BBI Solutions

Monoclonal or Polyclonal Development FAQs

The following are some of the most frequently asked questions we encounter from customers deciding between a monoclonal or polyclonal development strategy.

+ Which approach offers a more stable, reproducible supply?

Monoclonal antibodies have less lot-to-lot variability allowing for more control in long term manufacture and performance. Polyclonal response can change over time with additional immunisations and subsequent production bleeds. To guarantee long term, exact reproducibility with a polyclonal approach, it would be necessary to produce a large single lot.

+ What are the major differences in specificity?

Monoclonal antibodies are specific for a defined, single epitope and can be screened for selection of single epitope specificity. Polyclonal antibodies can be specific for a target antigen, particularly when antigen-affinity purified, but recognition will be across multiple epitopes. The specificity goals of the immunoassay will dictate which is the best choice.

+ Should I use a monoclonal or polyclonal for an anti-drug antibody (ADA) assay?

While the FDA guidelines indicate monoclonal or polyclonal antibodies can be used as a positive control for ADA, the current industry standard is the use of polyclonal antibodies. For PK assays, we recommend a monoclonal approach to reach the required specificity.

+ What advantages are possible with a monoclonal/polyclonal matched pair?

This can be beneficial for matched pair goals that require capture of multiple variants, related bacterial or viral strains, or rapidly changing pathogens. Also, the increased avidity of a polyclonal can improve capture, while monoclonal detection can improve specificity.

+ What are the budget and timing differences between the two services?

It varies depending on the quantity of antibody you require. The timeline to develop polyclonal antibody can be considerably shorter (4 months) compared to a longer development time required for a monoclonal (6-8 months). However, if you require a large quantity of antibody from a single lot, then the bleed schedule for polyclonal production can take longer than a single *in vitro* monoclonal batch production. Polyclonal is generally a more cost-effective method of obtaining a large quantity of antibody however purification and polishing requirements could narrow that cost difference.

+ What are the sensitivity differences between monoclonal and polyclonal antibodies?

This varies between antibodies of both types, but the recognition and binding opportunity across multiple epitopes can often increase the sensitivity and overall avidity in an assay. However, polyclonal sera may increase the likelihood of an elevated background signal due to cross-reactivity or sample matrix interference.

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Development & Production	Purification	Characterisation
+ Hybridoma development	+ Protein A purification	+ ELISA
+ Polyclonal antibody development	+ Protein G purification	+ Western Blot
+ *In vitro* roller bottle production	+ Antigen affinity purification	+ SDS-PAGE
	+ SEC polishing	+ Isoelectric Focusing (IEF)
	+ Low endotoxin purification	+ Endotoxin testing
		+ Matched pair evaluation
		+ SEC

Monoclonal Antibody Development Key Features and Benefits

Antigen Analysis	Option to receive a custom report, prepared by an immunologist, to identify the right antigen strategy for any goal
Detailed Project Plan	Identify goals, reagents, screening strategies and set contingency plans to ensure timely development
MultiPure	Generate purified discovery grade antibodies (typically 200ug to 800ug) from fusion candidates during hybridoma development to select clones based on end-use performance
Characterisation Assays	Characterise antibody candidates beyond standard indirect ELISA screening, so only the right antibodies go to subcloning
Technical Support	Hands-on support from project managers, technical sales team and immunology experts to interpret data and communicate options at every project milestone

Polyclonal Antibody Development Features and Benefits

Multiple Species Available	Rabbits, sheep, or goats are available to accommodate specificity and volume needs
Custom Purification Options	Purification of polyclonal serum is available by protein A affinity, protein G affinity, or custom antigen affinity columns
Coordination of Mono/ Poly co-developments	When customers are developing monoclonal and polyclonal antibodies together, the BBI technical team can integrate both strategies when screening to ensure final assay goals are met

Contact BBI Solutions today to develop the right antibodies for any application

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