

RAPID TRANSITION FROM DISCOVERY TO DEVELOPMENT

Following identification of a Fab candidate in discovery, the candidate was rapidly screened in 1000 unique expression strains at the 0.5mL scale. Several expression strategies were evaluated including a variety of secretion leaders directing transport of the heavy and light chains to the periplasmic space, in combination

with an array of host strains. Soluble target protein expression was assessed by binding activity using biolayer interferometry, and several high activity strains were identified (red dots). An interim standard was produced from a high activity production strain identified at the 0.5mL scale to support

further strain assessment. Several high activity strains were advanced to fermentation assessment to evaluate robustness. From a selected strain and fermentation process, 0.5 g of highly pure, properly folded Fab was delivered for further testing, less than 10 weeks from the initial gene cloning.

