

TRENDY V CHARAKTERIZACI BIOFARMACEUTIK

Lukáš Plaček

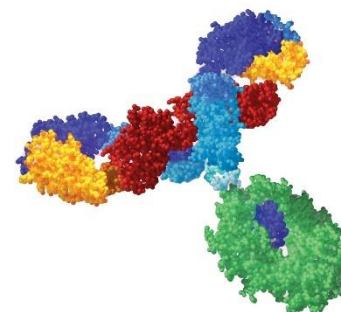
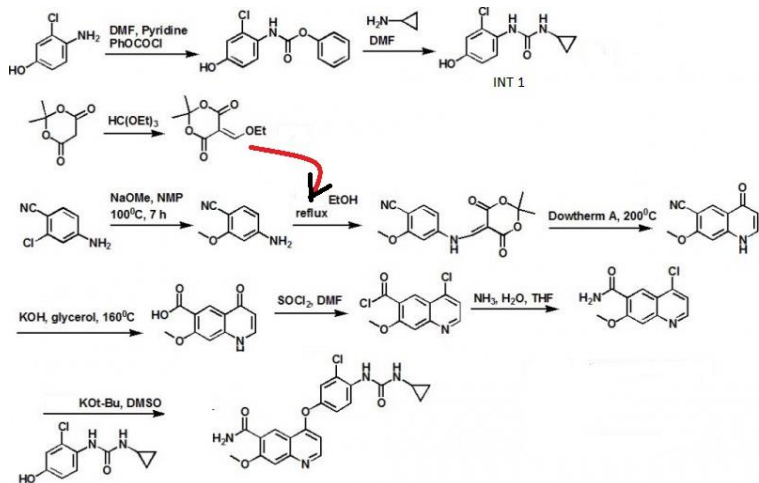


pragolab

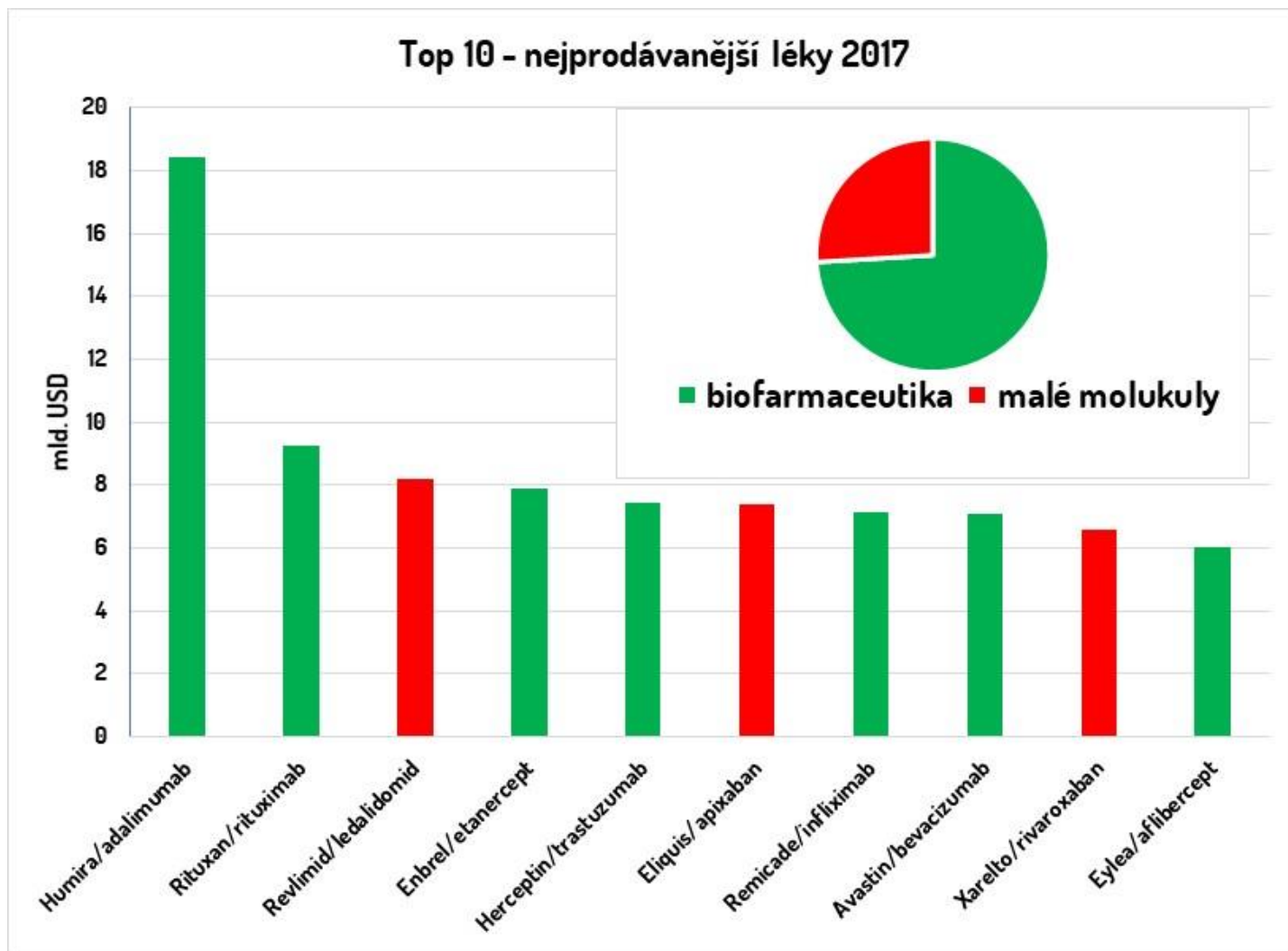
thermo
scientific

CO TO JE?

biopharmaceutical BIOLOGICAL **biologic** BIOLOGICAL
MEDICAL PRODUCTS biologické léčiva BIOPREPARÁTY
biopharma products *biofarmaka* biofarmaceutika **BIOLOGICAL**

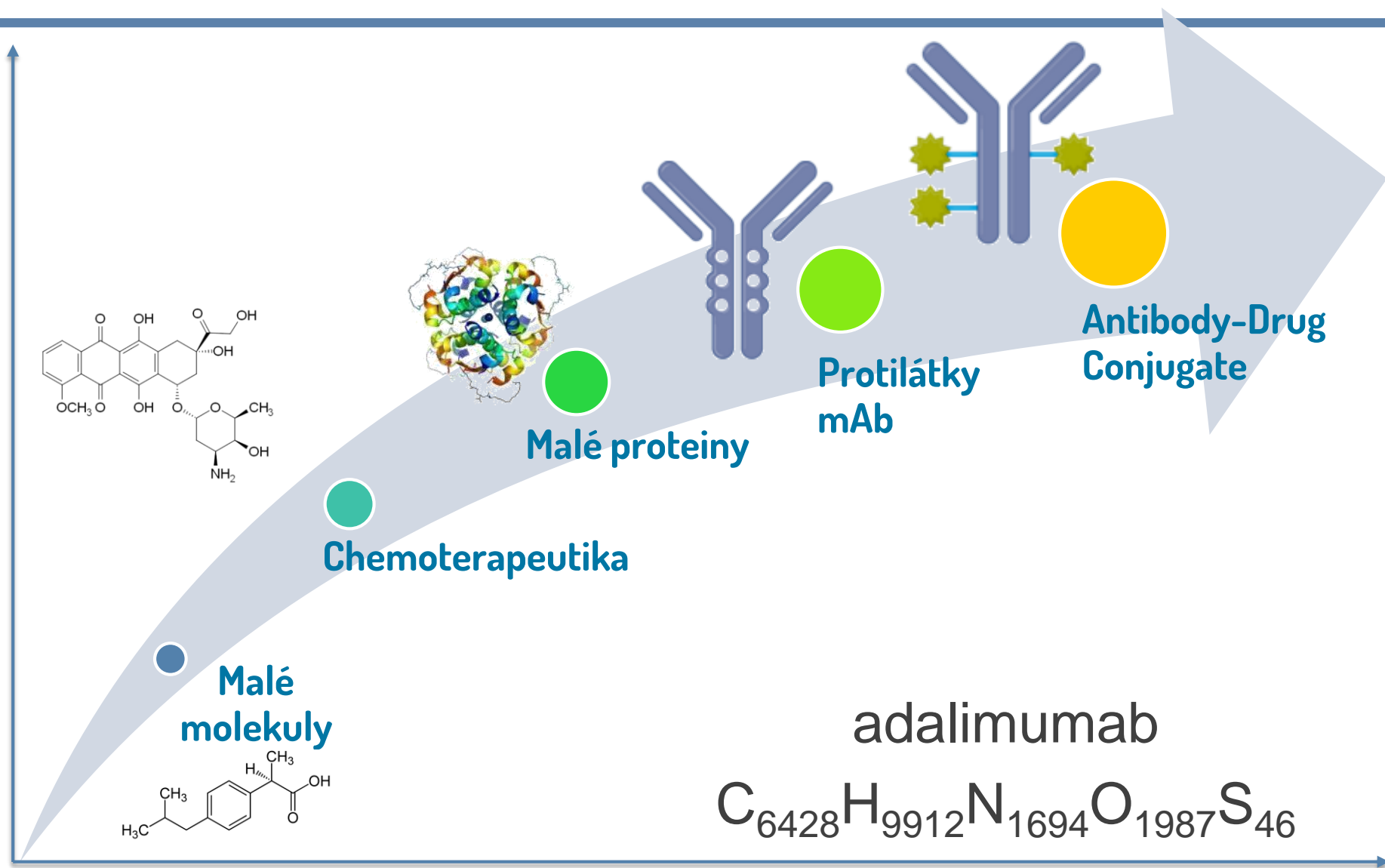


CO TO JE? PROČ?

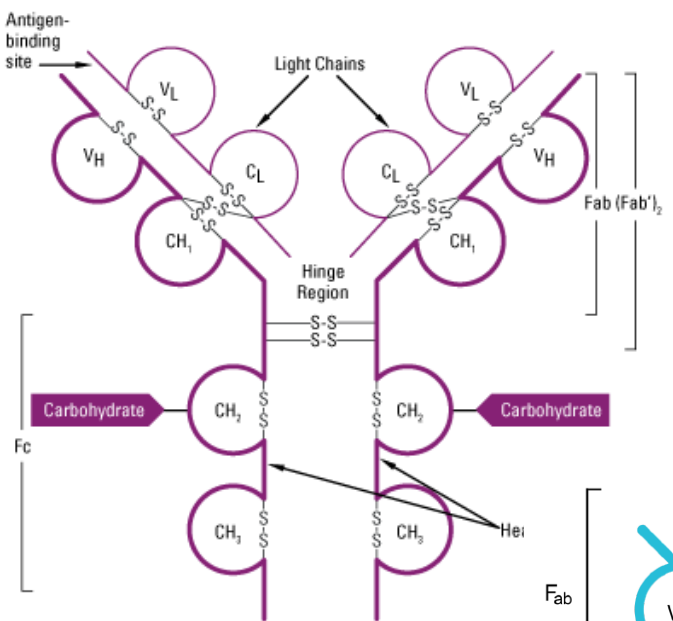


-UMAB
-XIMAB
-ZUMAB
-ERCEPT

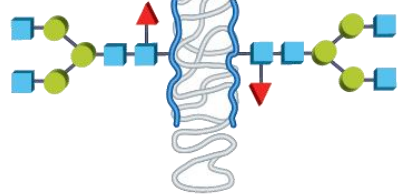
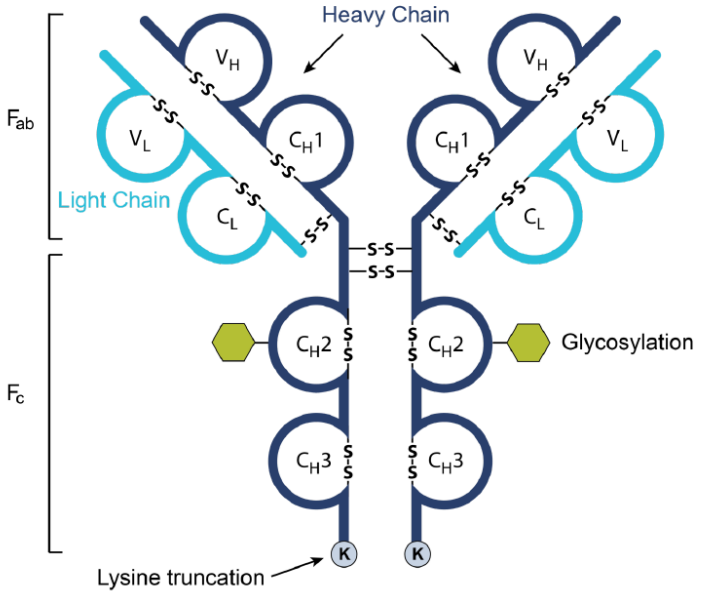
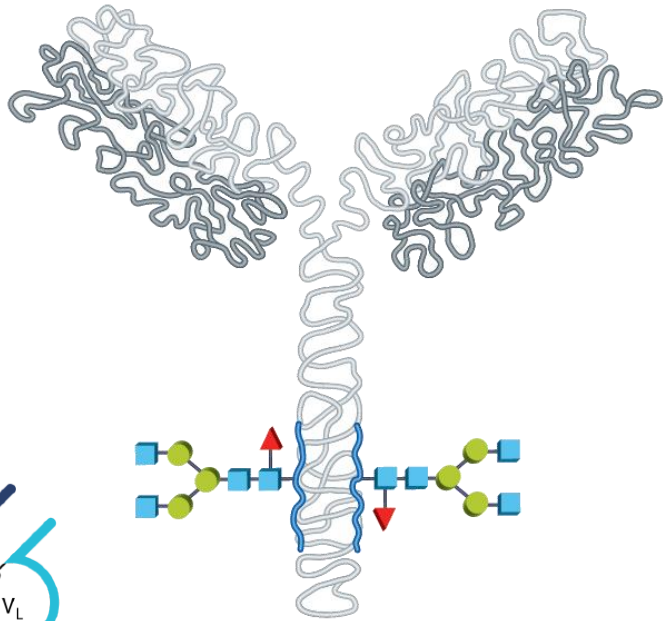
ANALYTICKÉ VÝZVY



ANALYTICKÉ VÝZVY

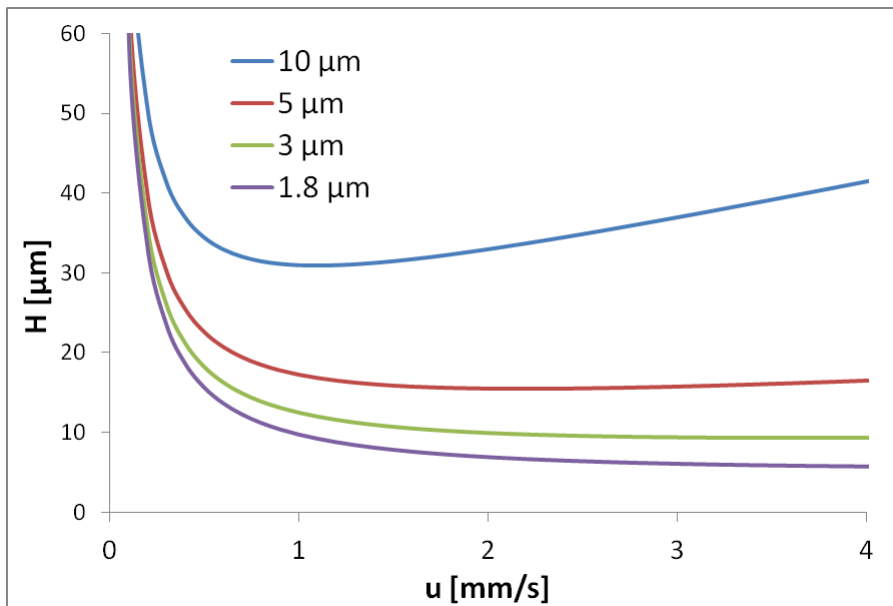


mAb

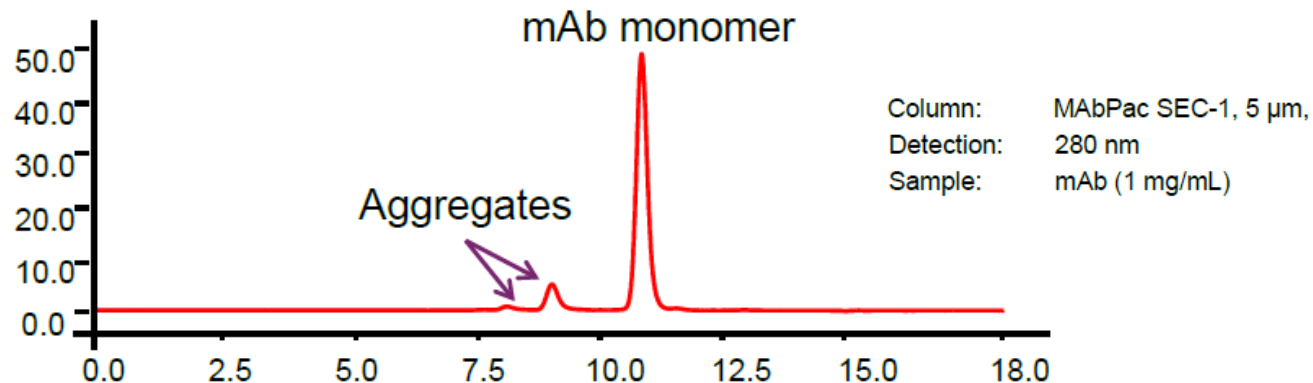
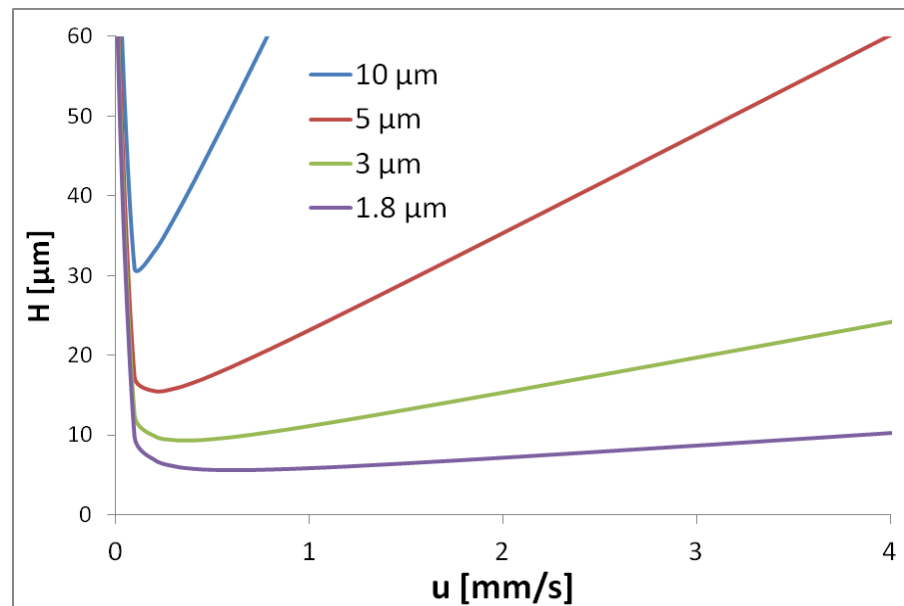


ČISTOTA

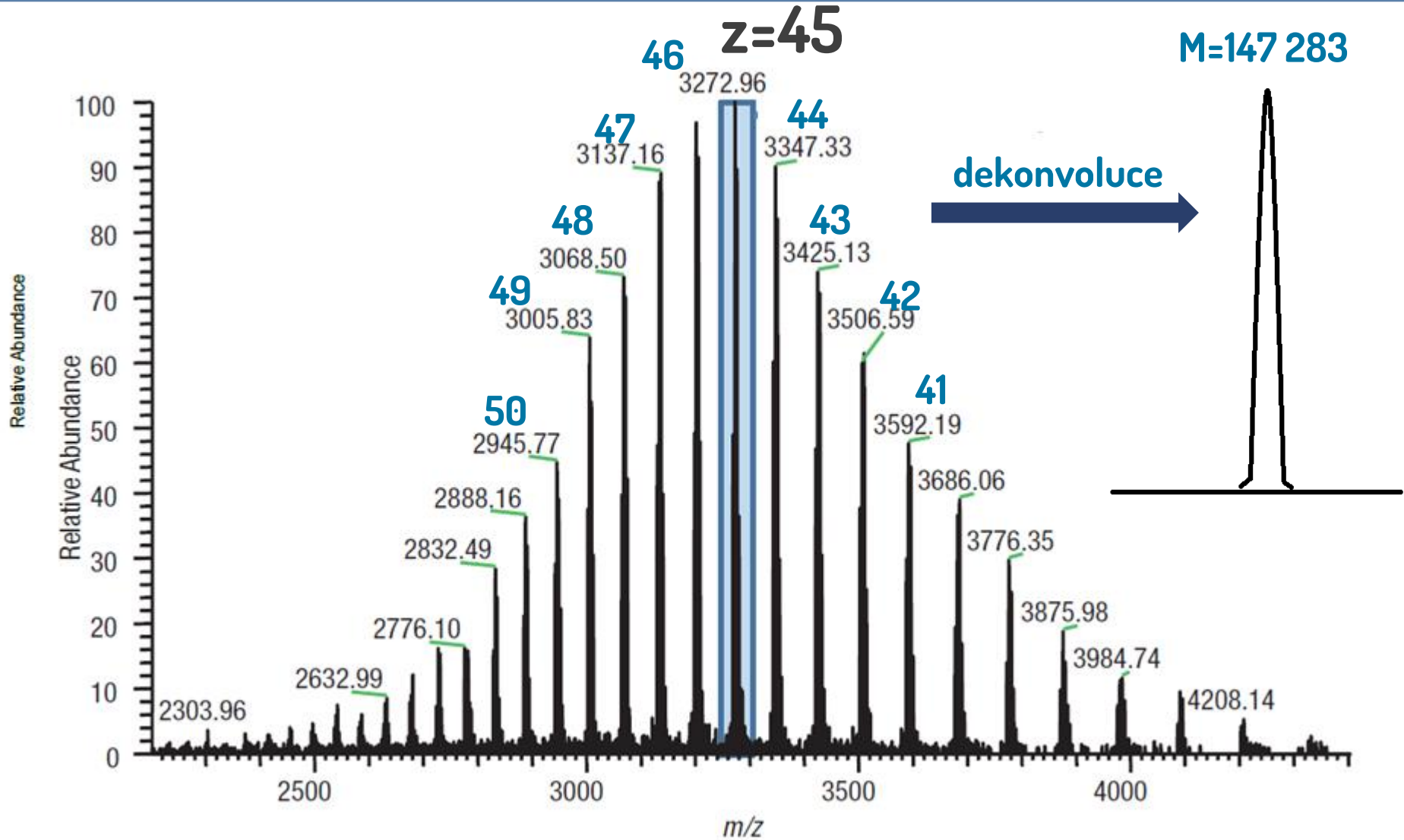
malé molekuly



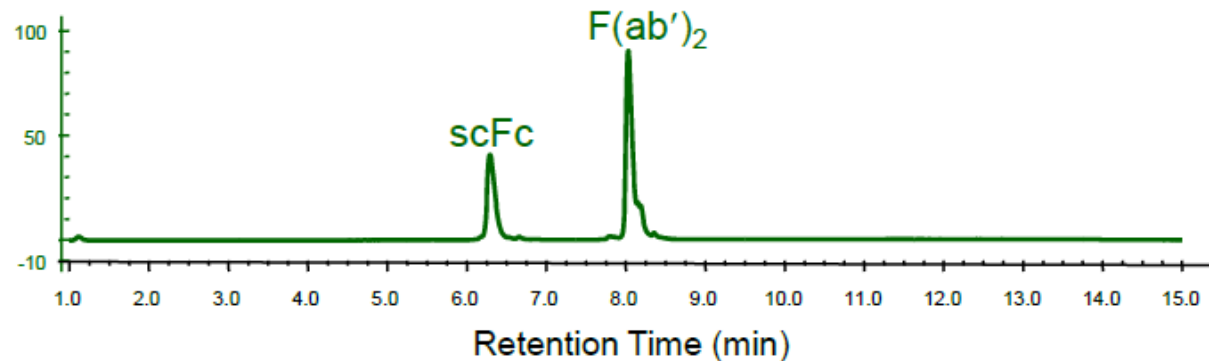
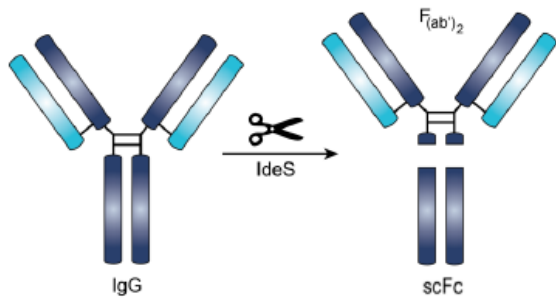
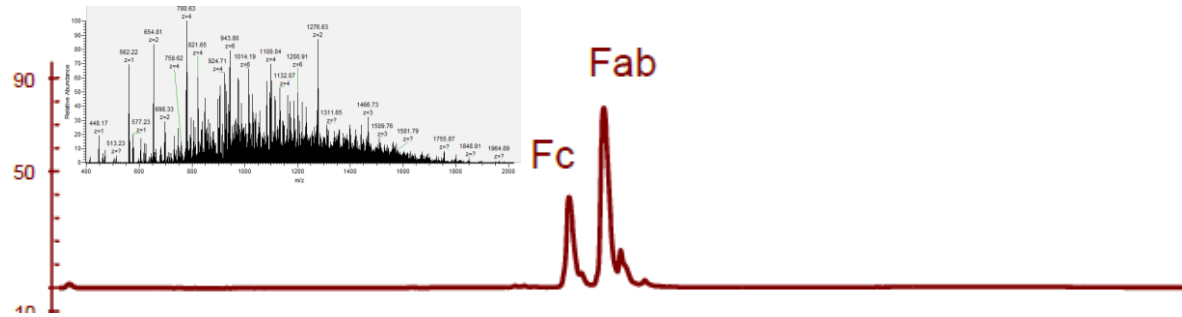
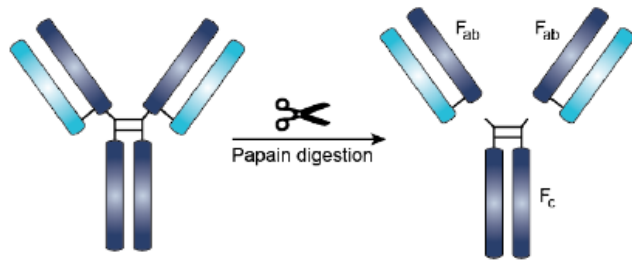
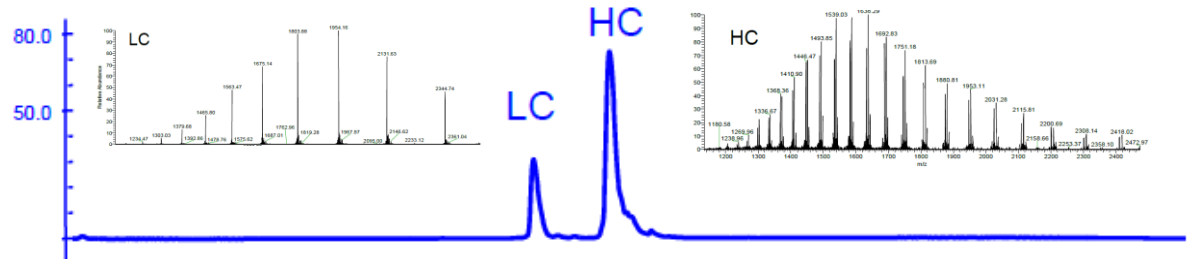
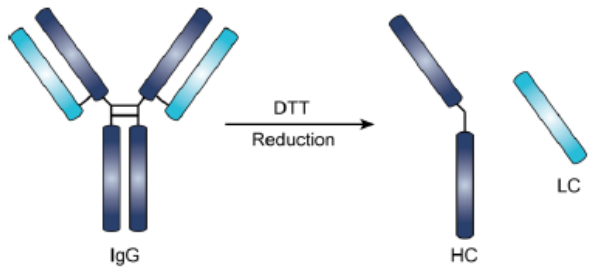
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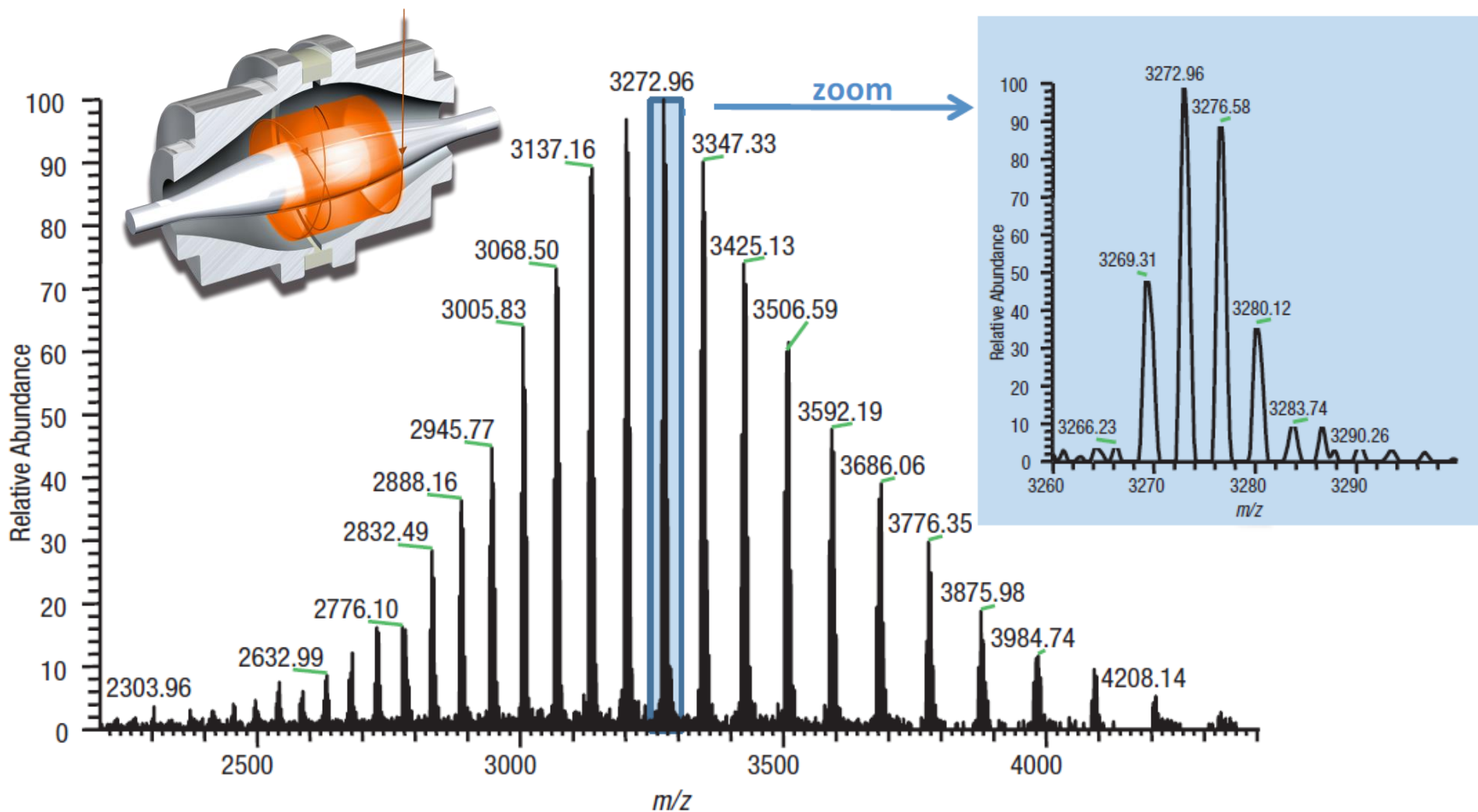
IDENTIFIKACE – INTACT MS



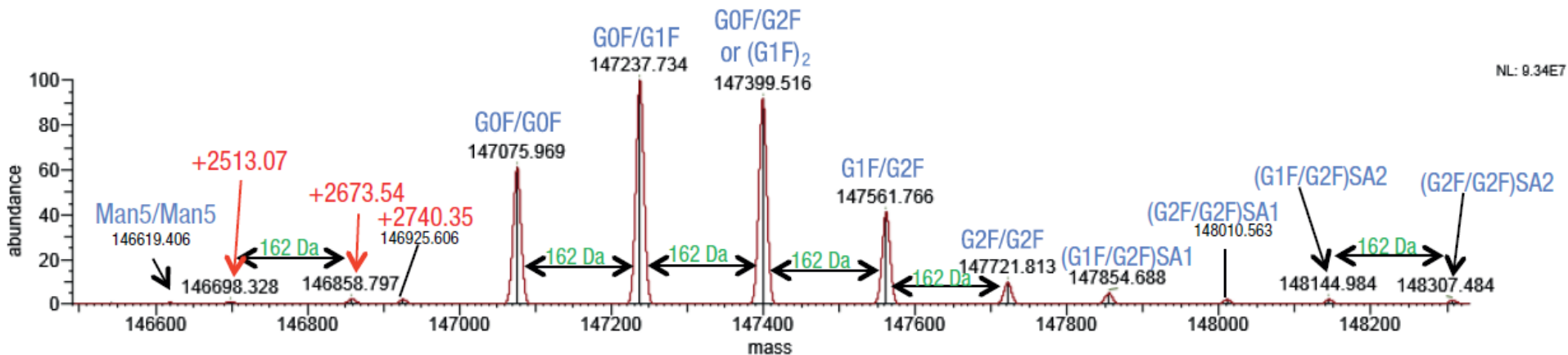
IDENTIFIKACE – SUBUNIT MS, TOP-DOWN MS/MS



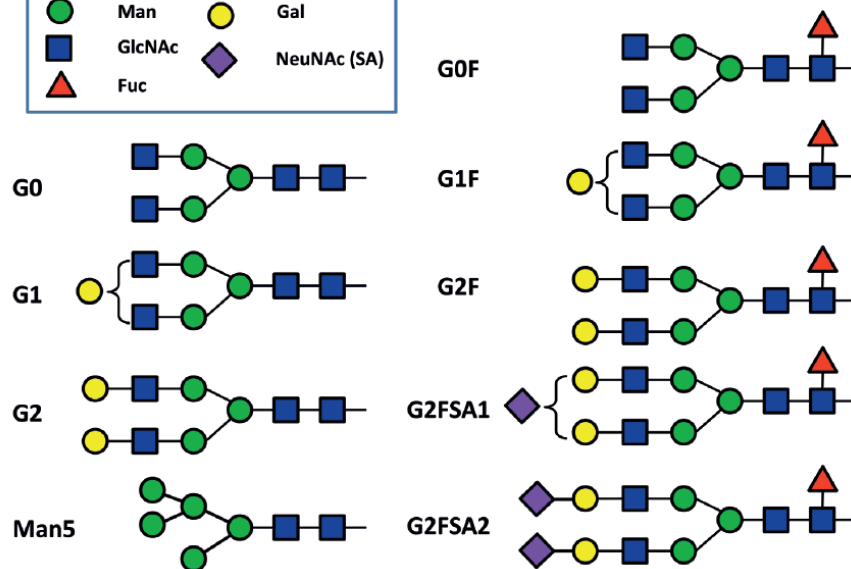
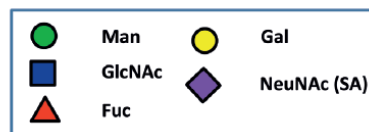
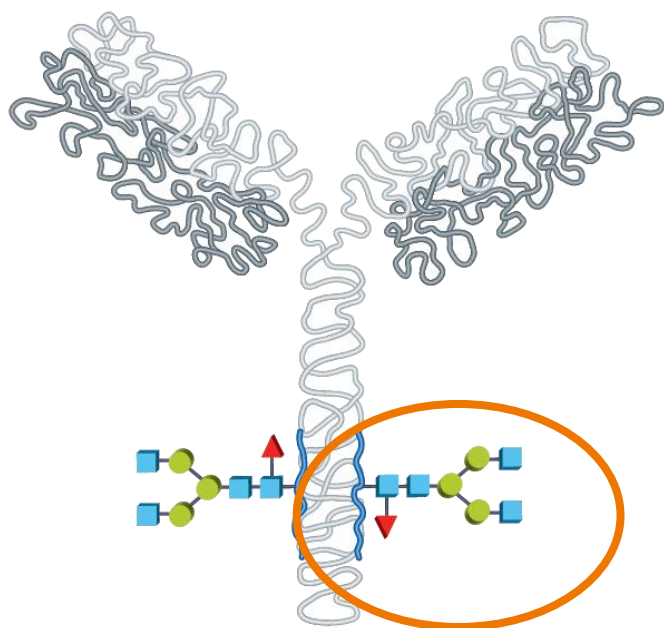
ANALYTICKÉ VÝZVY



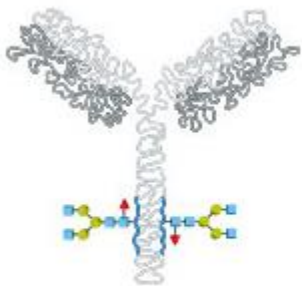
ANALYTICKÉ VÝZVY - GLYKOSILACE



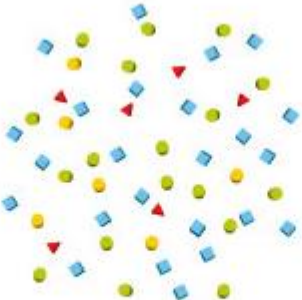
NL: 9.34E7



ANALYTICKÉ VÝZVY – GLYKOSILACE, IC-MS



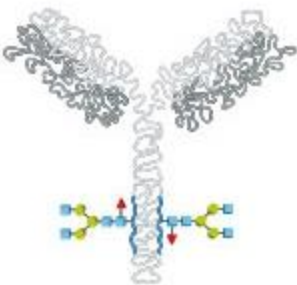
Glycoprotein



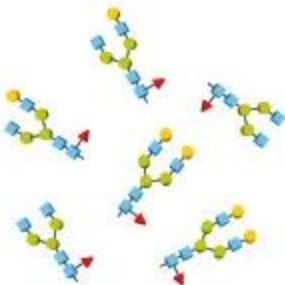
Monosaccharides



Ion Chromatography



Glycoprotein

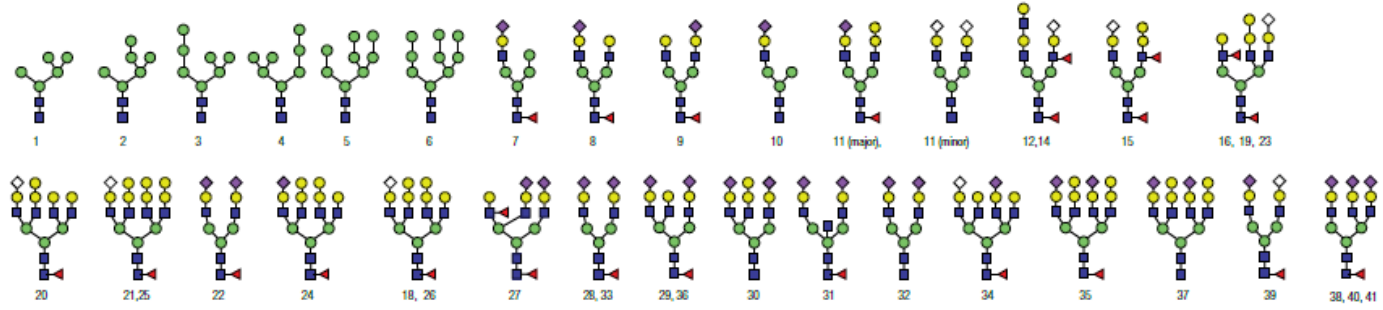
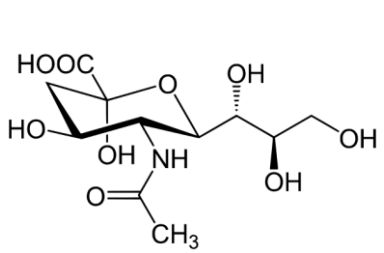
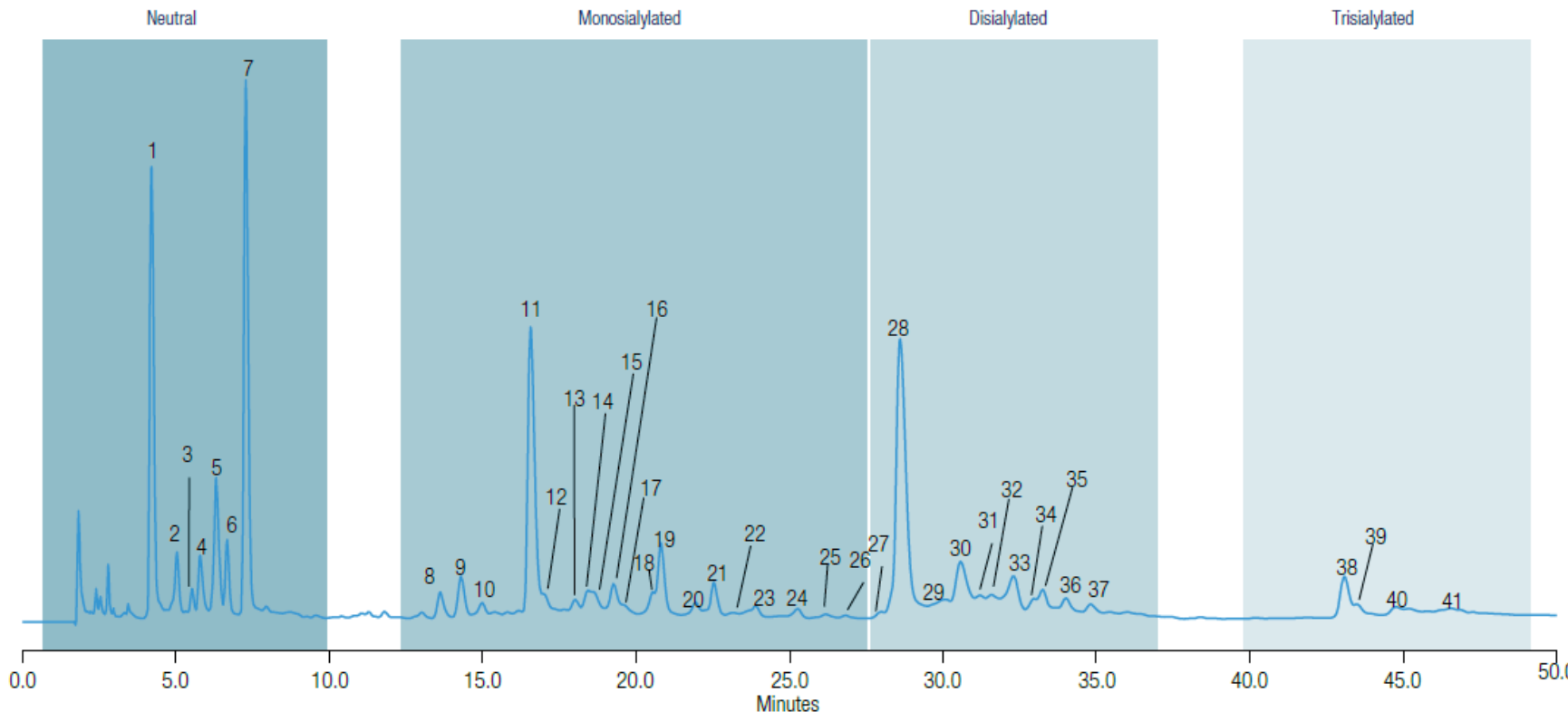


Released Glycans

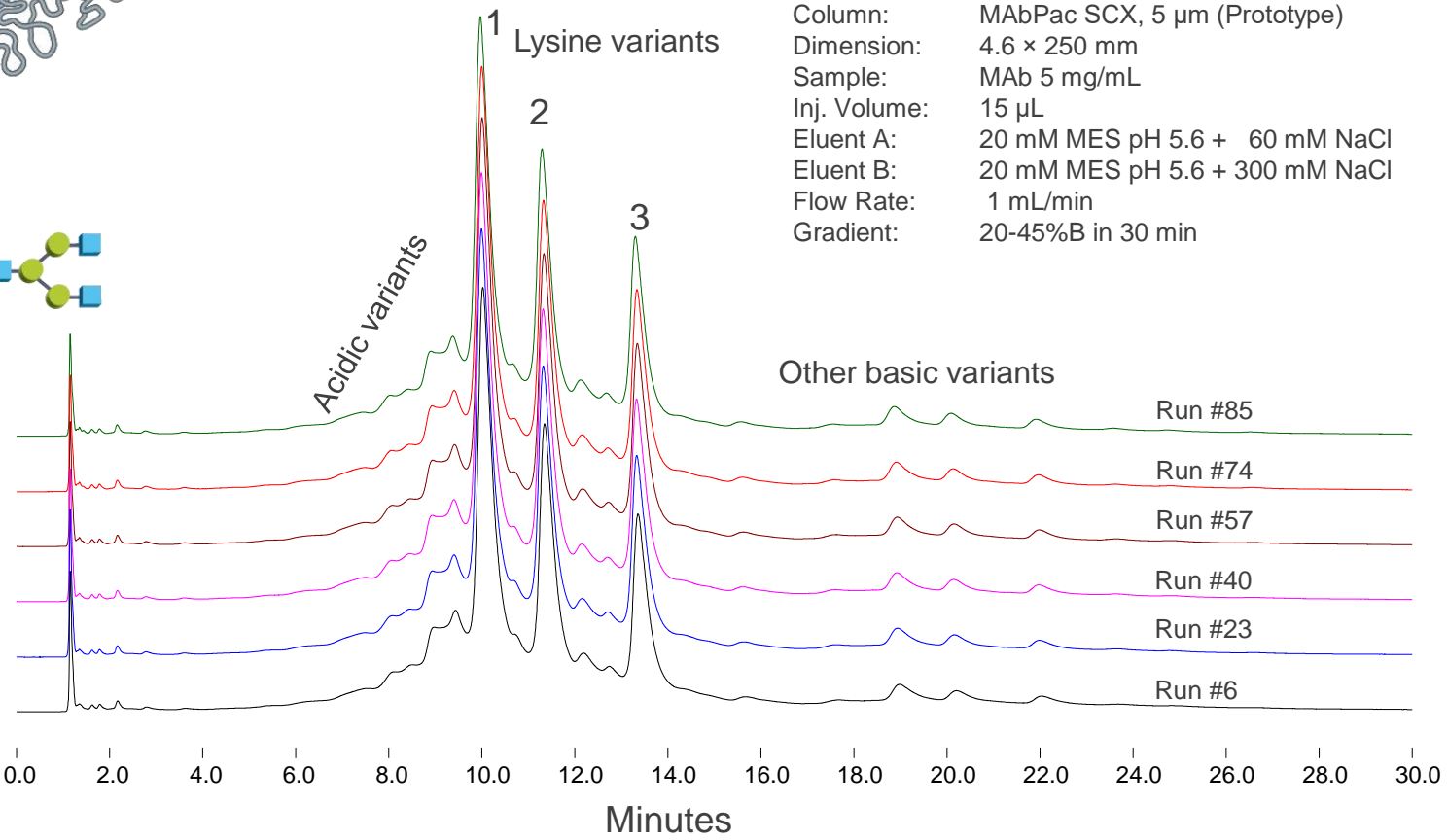
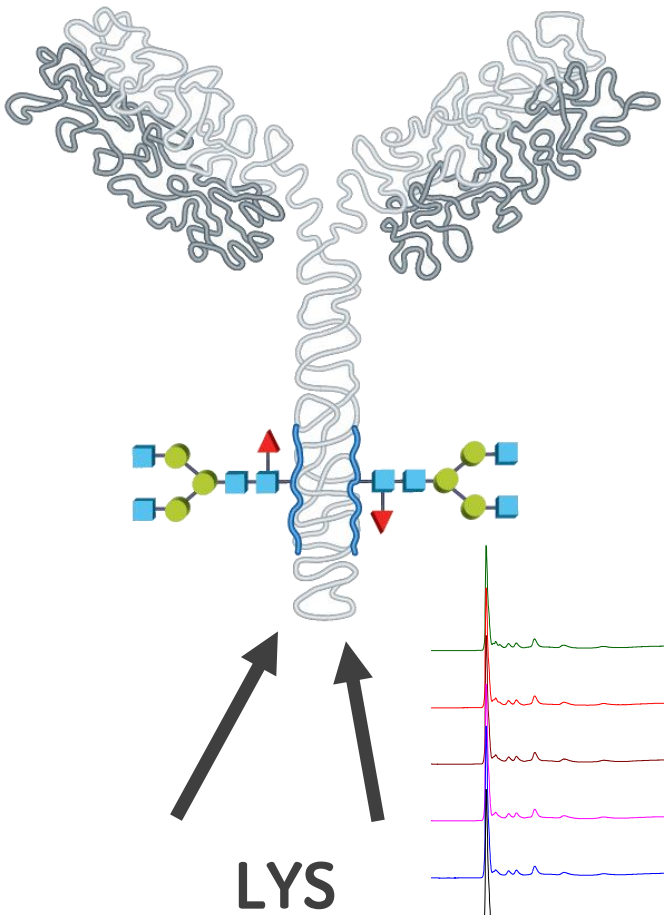


Ion Chromatography

ANALYTICKÉ VÝZVY – GLYKOSILACE, IC-MS

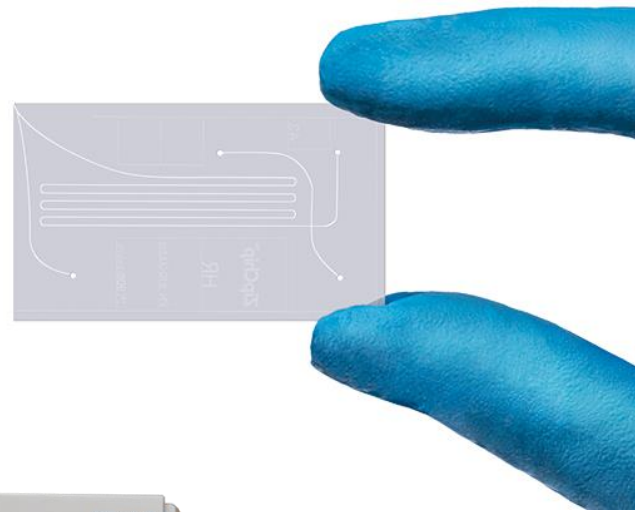
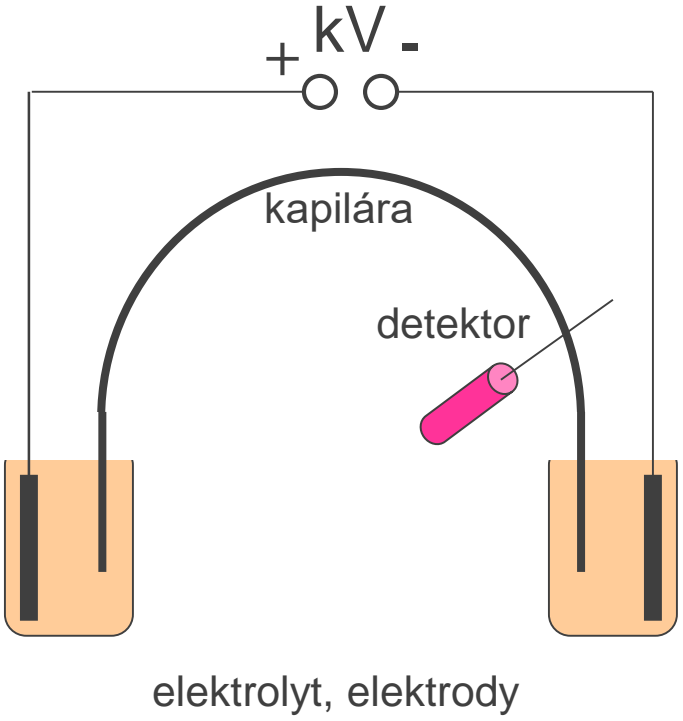


ANALYTICKÉ VÝZVY – CHARGE VARIANTS

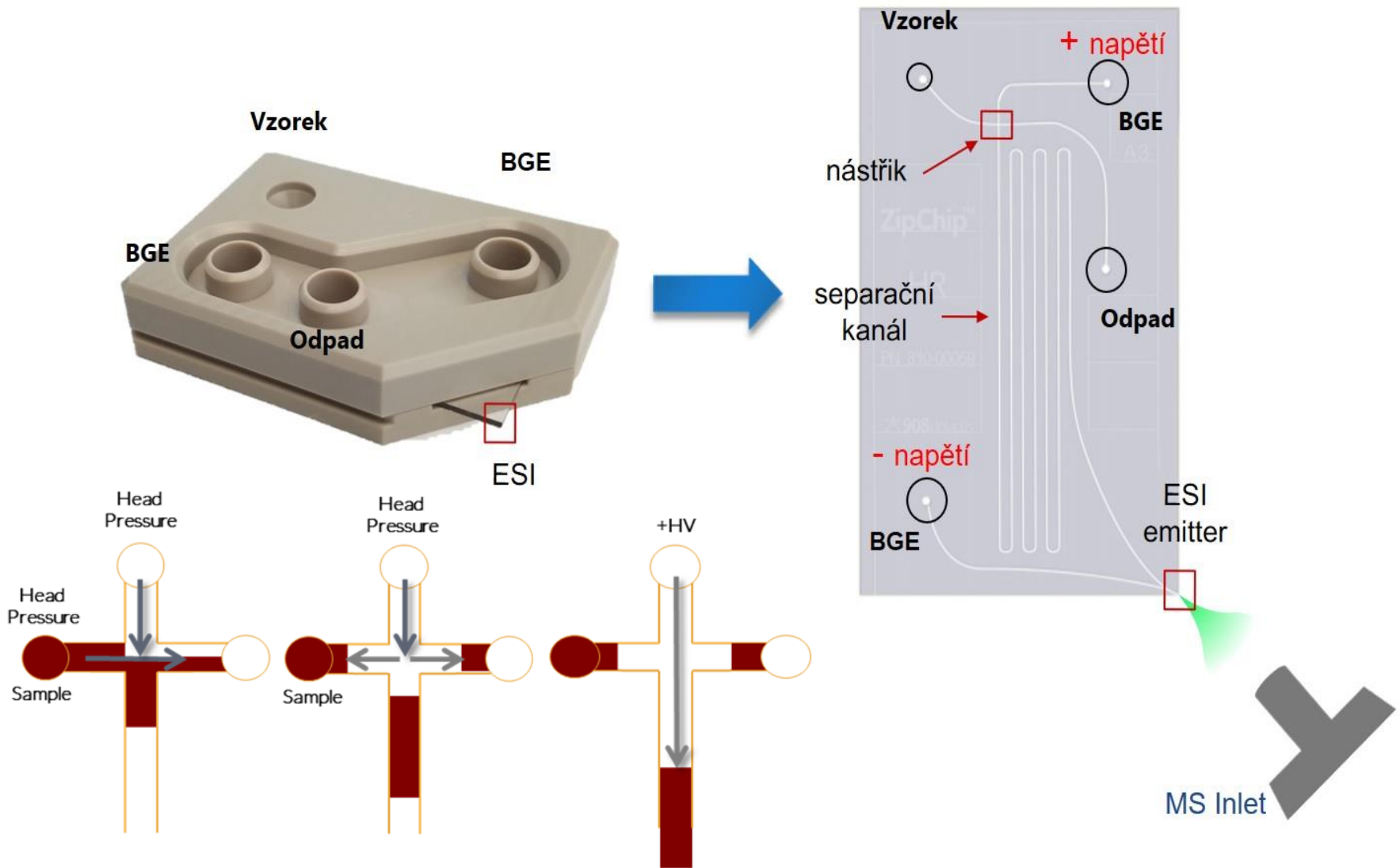


Column: MAbPac SCX, 5 μ m (Prototype)
 Dimension: 4.6 \times 250 mm
 Sample: MAb 5 mg/mL
 Inj. Volume: 15 μ L
 Eluent A: 20 mM MES pH 5.6 + 60 mM NaCl
 Eluent B: 20 mM MES pH 5.6 + 300 mM NaCl
 Flow Rate: 1 mL/min
 Gradient: 20-45%B in 30 min

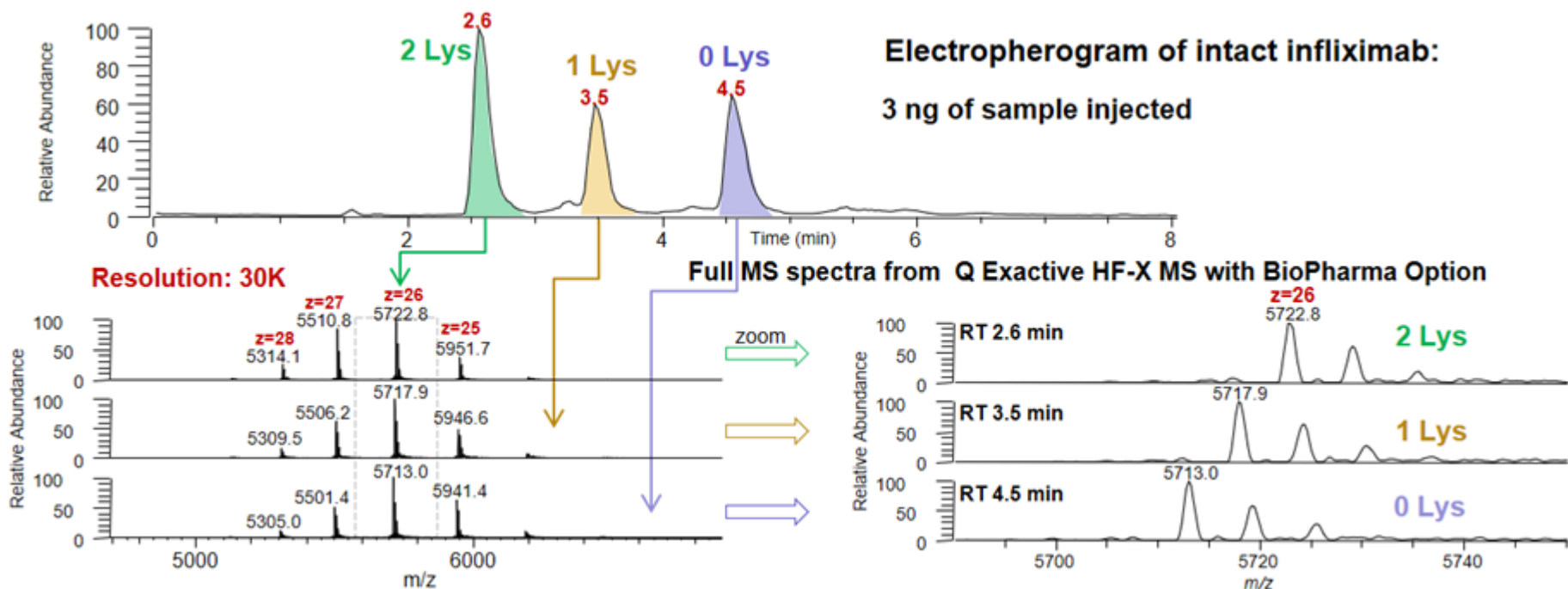
ANALYTICKÉ VÝZVY – CHARGE VARIANTS, CE-MS



ANALYTICKÉ VÝZVY – CHARGE VARIANTS CE-MS



ANALYTICKÉ VÝZVY – CHARGE VARIANTS CE-MS



Lys-Variant	Glycoform	Theor. average mass	Exp. average mass	Δ Mass (ppm)
2 Lys	G0F/G1F	148930.7	148929.2	9.8
2 Lys	G0F/G0F	148768.5	148767.8	4.8
2 Lys	(G1F)2 or (G0F/G2F)	149092.8	149092.6	1.3
1 Lys	G0F/G0F	148640.3	148639.7	4.3
1 Lys	G0F/G1F	148802.5	148801.2	8.6
1 Lys	(G1F)2 or (G0F/G2F)	148964.6	148964.9	-1.8
0 Lys	G0F/G0F	148512.2	148511.9	1.6
0 Lys	G0F/G1F	148674.3	148673.3	6.8
0 Lys	(G1F)2 or (G0F/G2F)	148836.5	148835.7	5.1

ANALYTICKÉ VÝZVY



Aggregate analysis

Check monomer vs
Aggregates

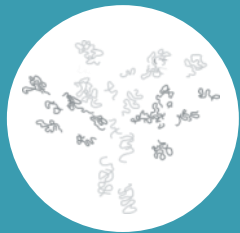
High salt condition,
biocompatible, low
dispersion,
reproducibility



Intact protein analysis

Check purity of the
antibody

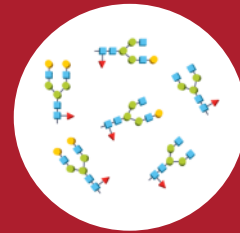
Biocompatible,
gradient and
thermostating
capabilities



Peptide mapping

Confirm sequence

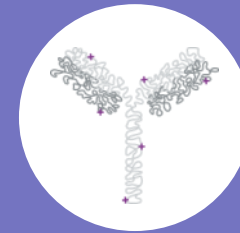
Analytical
reproducibility
Peak capacity



Glycan analysis

Check glycan
presence and
structure

Gradient capabilities



Charge variant analysis

Check charge
variation within
antibody sample

Biocompatible
selectivity

ANALYTICKÉ VÝZVY



Vanquish
UHPLC



Q Exactive
BioPharma



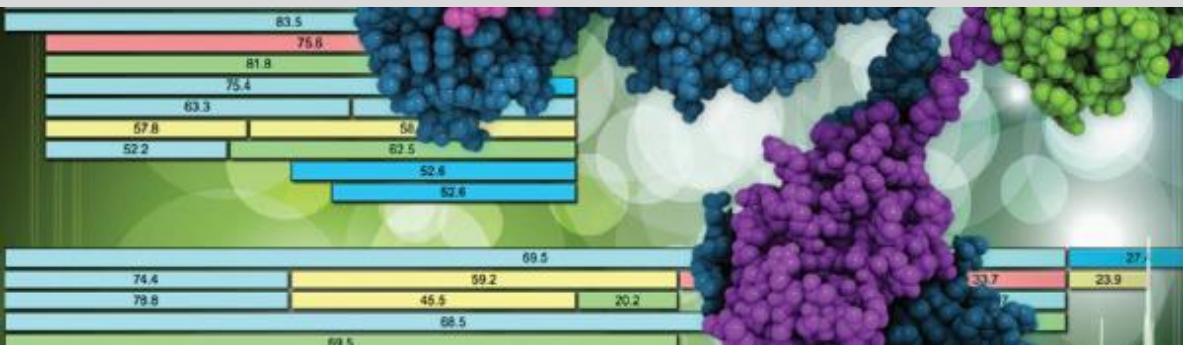
Dedicated CCS



Compliant IC



Fit-for-Purpos
Software



Thermo Scientific
BioPharma Finder Software



www.pragolab.cz



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