

PL9006: Key publications on the characterization of vaccines with multi-angle and dynamic light scattering

Summary

This document lists key publications using multi-angle and dynamic light scattering for the characterization of vaccine agents such as viruses, virus-like particles, mRNA or DNA vectors, polysaccharides, and protein-polysaccharide conjugates.

Viruses

- Quantitation of influenza virus using field-flow fractionation and multi-angle light scattering for quantifying influenza A particles

Bousse, T. et al., *Journal of Virological Methods* **193**(2), 589-596 (2013).
<https://doi.org/10.1016/j.jviromet.2013.07.026>

- Formulation and coating of microneedles with inactivated influenza virus to improve vaccine stability and immunogenicity

Kim, Y.C. et al. *Journal of Controlled Release*. **142**(2), 187-195 (2010).
[http://doi.org/10.1016/j.jconrel.2009.10.013](https://doi.org/10.1016/j.jconrel.2009.10.013)

- Biophysical characterization of influenza virus subpopulations using field flow fractionation and multiangle light scattering: Correlation of particle counts, size distribution and infectivity

Wie, Z. et al. *J. Virological Methods* **144**(1-2), 122-132 (2007).
[http://doi.org/10.1016/j.jviromet.2007.04.008](https://doi.org/10.1016/j.jviromet.2007.04.008)

Virus-like Particles

- Asymmetrical flow field-flow fractionation coupled with multi-angle laser light scattering for stability comparison of virus-like particles in different solution environments

Chen, Y. et al. *Vaccine* **34**(27), 3164-3170 (2016).
<http://doi.org/10.1016/j.vaccine.2016.04.046>

- Formulation studies during preclinical development of influenza hemagglutinin and virus-like particle vaccine candidates

Wahome, N. et al. in: *Methods in Molecular Biology*. Vol 1404. Humana Press Inc.; (2016) 393-421.
http://doi.org/10.1007/978-1-4939-3389-1_27

- Aggregation and antigenicity of virus like particle in salt solution-A case study with hepatitis B surface antigen

Chen, Y. et al. *Vaccine* **33**(35), 4300-4306 (2015).
<http://doi.org/10.1016/j.vaccine.2015.03.078>

- A rapid and simple screening method to identify conditions for enhanced stability of modular vaccine candidates

Tekewe, A. et al. *Biochemical Engineering Journal* **100**, 50-58 (2015).
<http://doi.org/10.1016/j.bej.2015.04.004>

- Virus-like Particle Formulation Optimization by Miniaturized High-Throughput Screening

Mohr, J. et al. *Methods* **60**(3), 248–256 (2013).
<https://doi.org/10.1016/j.ymeth.2013.04.019>

- Development of a stable virus-like particle vaccine formulation against chikungunya virus and investigation of the effects of polyanions
Kramer, R.M. et al. *Journal of Pharmaceutical Science* **102**(12), 4305-4314 (2013).
<http://doi.org/10.1002/jps.23749>
- Quantitative characterization of virus-like particles by asymmetrical flow field flow fractionation, electrospray differential mobility analysis, and transmission electron microscopy
Pease, L.F. et al., *Biotechnology and Bioengineering* **102**(3) 845-855 (2009).
<https://doi.org/10.1002/bit.22085>
- Characterization of virus-like particle assembly for DNA delivery using asymmetrical flow field-flow fractionation and light scattering
Citkowicz, A., Petry, H. *Analytical Biochemistry* **376**, 163-172 (2008).
<https://doi.org/10.1016/j.ab.2008.02.011>
- Quantitative analysis of virus-like particle size and distribution by field-flow fractionation
Chuan, Y.P. et al., *Biotechnology and Bioengineering* **99**(6) 1425-1433 (2008).
<https://doi.org/10.1002/bit.21710>

RNA/DNA vectors

- Improved multidetector asymmetrical-flow field-flow fractionation method for particle sizing and concentration measurements of lipid-based nanocarriers for RNA delivery
Mildner, R. et al. *European Journal of Pharmaceutics and Biopharmaceutics* **163**, 252-265 (2021)
<https://doi.org/10.1016/j.ejpb.2021.03.004>
- Advanced nanomedicine characterization by DLS and AF4-UV-MALS: Application to a HIV nanovaccine
Klein, M. et al. *Journal of Pharmaceutical and Biomedical Analysis* **179**, 113017 (2020).
[http://doi.org/10.1016/j.jpba.2019.113017](https://doi.org/10.1016/j.jpba.2019.113017)

- Impact of lipid nanoparticle size on mRNA vaccine immunogenicity

Hassett, K.J. et al. *Journal of Controlled Release* **335**, 237-246 (2021)
<https://doi.org/10.1016/j.jconrel.2021.05.021>

Nanoparticles

- Measuring particle size distribution by asymmetric flow field flow fractionation: a powerful method for the preclinical characterization of lipid-based nanoparticles
Caputo, F. et al., *Mol. Pharm.* **16** (2), 756-767 (2019).
<https://doi.org/10.1021/acs.molpharmaceut.8b01033>
- Validation of an FFF-MALS Method to Characterize the Production and Functionalization of Outer-Membrane Vesicles for Conjugate Vaccines
Robert M. F., et al. *Analytical Chemistry* **94**(35), 12033-12041 (2022).
<https://doi.org/10.1021/acs.analchem.2c01590>.

Polysaccharides

- Stabilization study of inactivated foot and mouth disease virus vaccine by size-exclusion HPLC and differential scanning calorimetry
Yang, Y. et al. *Vaccine* **35**(18), 2413-2419 (2017).
<http://doi.org/10.1016/j.vaccine.2017.03.037>
- Alignment of Absolute and Relative Molecular Size Specifications for a Polyvalent Pneumococcal Polysaccharide Vaccine (PNEUMOVAX®23)
MacNair, J.E. et al. *Biologicals* **33**(1), 49–58 (2005).
<https://doi.org/10.1016/j.biologicals.2004.11.002>

Protein-polysaccharide conjugates

- Higher mass meningococcal group C-tetanus toxoid vaccines conjugated with carbodiimide correlate with greater immunogenicity
Lockyer, K. et al. *Vaccine* **38**(13), 2859-2869 (2020).
<https://doi.org/10.1016/j.vaccine.2020.02.012>

- Structural Correlates of Carrier Protein Recognition in Tetanus Toxoid-Conjugated Bacterial Polysaccharide Vaccines
Lockyer, K. et al. *Vaccine* **33**(11), 1345–1352 (2015).
<https://doi.org/10.1016/j.vaccine.2015.01.046>
- Structural organization of NadAΔ351-405, a recombinant MenB vaccine component, by its physico-chemical characterization at drug substance level
Magagnoli, C. et al. *Vaccine* **27**(15), 2156-2170 (2009).
<http://doi.org/10.1016/j.vaccine.2009.01.099>
- Novel configurations of high molecular weight species of the pertussis toxin vaccine component
Fowler, S. et al. *Vaccine* **21**(19-20), 2678-2688 (2003).
[http://doi.org/10.1016/S0264-410X\(03\)00105-1](http://doi.org/10.1016/S0264-410X(03)00105-1)
- Evaluation of meningococcal C oligosaccharide conjugate vaccines by size-exclusion chromatography/multi-angle laser light scattering
Jumel, K., Ho, M.M., Bolgiano, B. *Biotechnological Applications of Biochemistry* **36**(3), 219 (2002).
<http://doi.org/10.1042/ba20020066>
- Improved stability of a protein vaccine through elimination of a partially unfolded state
McHugh, C.A., et al. *Protein Science* **13**(10), 2736-2743 (2009). <http://doi.org/10.1110/ps.04897904>
- Structure of the influenza virus A H5N1 nucleoprotein: implications for RNA binding, oligomerization, and vaccine design
Ng, A.K. et al. *FASEB J.* **22** (10), 3638-3647 (2008).
<https://doi.org/10.1096/fj.08-112110>
- Evaluation of on-line high-performance size-exclusion chromatography, differential refractometry, and multi-angle laser light scattering analysis for the monitoring of the oligomeric state of human immunodeficiency virus vaccine protein antigen
Barackman, J. et al. *Journal of Chromatography A* **1043**(1), 57–64 (2004).
<https://doi.org/10.1016/j.chroma.2004.02.011>

Peptides

- Chromatographic characterization of synthetic peptides: SPf66 malaria vaccine
Santoveña, A. et al. *Journal of Chromatography B - Analytical Technology in the Biomedical and Life Sciences* **766**(1), 3-12 (2002).
[http://doi.org/10.1016/S0378-4347\(01\)00392-9](http://doi.org/10.1016/S0378-4347(01)00392-9)

Antigen proteins

- Structure-based design of Nipah virus vaccines: a generalizable approach to paramyxovirus immunogen developments
Loomis, Rebecca J., et al. *Frontiers in Immunology* **11** (2020): 842.
<https://doi.org/10.3389/fimmu.2020.00842>.
- Utilizing Dynamic Light Scattering as a Process Analytical Technology for Protein Folding and Aggregation Monitoring in Vaccine Manufacturing



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