separation, wherein the mass spectrometer is coupled to the liquid chromatography system.

13. The method of claim 12, wherein the liquid chromatography system is a nano liquid chromatography system.

14. The method of claim 1, wherein the mass spectrometer is a tandem mass spectrometer.

15. The method of claim 1, wherein the protein is a host-cell protein.

16. A method for quantification of at least one protein in at least one visible or sub-visible particle in a sample, comprising:

isolating and capturing the at least one visible or sub-visible particle;

analyzing the at least one visible or sub-visible particle to identify a presence of the at least one protein using Raman spectroscopy;

subjecting the at least one visible or sub-visible particle to a separation step to produce at least one separated protein; and

subjecting the at least one separated protein to mass spectrometry analysis to quantify the at least one protein.

17. The method of claim 16, wherein the at least one protein is a host-cell protein.

18. The method of claim 16, wherein the at least one visible or sub-visible particle is an aggregate of a protein.

19. A method for characterization of a host cell-protein in at least one visible or sub-visible particle in a sample, comprising:

isolating and capturing the at least one visible or sub-visible particle;

analyzing the at least one visible or sub-visible particle to identify a presence of a protein using Raman spectroscopy;

subjecting the at least one visible or sub-visible particle to a separation step to produce a separated protein; and

subjecting the separated protein to mass spectrometry analysis to characterize the protein to determine if the protein is the host cell-protein.