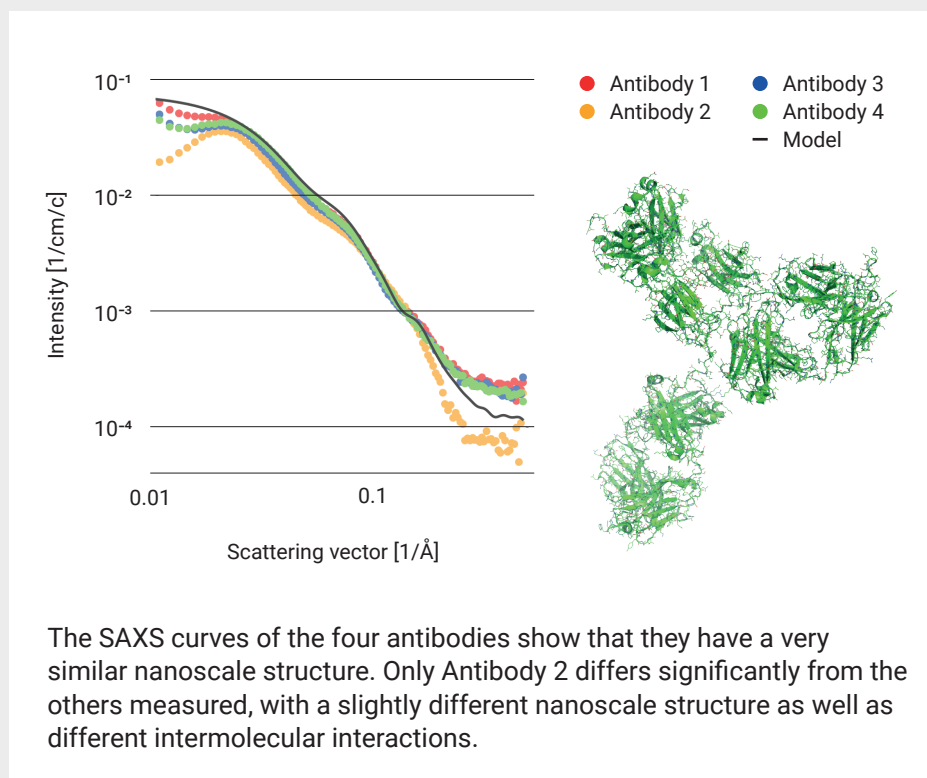


Verifying the similarity of monoclonal antibodies

Alvotech has the ambition to become a global market leader in biosimilars and to bring high quality and cost effective biological medicine to patients across the globe. Biosimilars are biopharmaceuticals with comparable quality, safety and efficacy to a reference product, but typically offered at a affordable cost.

In this project the LINX team at University of Copenhagen performed small-angle X-ray scattering (SAXS) experiments to compare the structure of four different monoclonal antibody drugs to demonstrate the suitability of SAXS for verifying the similarity of antibody structures at nanoscale.

The experiments show that the structures of the four antibodies are very similar. Only one of the antibody stands out as having a slightly different structure than the others.



What we did

- Alvotech provided four samples of different monoclonal antibodies used as therapeutical drugs
- The samples were measured with SAXS at the BioXolver instrument at the Department of Pharmacology at University of Copenhagen
- The data was analysed and the results indicate that all tested samples were overall very similar, with the exception of one antibody which appears to have a more flexible structure
- The radius of gyration of one of the antibodies was determined from the data to 5.4 nm
- The samples were also measured at elevated temperatures (70°C) to test their stability

What's next?

A natural next step would be to study the effect of different pharmaceutical formulations on the intramolecular interactions.

— The work performed in this project has provided us useful information and showed that SAXS is a very interesting technique for studying the structure of the antibodies we are developing and identifying similarities and differences between different biological molecules. This technique might be used for our analytical similarity assessment and comparability with the originator.

Jon Valgeirsson, Director analytical method development and emerging technologies, Alvotech

In the LINX project, researchers at leading Danish universities collaborate with scientists in industry to solve industry relevant problems using advanced neutron and X-ray techniques. The Arleth group at University of Copenhagen contributes with their expertise in small-angle scattering techniques.

Read more
linxproject.dk

Contact
Lise Arleth: arleth@nbi.ku.dk