

A person with a backpack is sitting on a rocky ledge, looking out over a vast, hazy landscape at sunset. The sun is low on the horizon, creating a warm, golden glow over the mountains and valleys. The person is in silhouette, wearing a light-colored shirt and dark pants.

Anti-PEG antibodies: past, present and future difficulties in a regulated environment

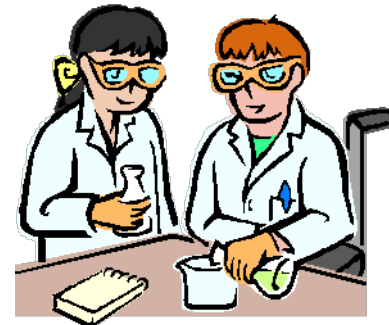
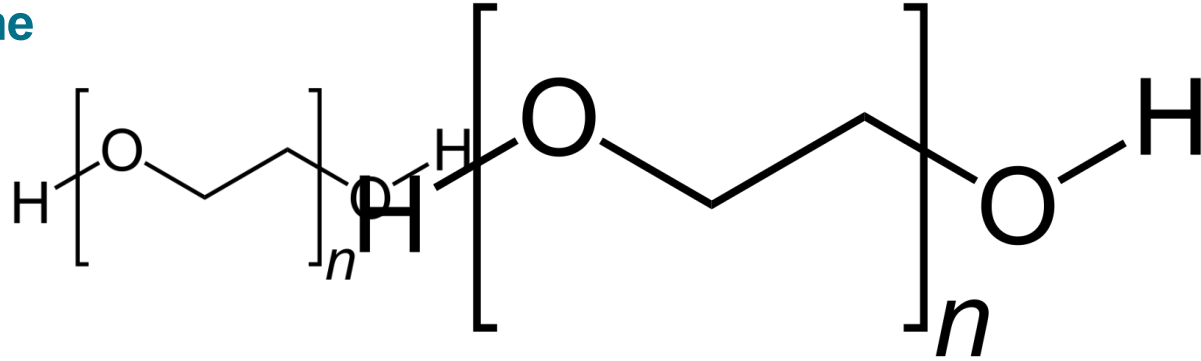
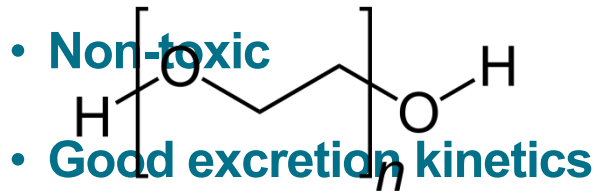
Zoe Whiffen

Scientist, LGC

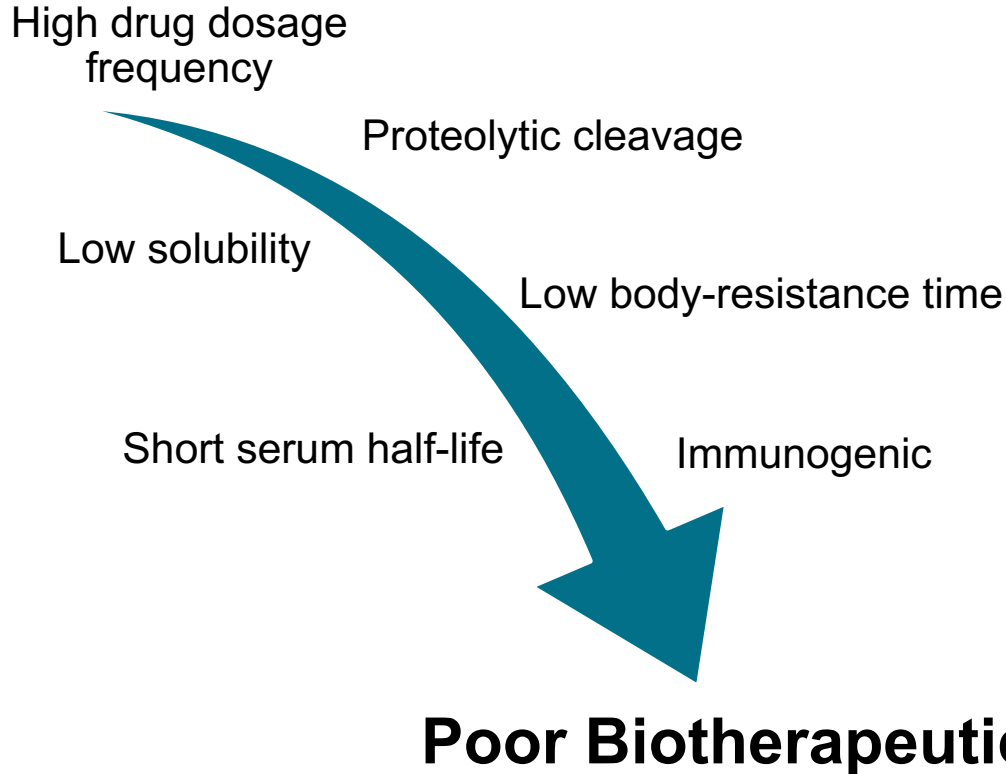
PEG: The basics



- Hydrophilic
- Chemically inert backbone



Common Limitations of Large Molecule Drugs



The Use of PEG

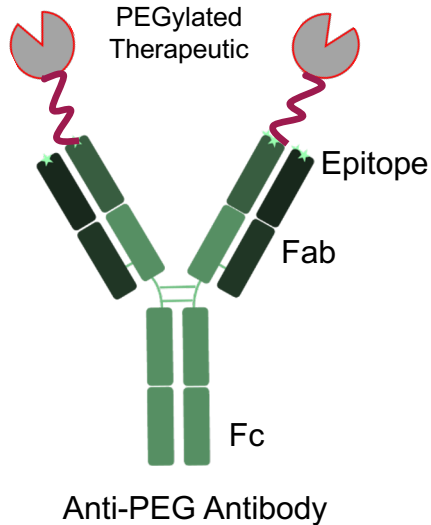


Immunogenicity



Efficacy

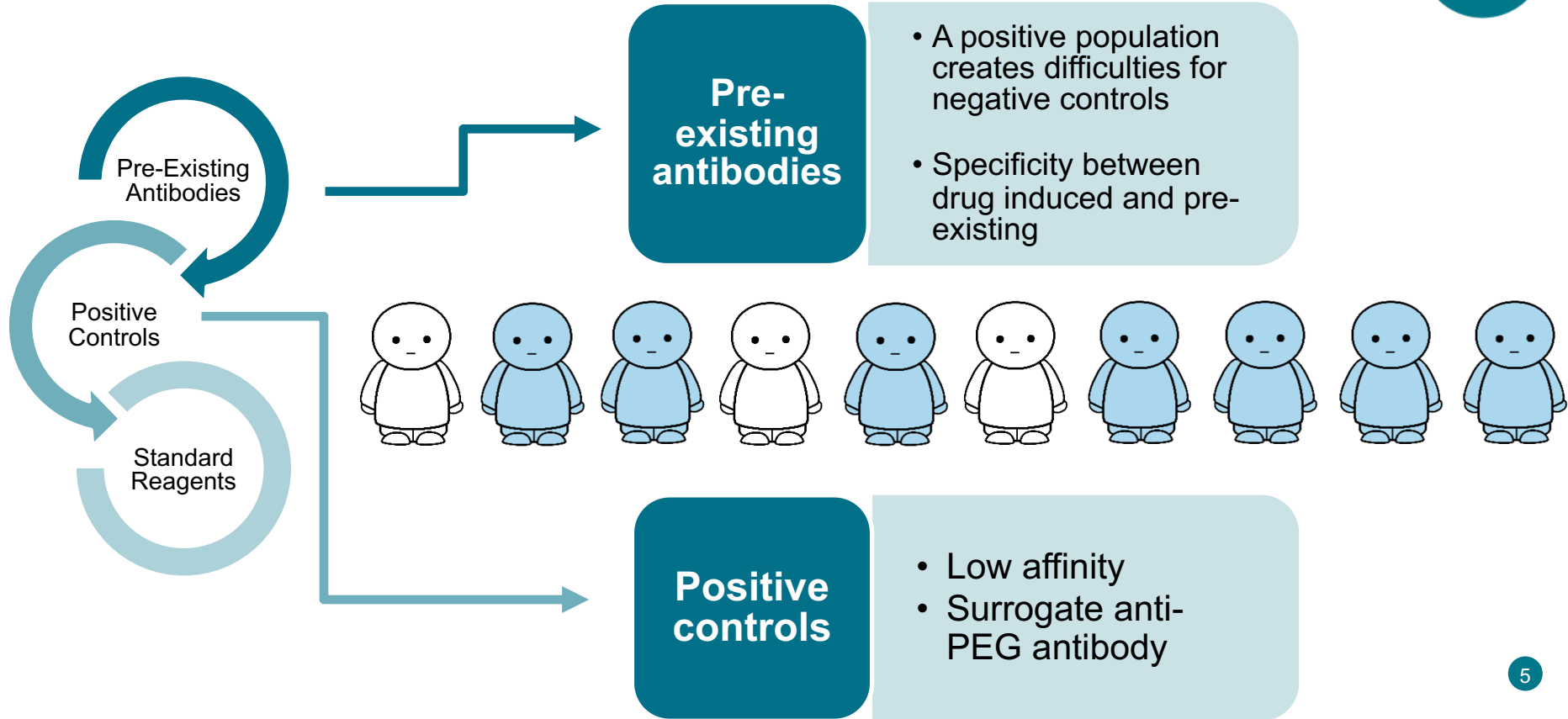
- Neutralising affect
- Changing pharmacokinetic profile
- Reduced clinical response
- Change in biodistribution



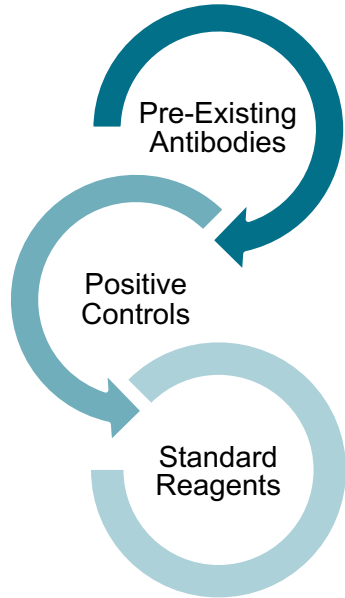
Safety

- Serious adverse events
- Disease progression
- Hypersensitivity reaction

Difficulties of Anti-PEG antibody assays

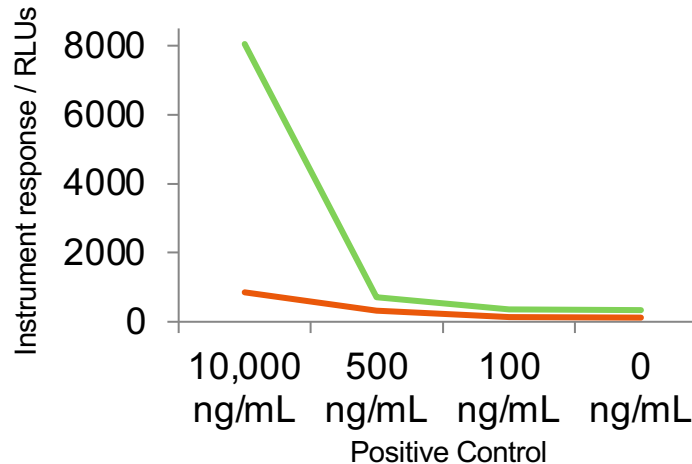


Difficulties of Anti-PEG antibody assays



Standard Reagents

- Interfering detergents
- Surfactants

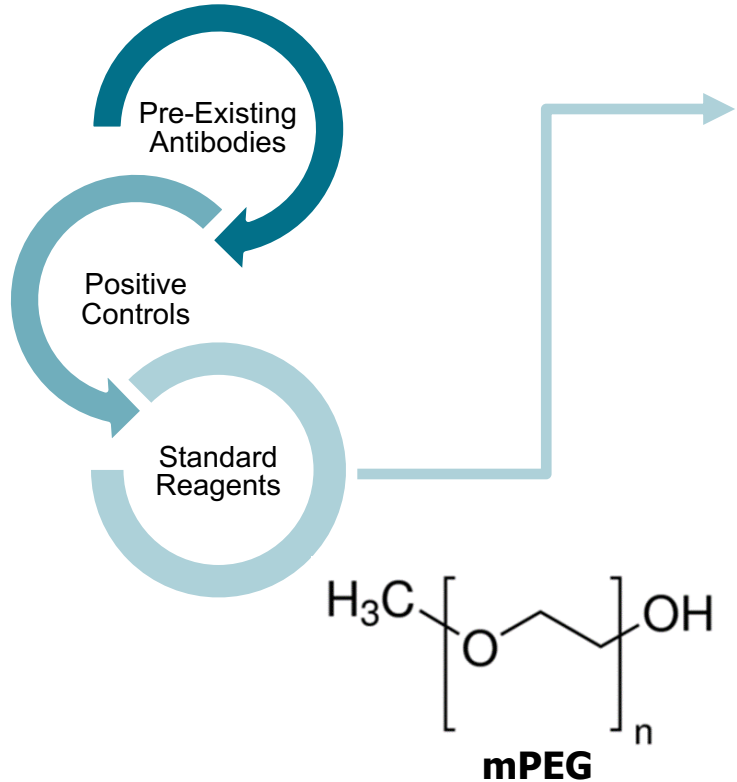


— With Surfactants

— Without Surfactants

Mock data representing previous experience with anti-PEG antibody assays

Difficulties of Anti-PEG antibody assays



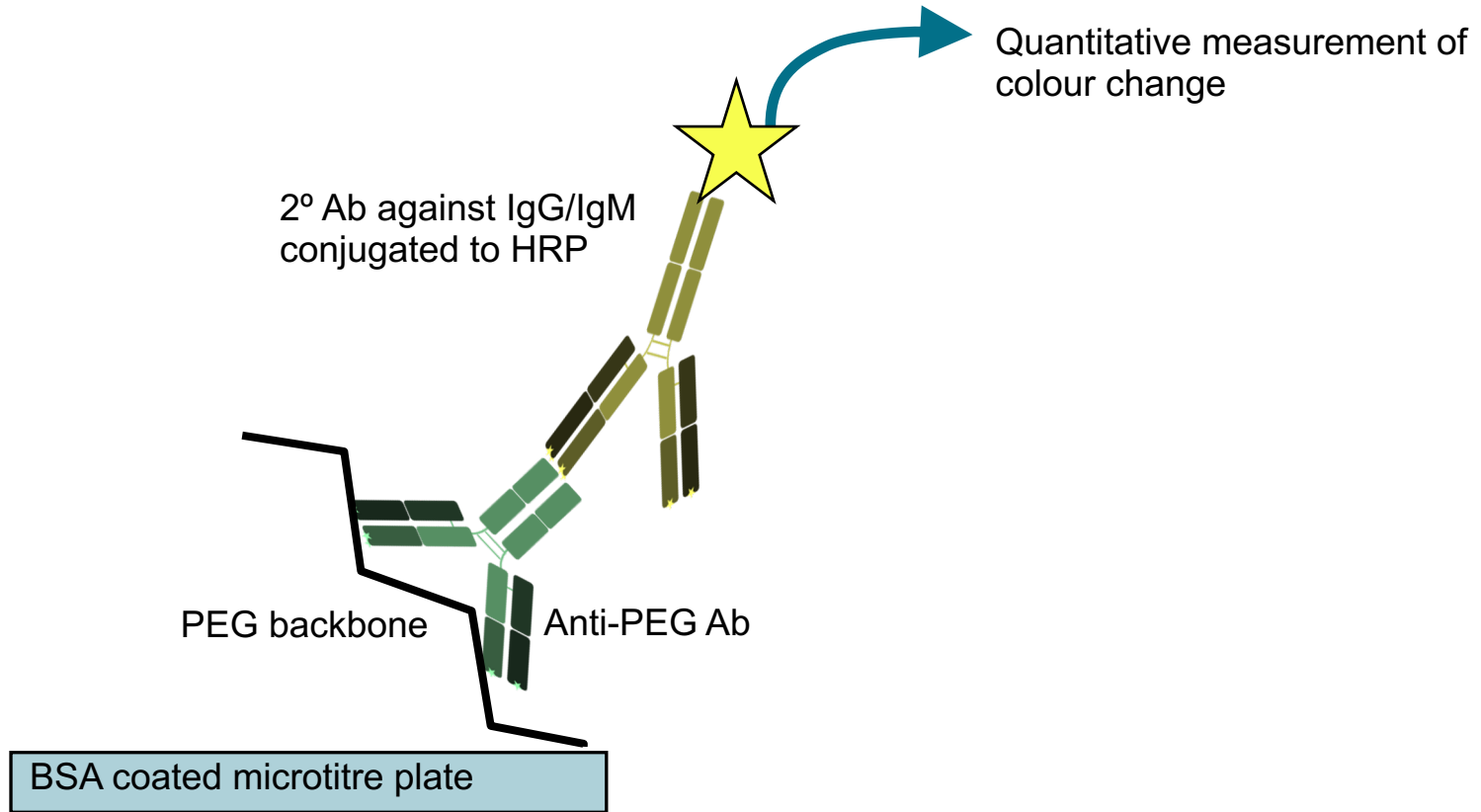
Standard Reagents

- Confirmatory drug

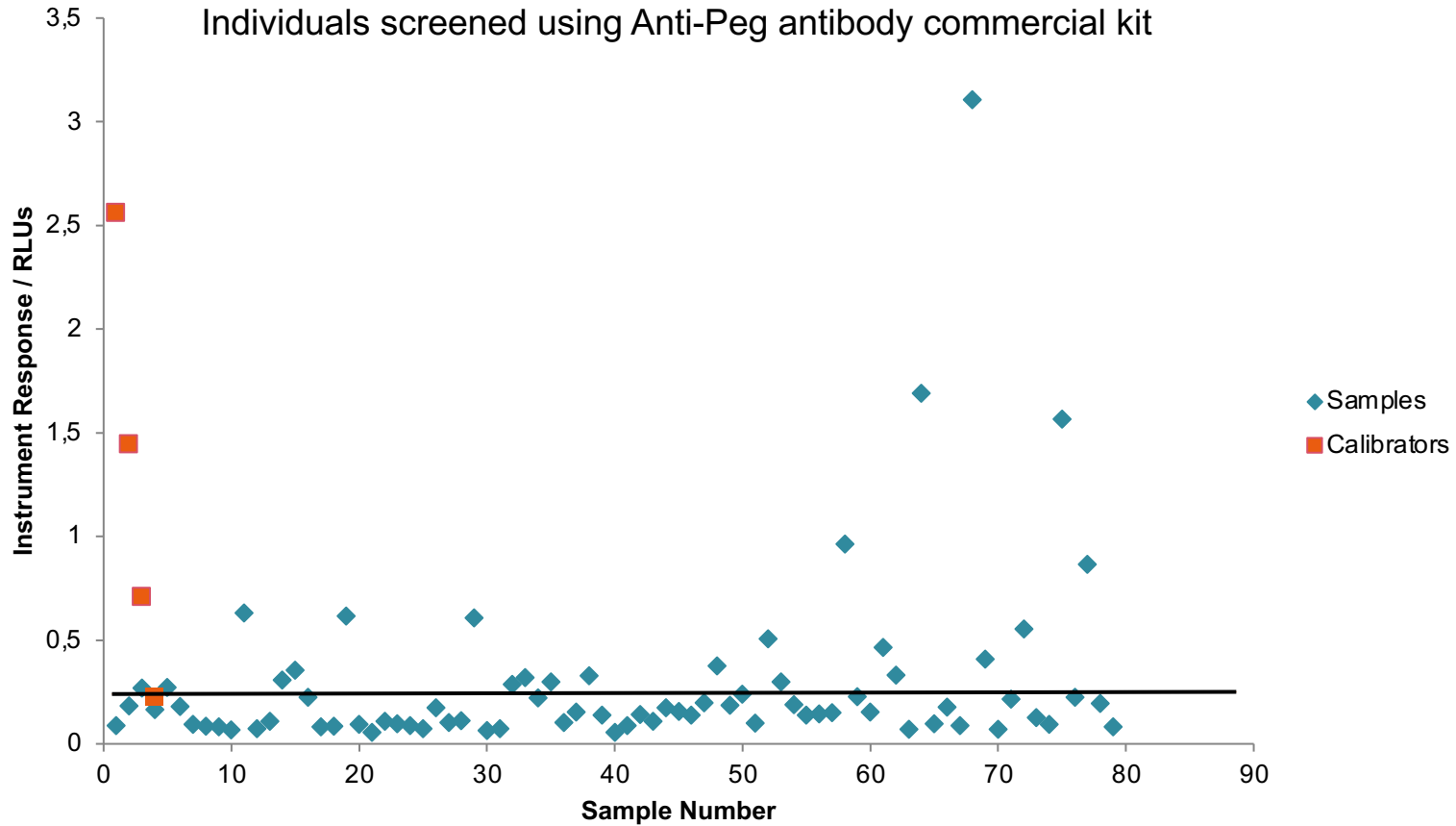
	Screening assay		Confirmatory assay	
	1	2	1	2
High PC	2364	2398	138	131
Mid PC	703	712	139	139
Low PC	127	125	155	162
Negative Control	118	129	133	130
Sample 1	135	123	154	157
Sample 2	144	165	187	187
Sample 3	111	123	245	232
Sample 4	127	122	165	176

Mock data representing previous experience with anti-PEG antibody assays

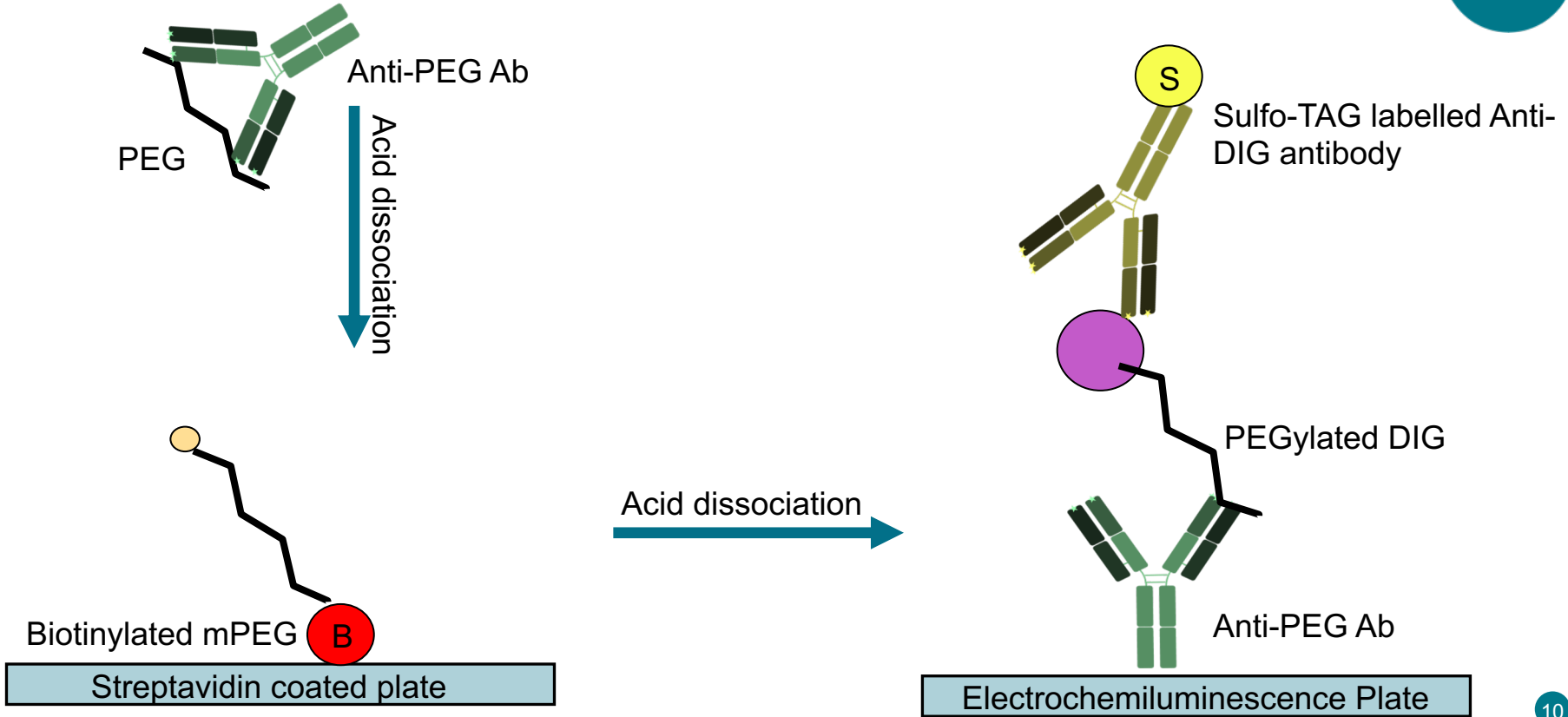
Back to Basics: Anti-PEG antibody kits?



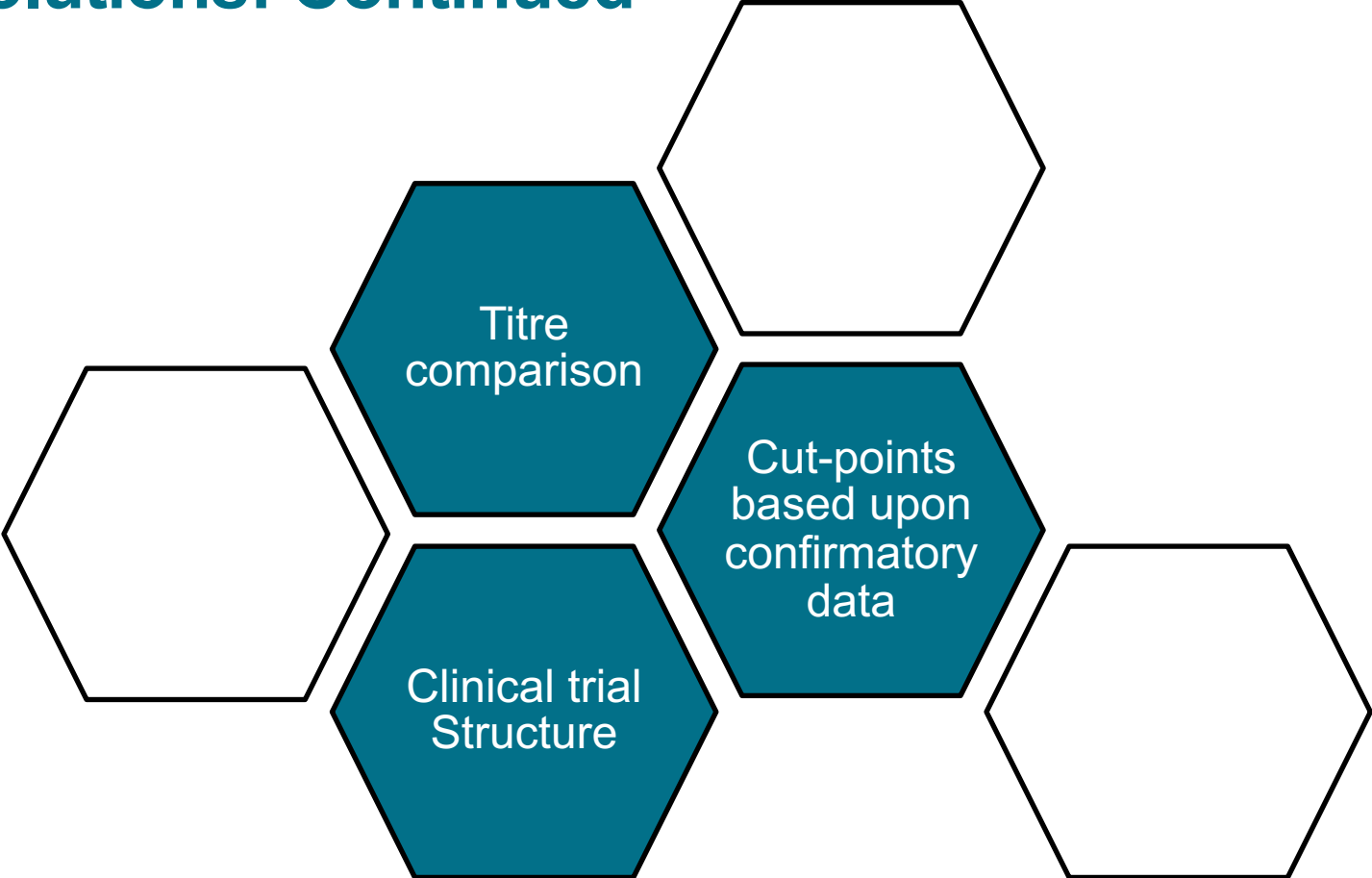
Individuals screened using Anti-Peg antibody commercial kit



Solutions: SPEAD format



Solutions: Continued



Thank you for listening

Any questions?

