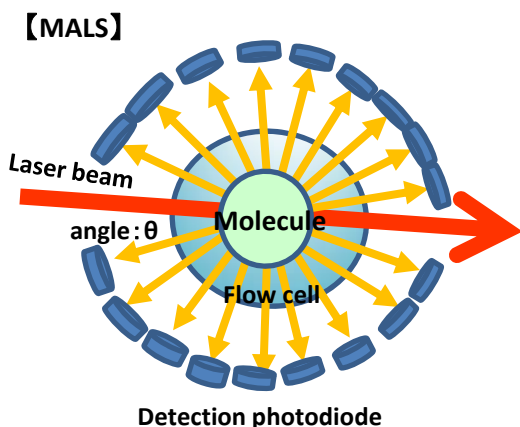


SEC-MALS Analysis under GMP

— Molecular Weight Determination of Aggregates —

Evaluation of aggregates is indispensable for the quality test of antibody drugs. Absolute molecular weight distribution, mean absolute molecular weight, and radius of gyration of macromolecules are determined by SEC-MALS without constructing a calibration curve. In this report, aggregates were prepared by heating the human IgG antibody, and the molecular weight of the aggregates was determined by SEC-MALS.

Principle of SEC-MALS



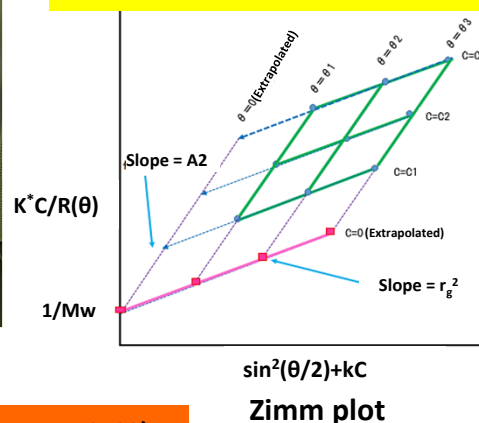
Multi Angle Light Scattering (MALS) detector:
Scattered light is detected by 18 photodiodes.



Refractive Index (RI) detector for measuring concentration

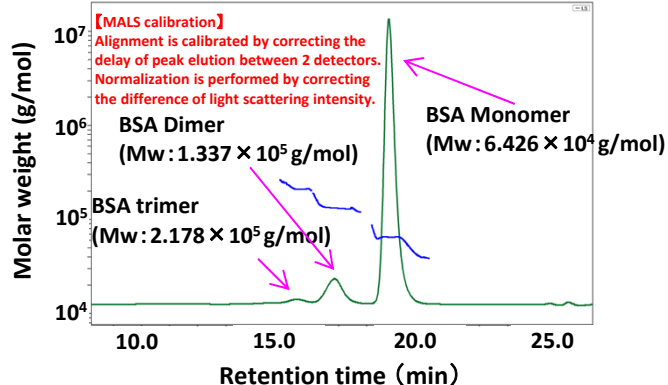
$$\frac{K^*C}{R(\theta)} = \frac{16\pi^2 n_0^2}{3M\lambda_0^2} < r_g^2 > \sin^2\left(\frac{\theta}{2}\right) + \frac{1}{Mw}$$

Absolute molecular weight (Mw) and radius of gyration (r_g) are calculated from concentration (measured by RI) and light scattering intensity (measured by MALS).

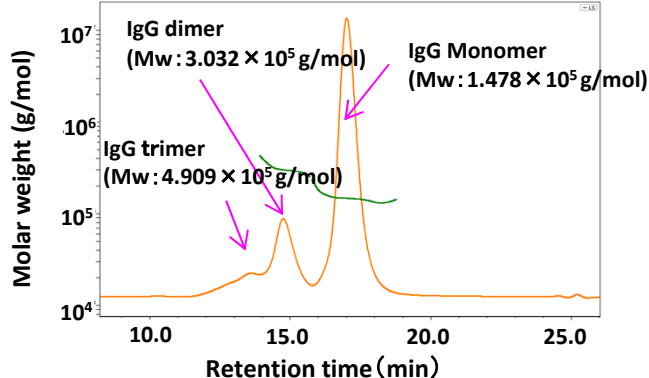


SOP: Operation and maintenance method of SEC-MALS (SOP No. NME18700)

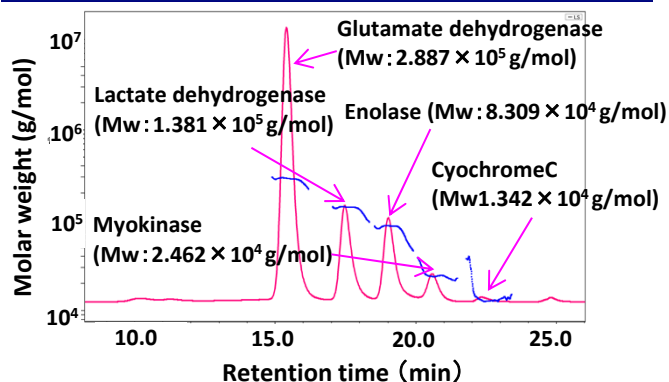
Analysis of BSA (For MALS calibration)



Analysis of Antibody



Analysis of Molecular Weight Markers



Analysis of Antibody Aggregates

