



**ThermoFisher**  
SCIENTIFIC

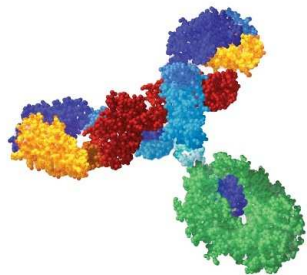
pragolab

## Orbitální pasti ve vývoji biofarmak

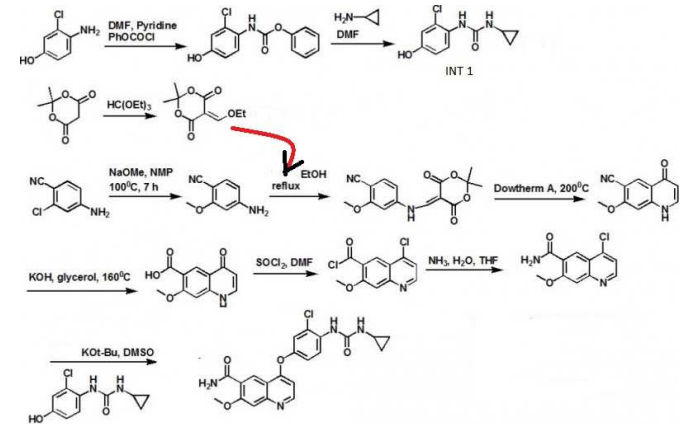
Lukáš Plaček

The world leader in serving science

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

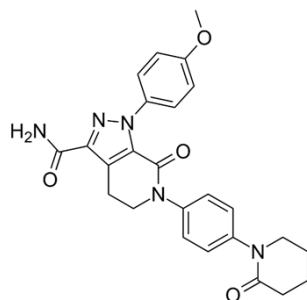


VS.

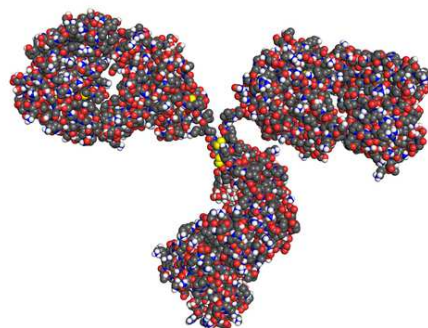


# Přístupy k analýze biofarmak

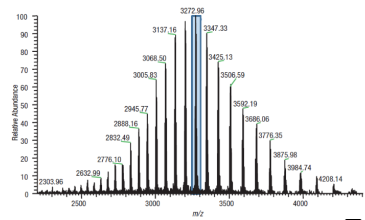
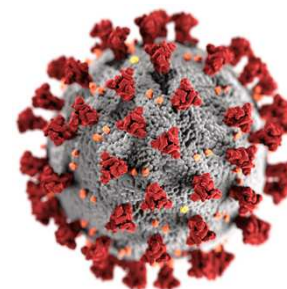
chemické  
(syntetické)



biologické



vakcíny

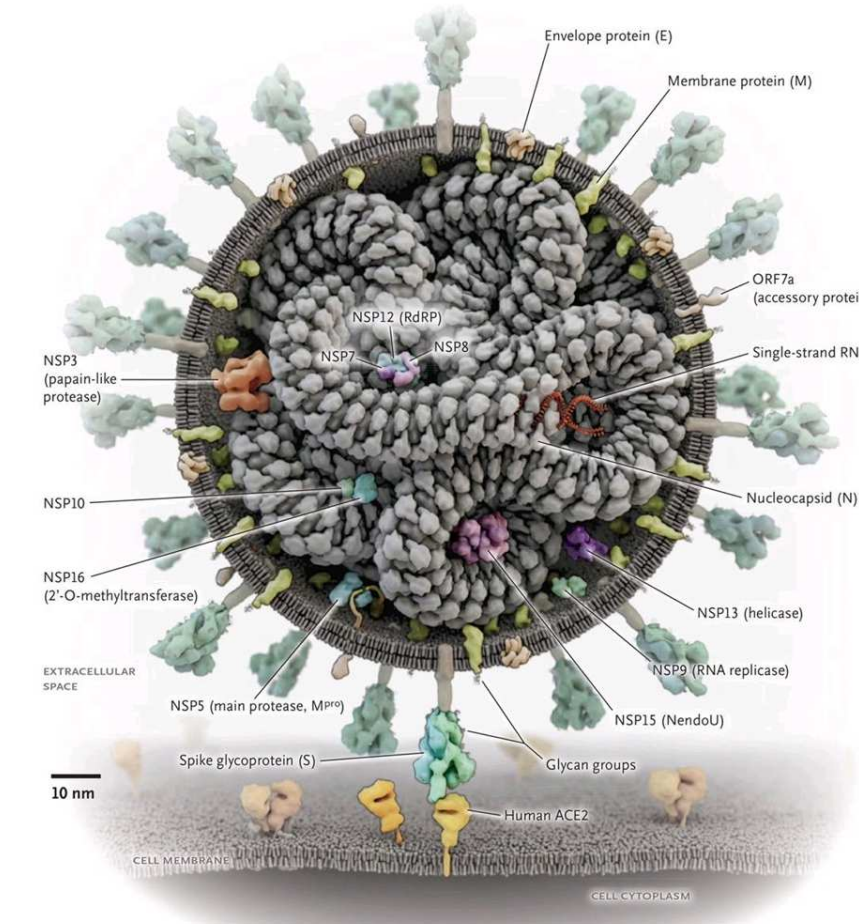


analytické testy  
(separační techniky, MS, NMR)

mikrobiologické a molekulárně  
biologické testy (ELISA, SDS-PAGE)



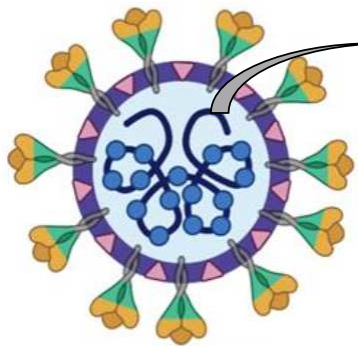
# Koronavirus a vývoj vakcín



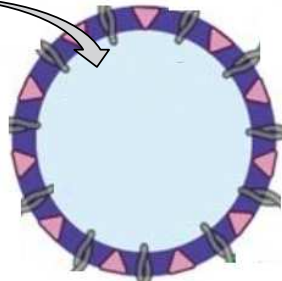
N Engl J Med 2020; 382:2261-2264



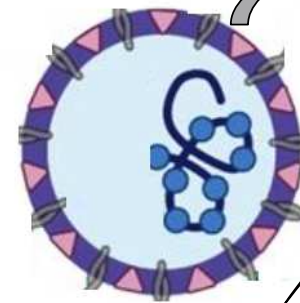
# Vakcíny vs. biofarmaka



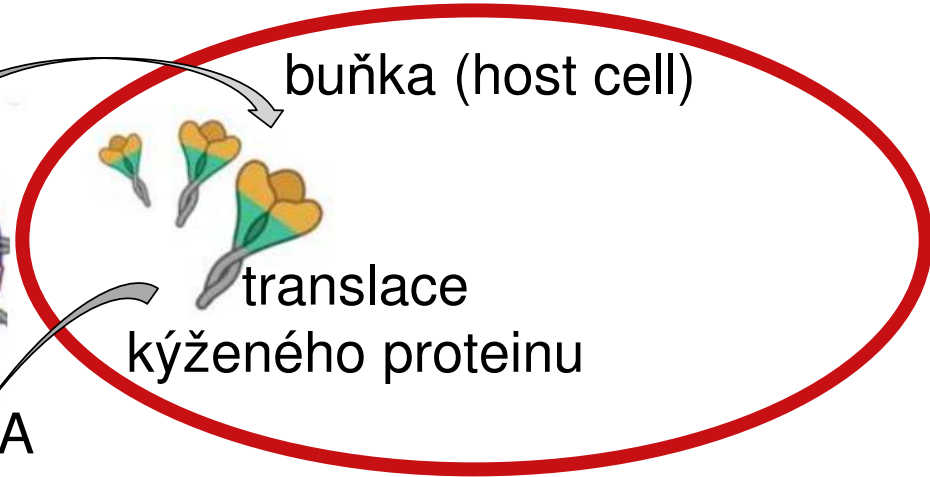
virus



příprava vektoru

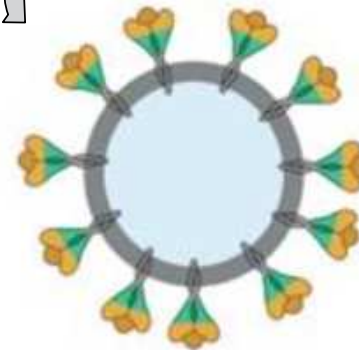


vektor s DNA



buňka (host cell)

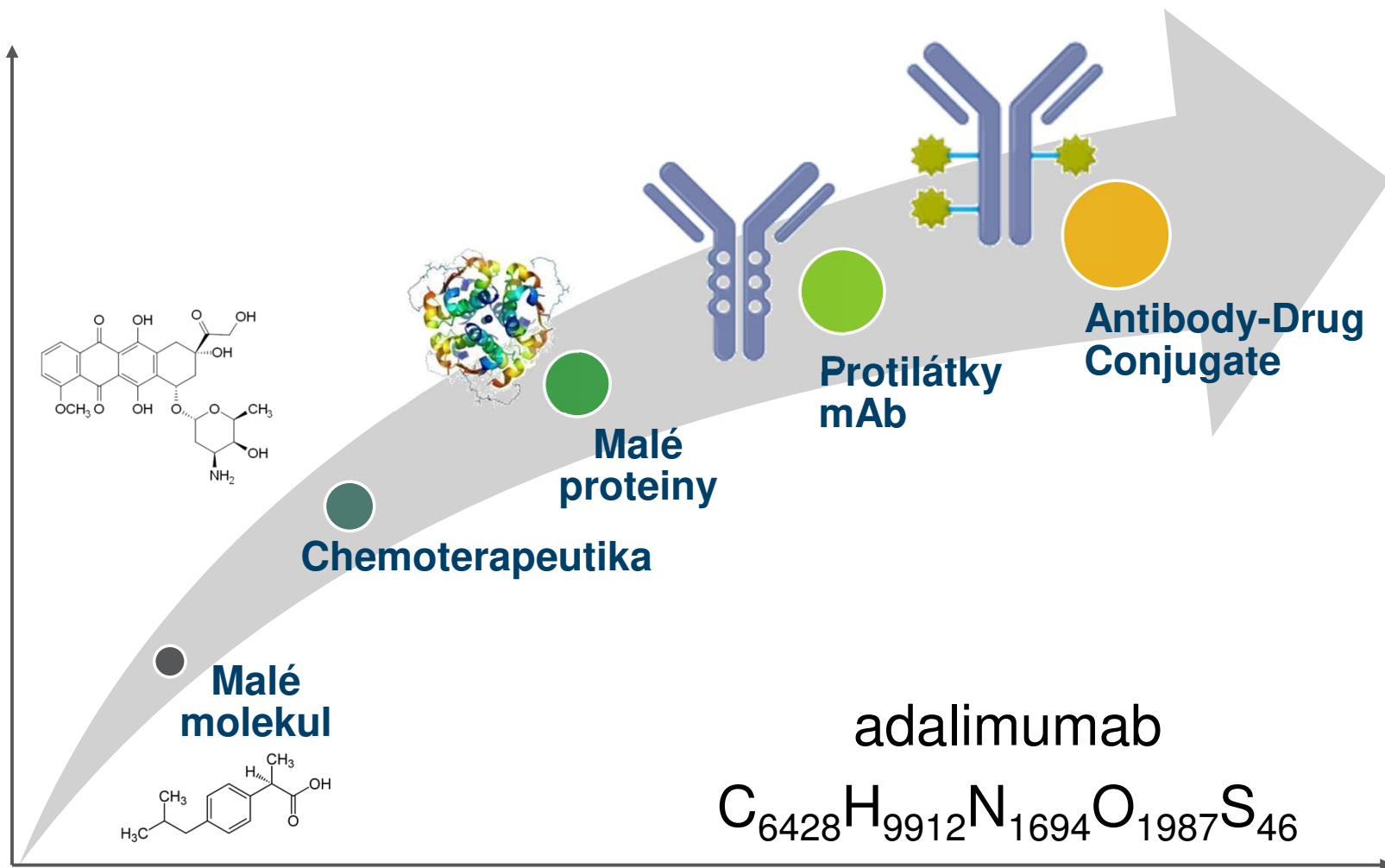
translace  
kýženého proteinu



finální forma

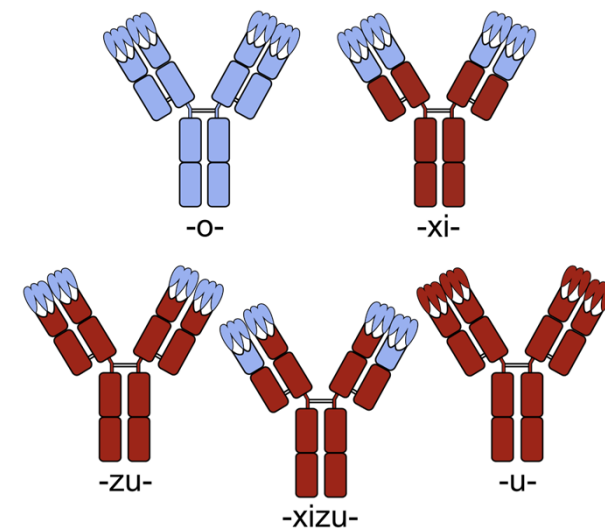
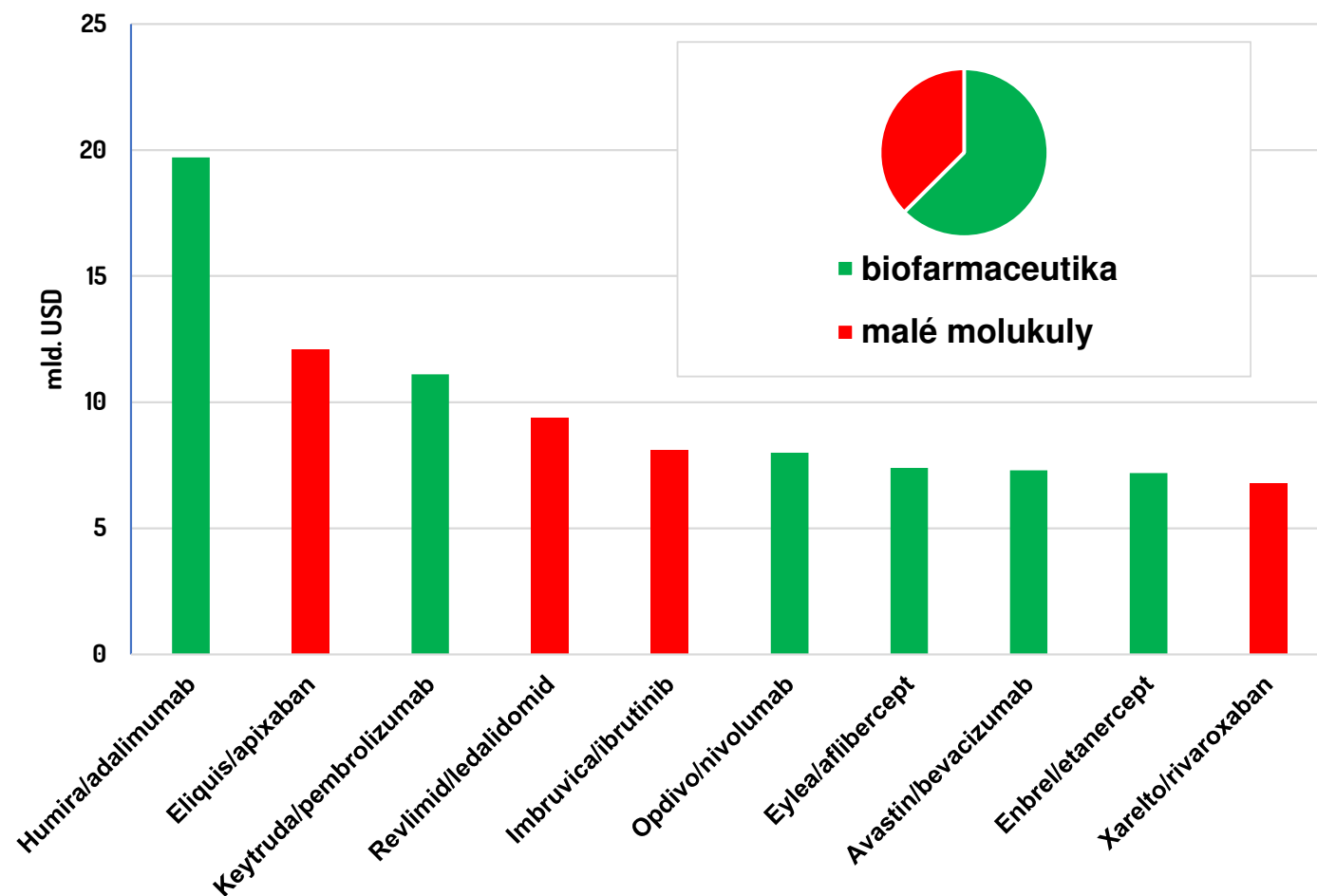


# Analytické výzvy při vývoji biofarmak



# Prodeje biofarmak 2019

## Top 10 - nejprodávanější léky 2019

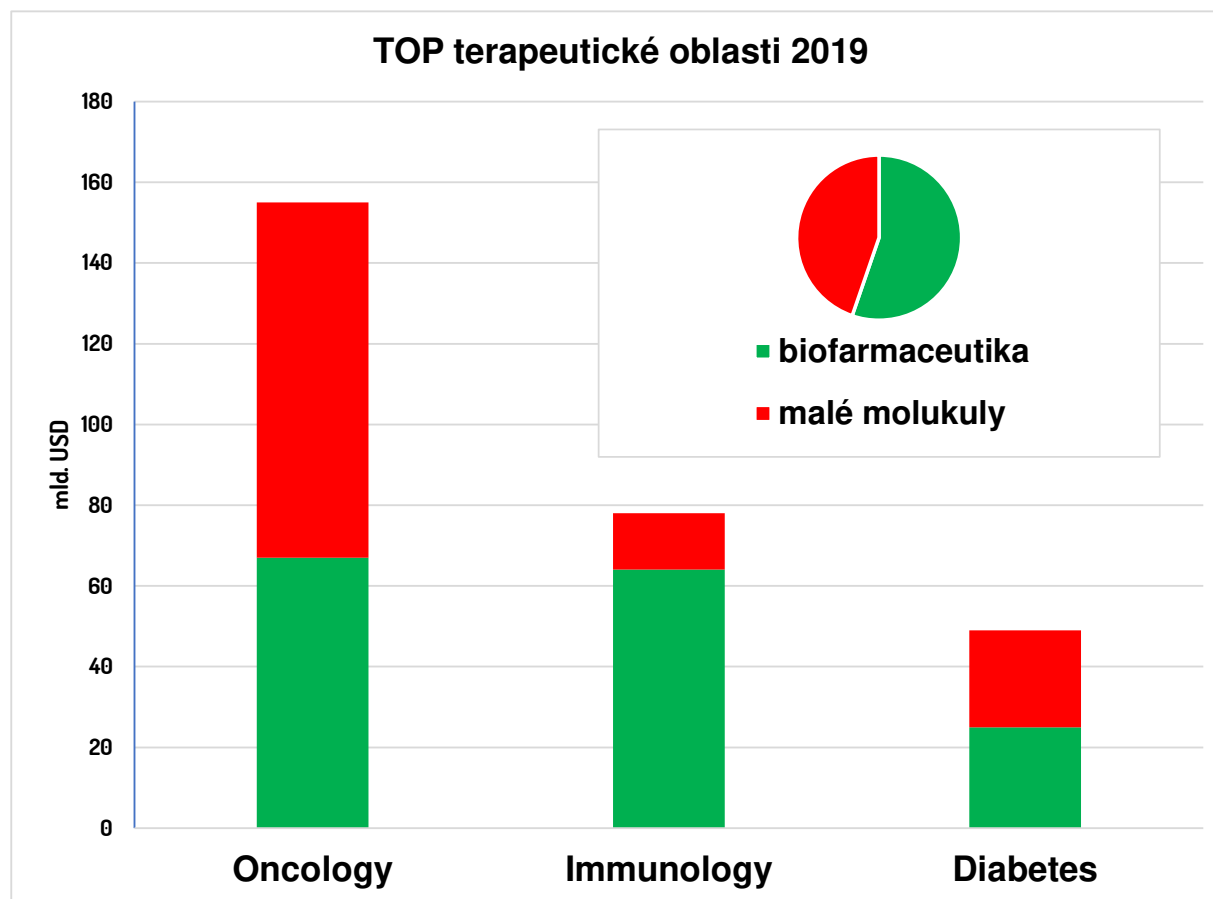


**-UMAB**  
**-XIMAB**  
**-ZUMAB**  
**-ERCEPT**

<https://www.pharmacompass.com/>



# Prodeje biofarmak 2019

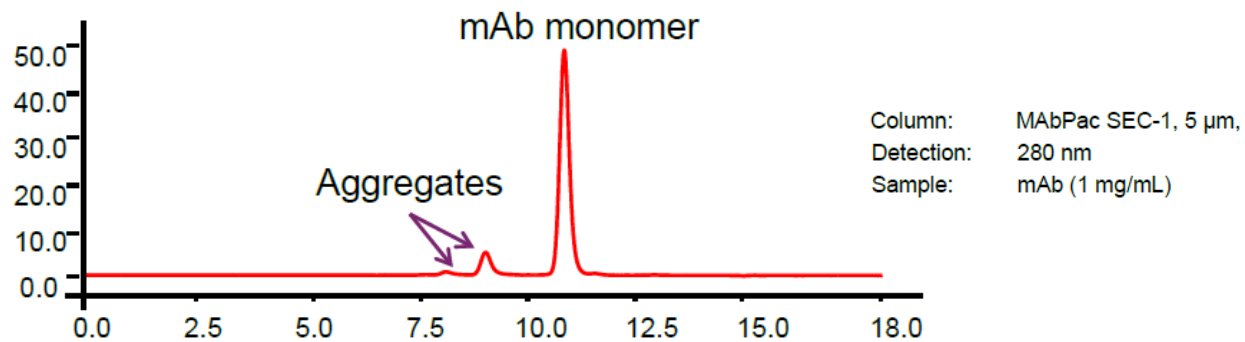


<https://www.pharmacompass.com/>

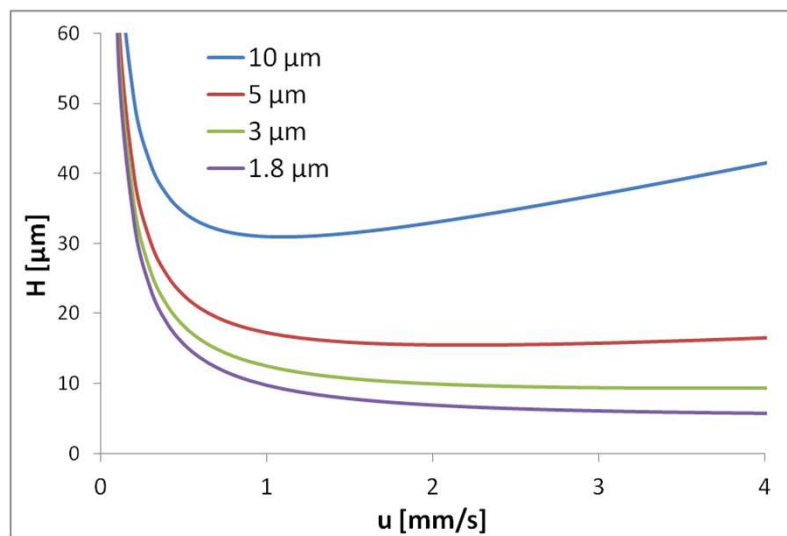




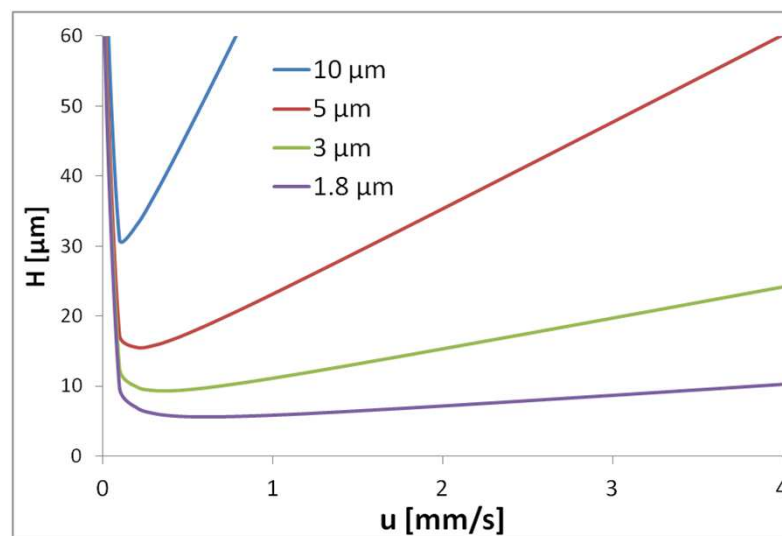
# Chromatografická separace



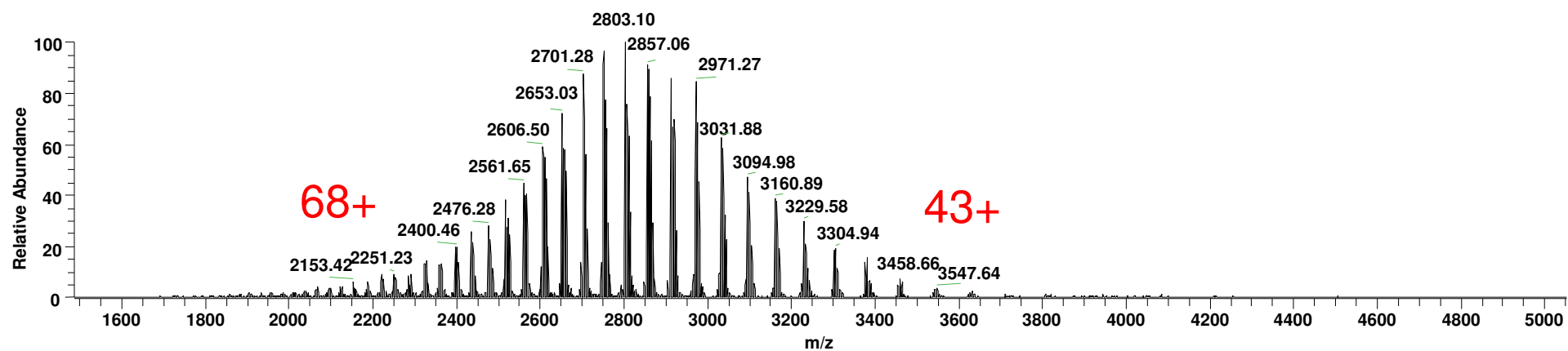
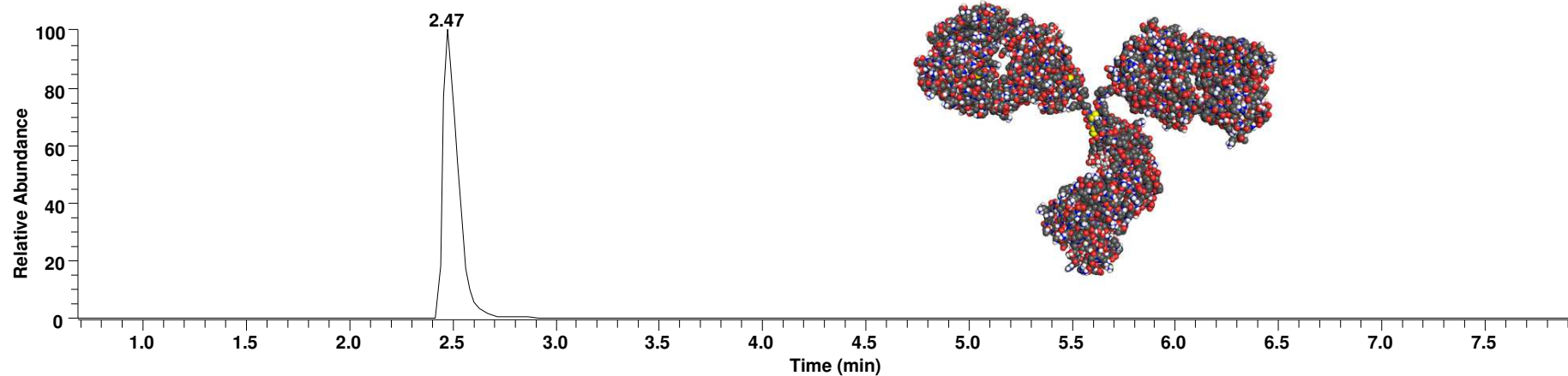
malé molekuly



mAb

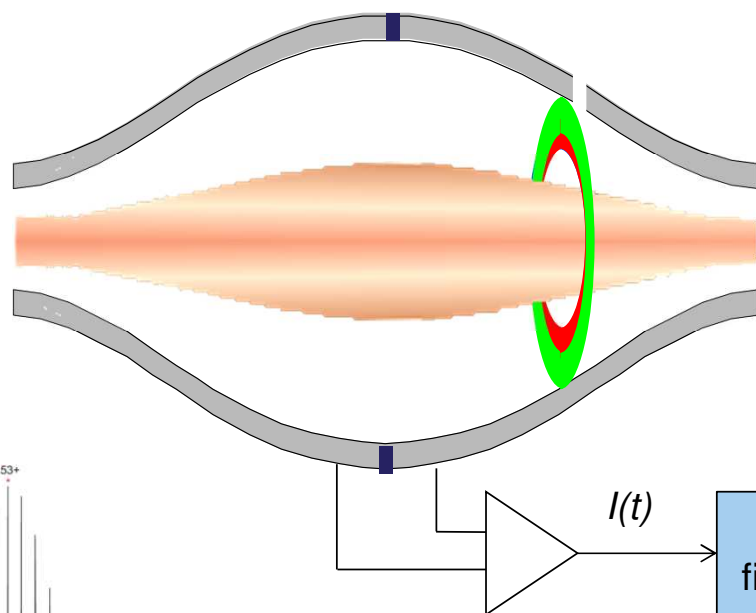


# Hmotnostní spektrometrie, HRMS



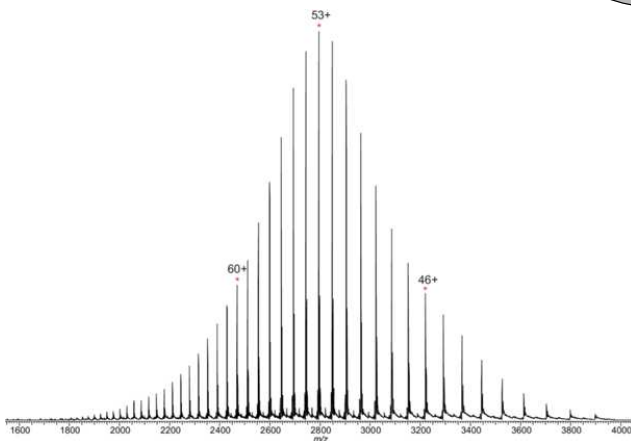
# Orbitální iontová past, Orbitrap

pojem „skenování“ prosím s rezervou

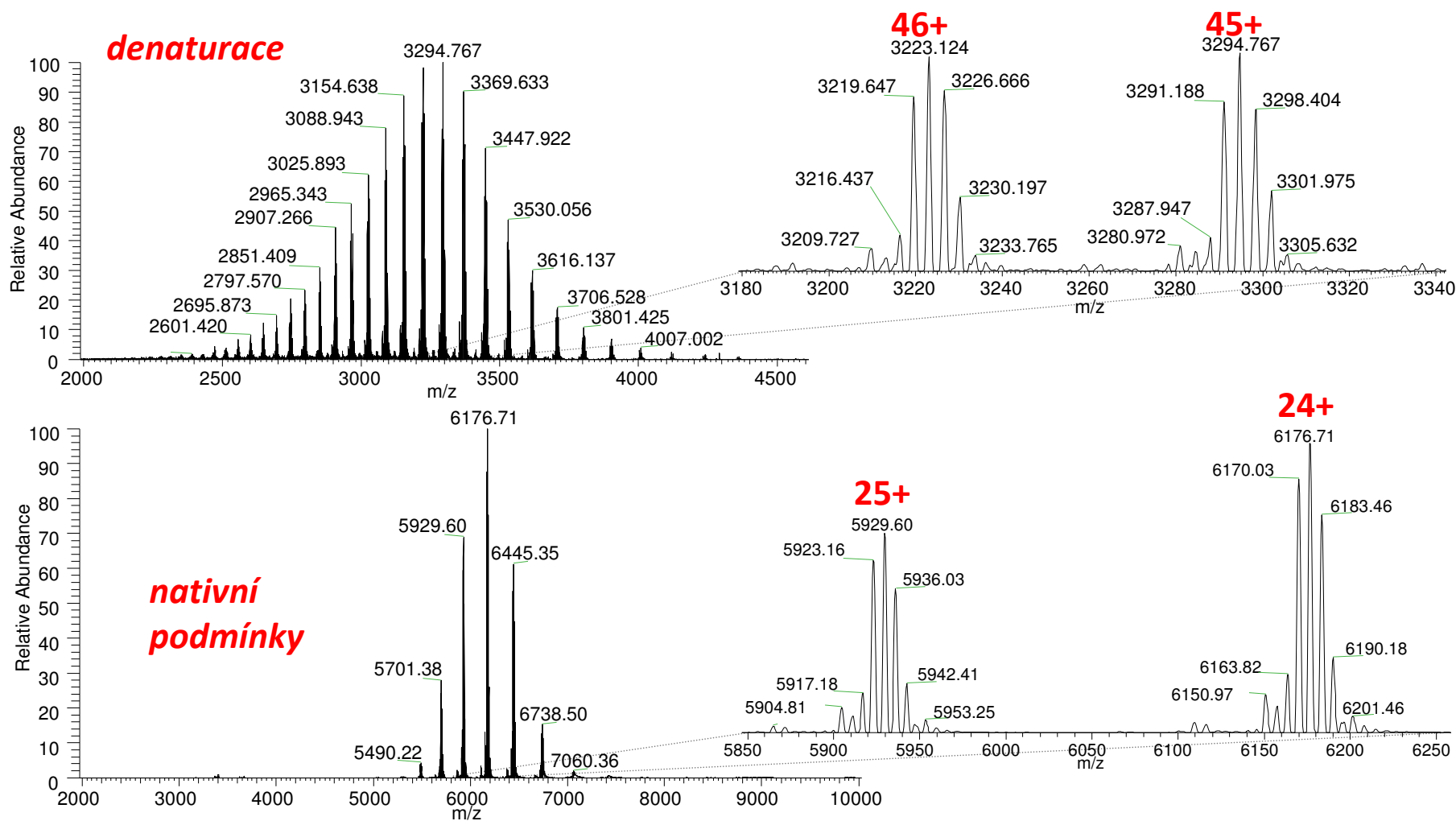

$$F(\omega_m) = \sum_{n=0}^{N-1} f(t_n) \exp\left(\frac{-inm}{N}\right)$$

+ zero filling  
+ apodization  
....

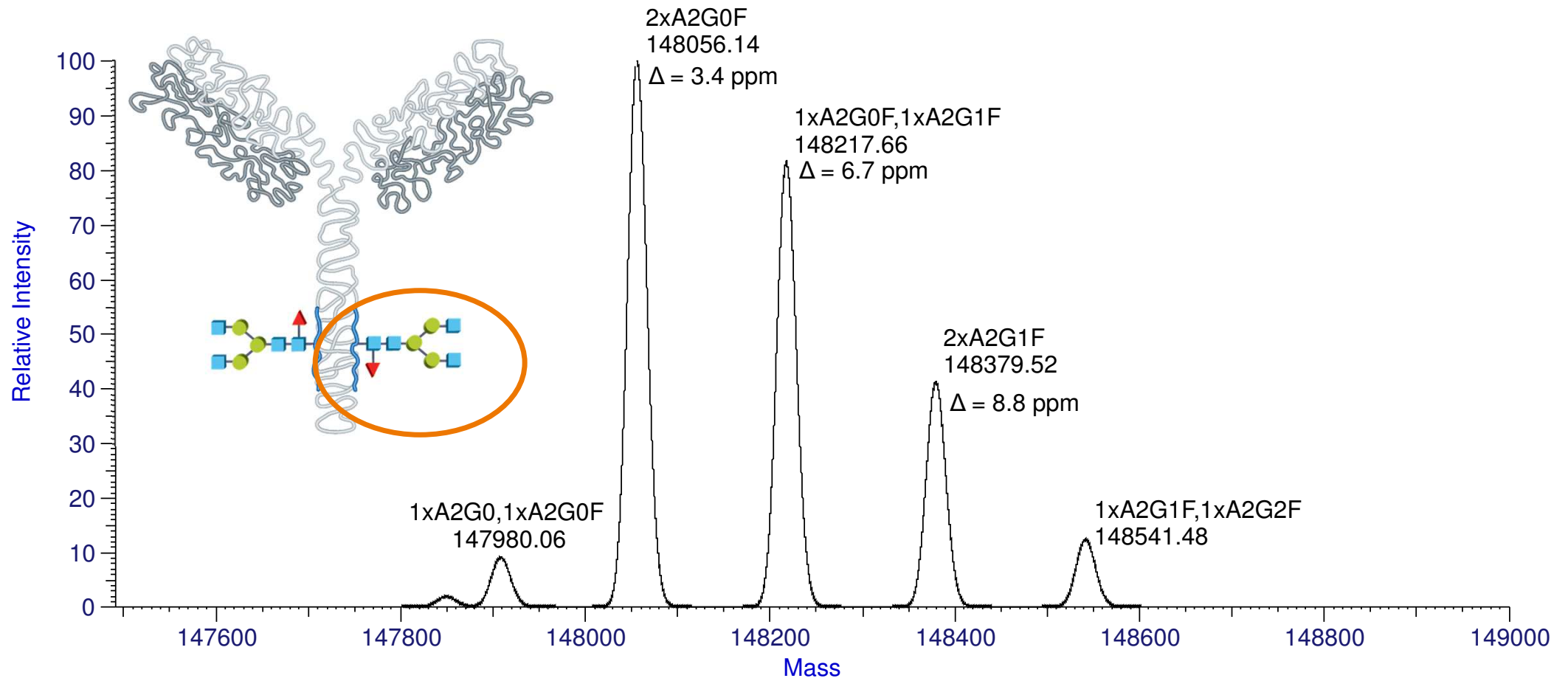
int(m/z)



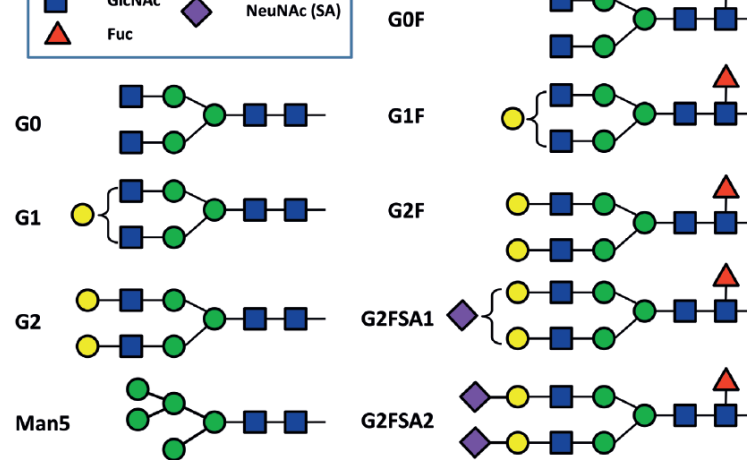
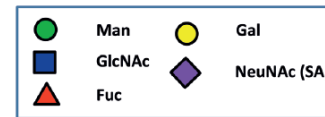
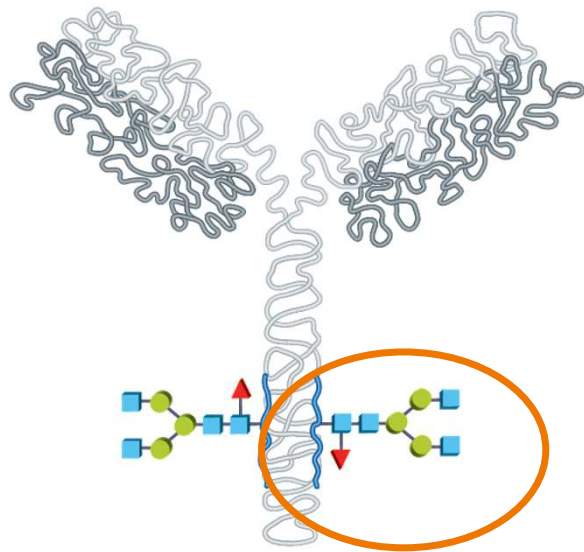
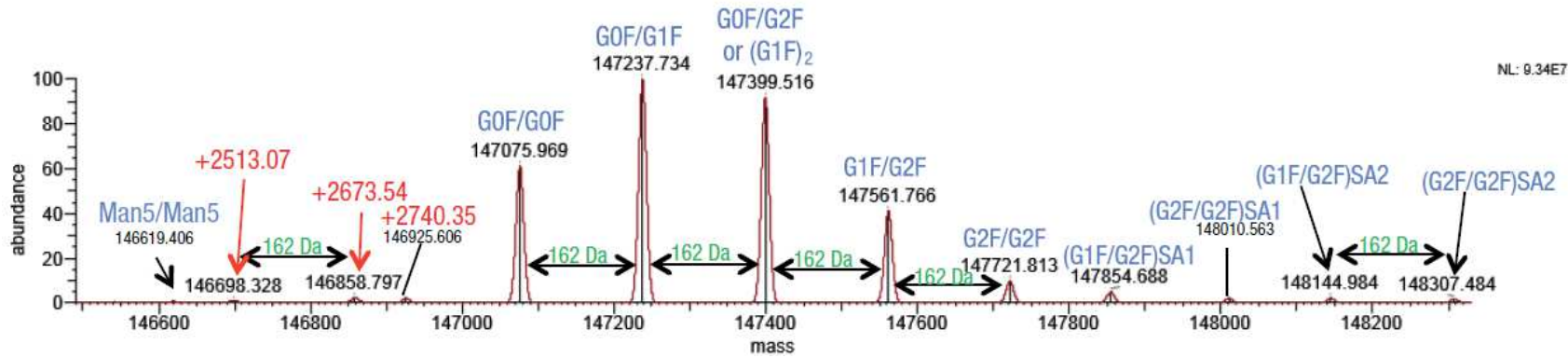
# Hmotnostní spektrometrie, HRMS



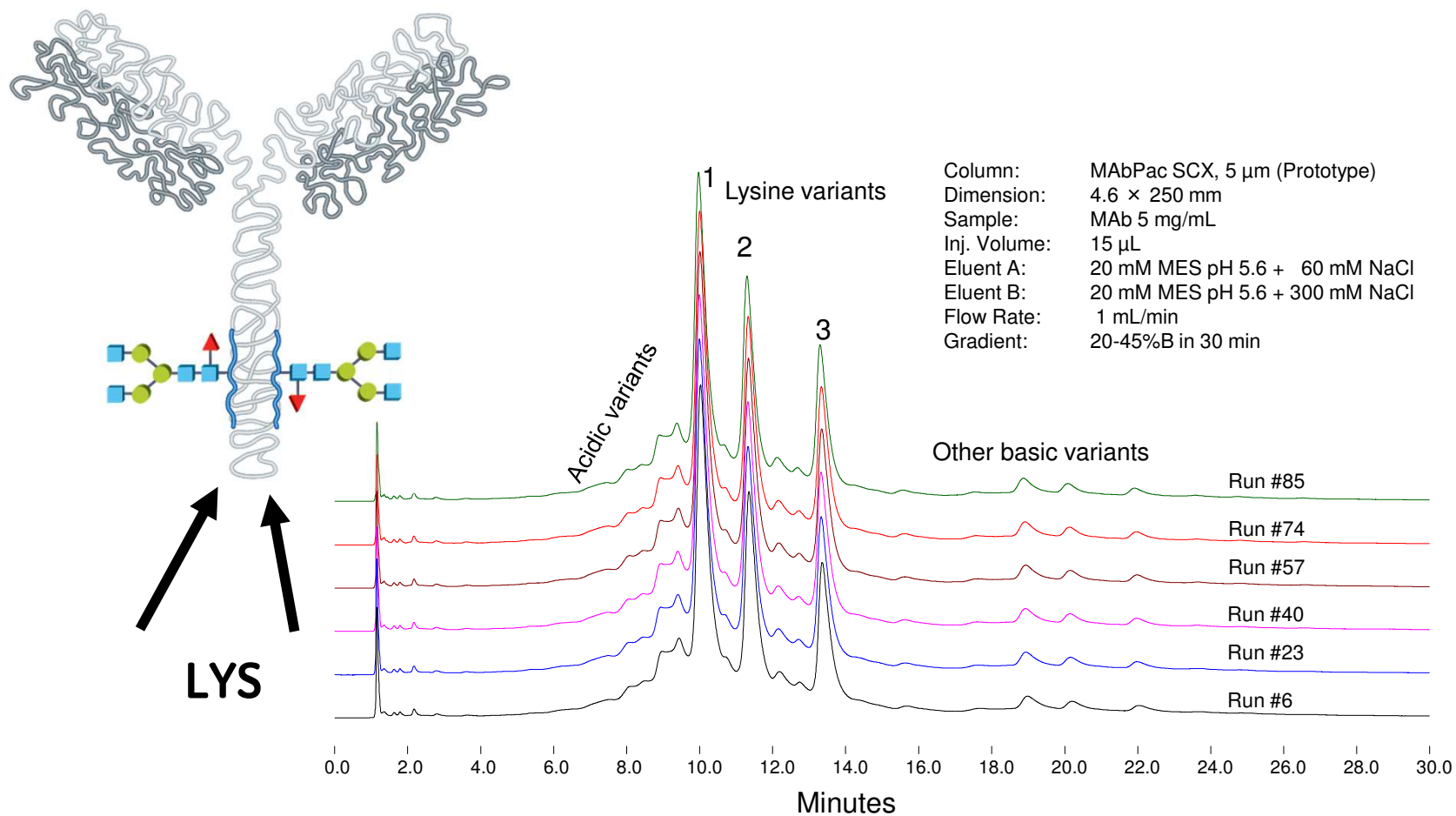
# Glykosylace



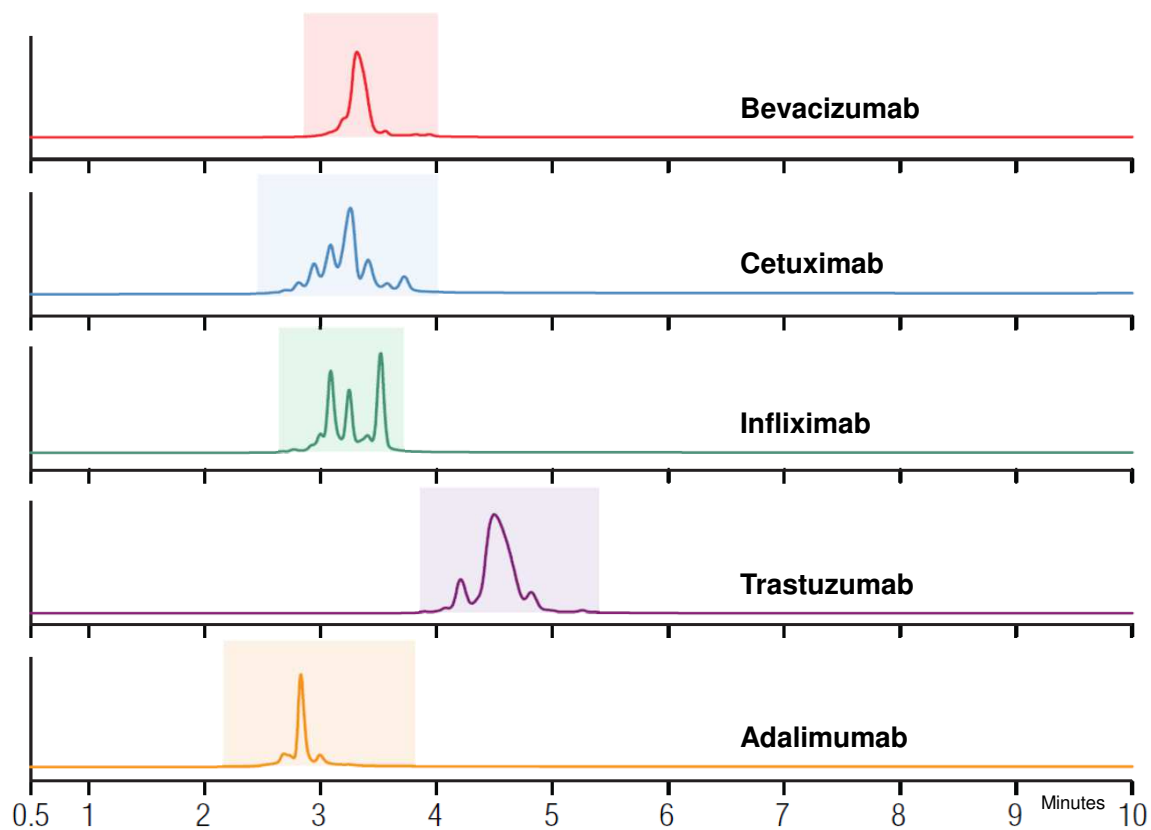
# Glykosylace



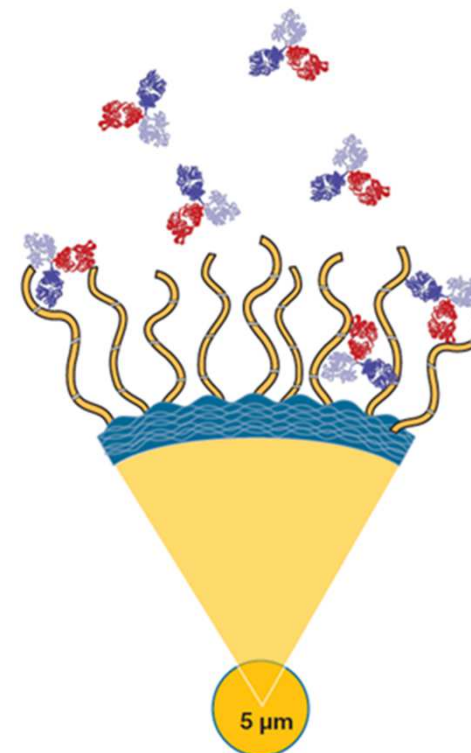
# Nábojové varianty



# Nábojové varianty

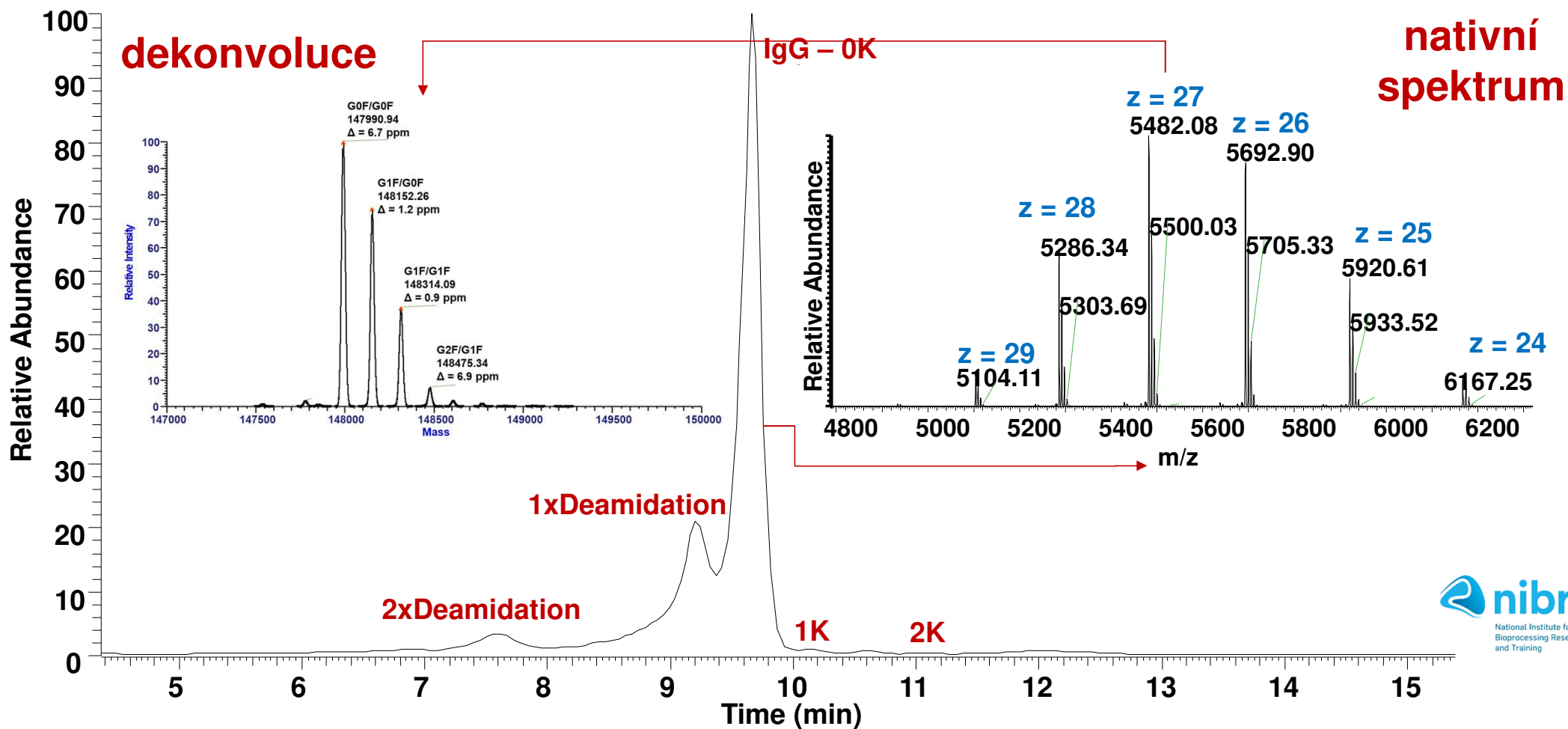


pH 5.6-10.2 in 10 min, **MAbPac SCX-10** (5  $\mu$ m), 2 x 50 mm

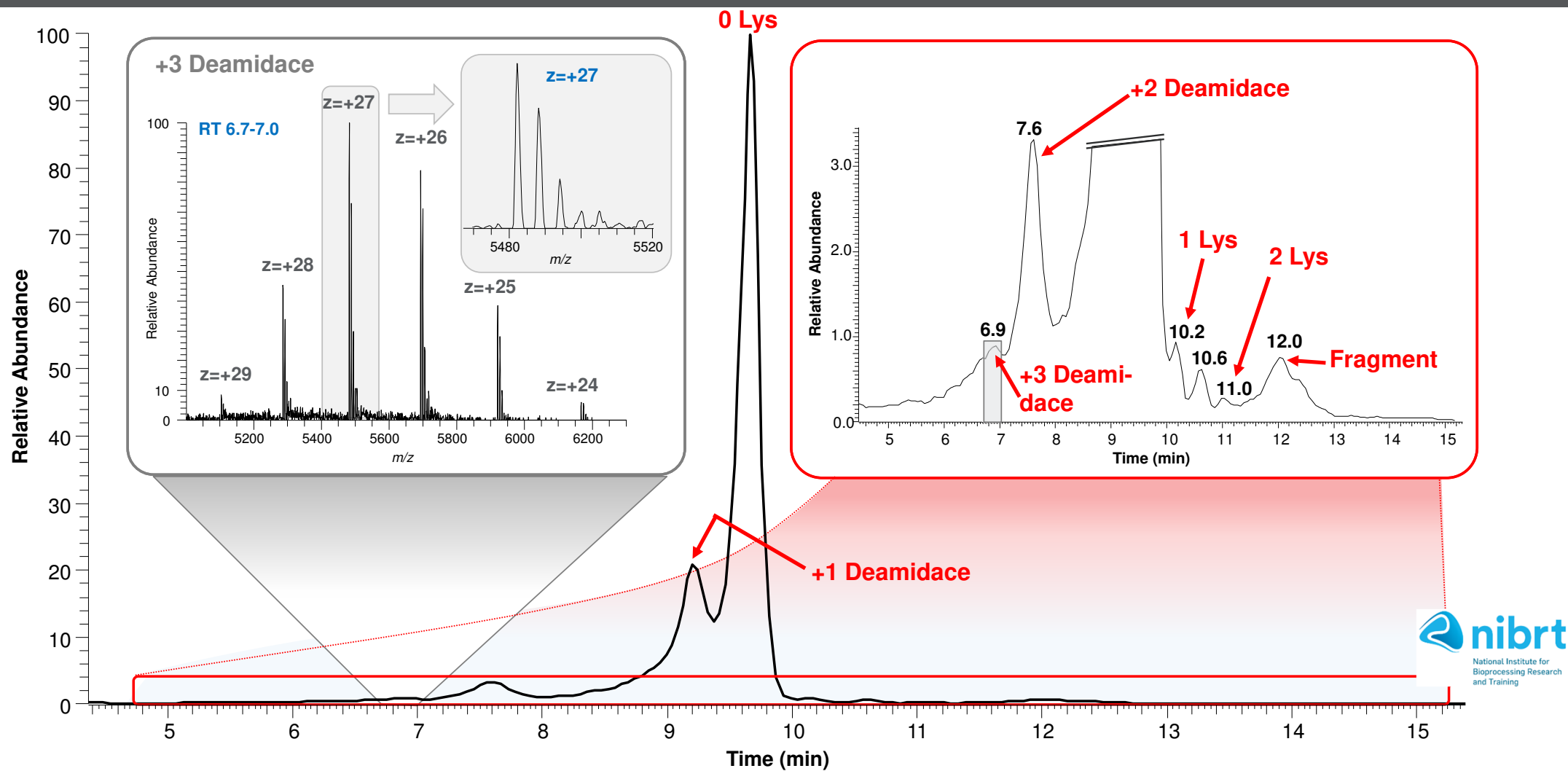




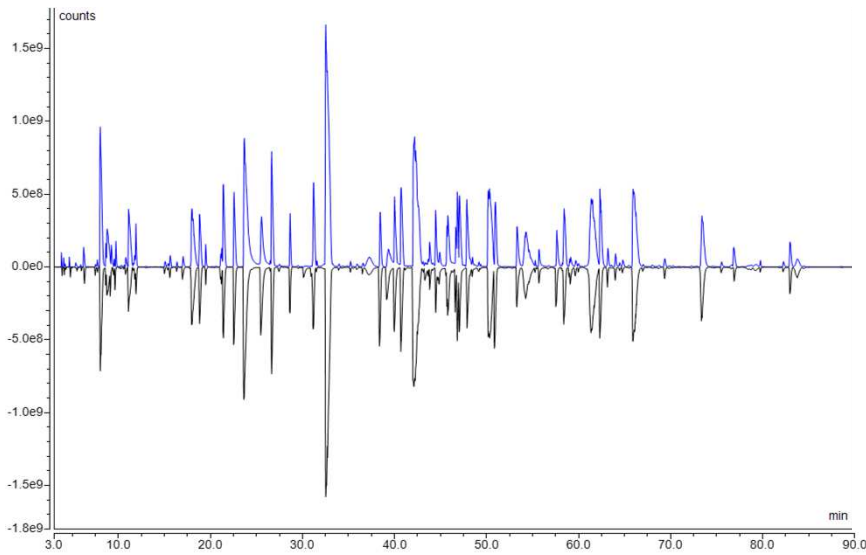
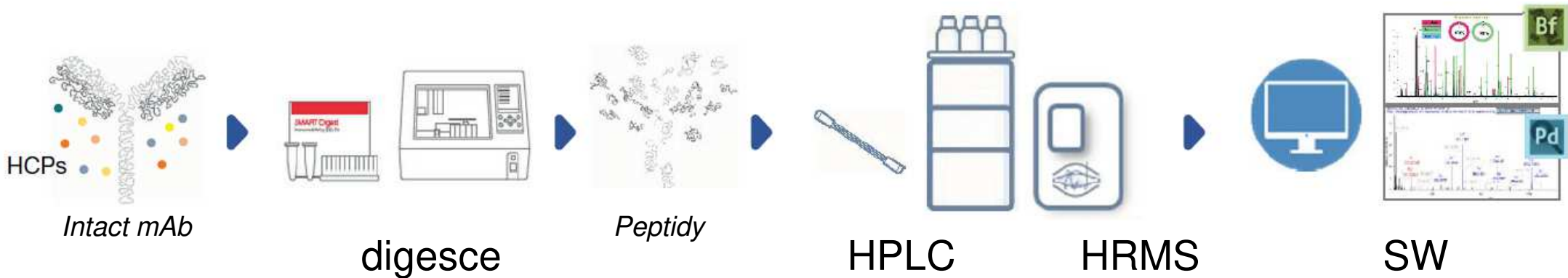
# Nábojové varianty



# Nábojové varianty

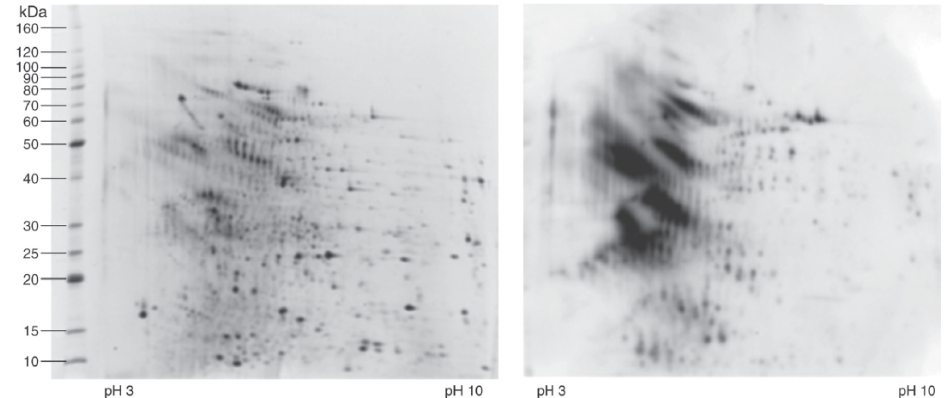


# Host cell proteins



VS.

## SDS-PAGE



USP 39 Published General Chapter <1132>  
 Residual Host Cell Protein Measurement in Biopharmaceuticals





[www.pragolab.cz](http://www.pragolab.cz)



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