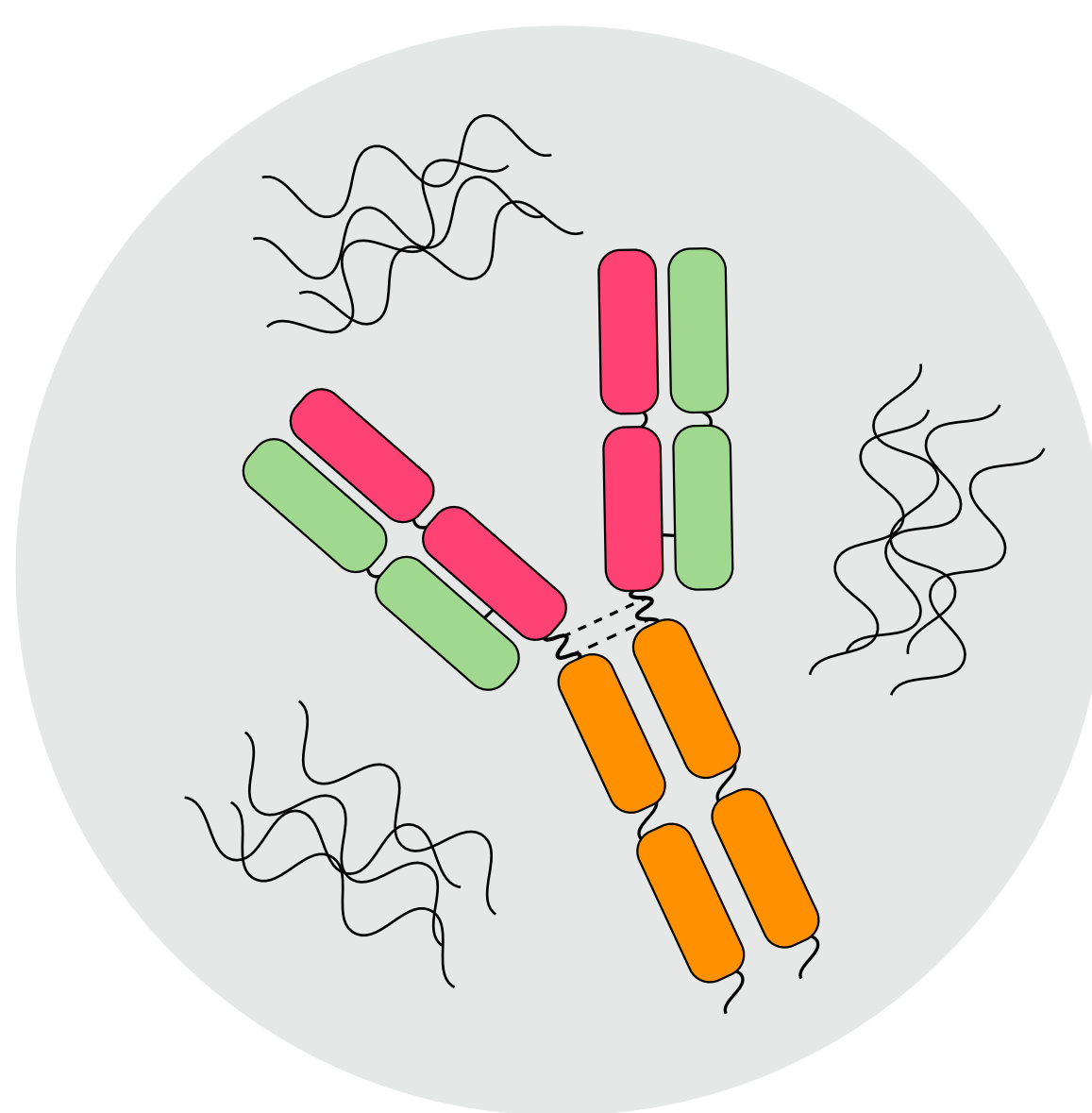
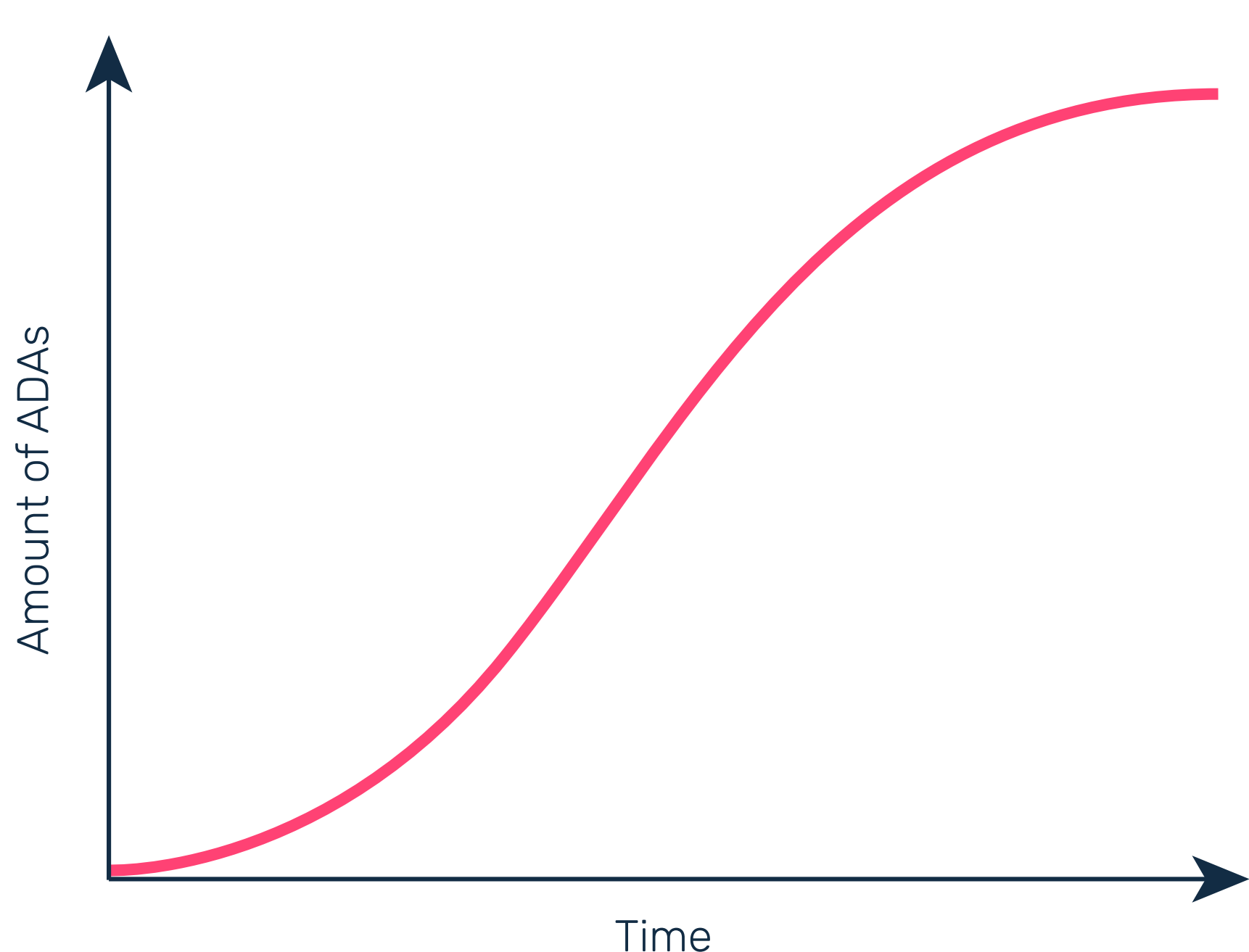


The **FACTS** about anti-drug antibodies

The potential for a drug to induce an immune response in patients may be a critical factor in its clinical success. Anti-drug antibodies (ADAs) can impact the efficacy of the drug as well as lead to adverse safety events, so it is necessary to have in place a bioanalytical assay that can accurately determine the ADA response in patients.

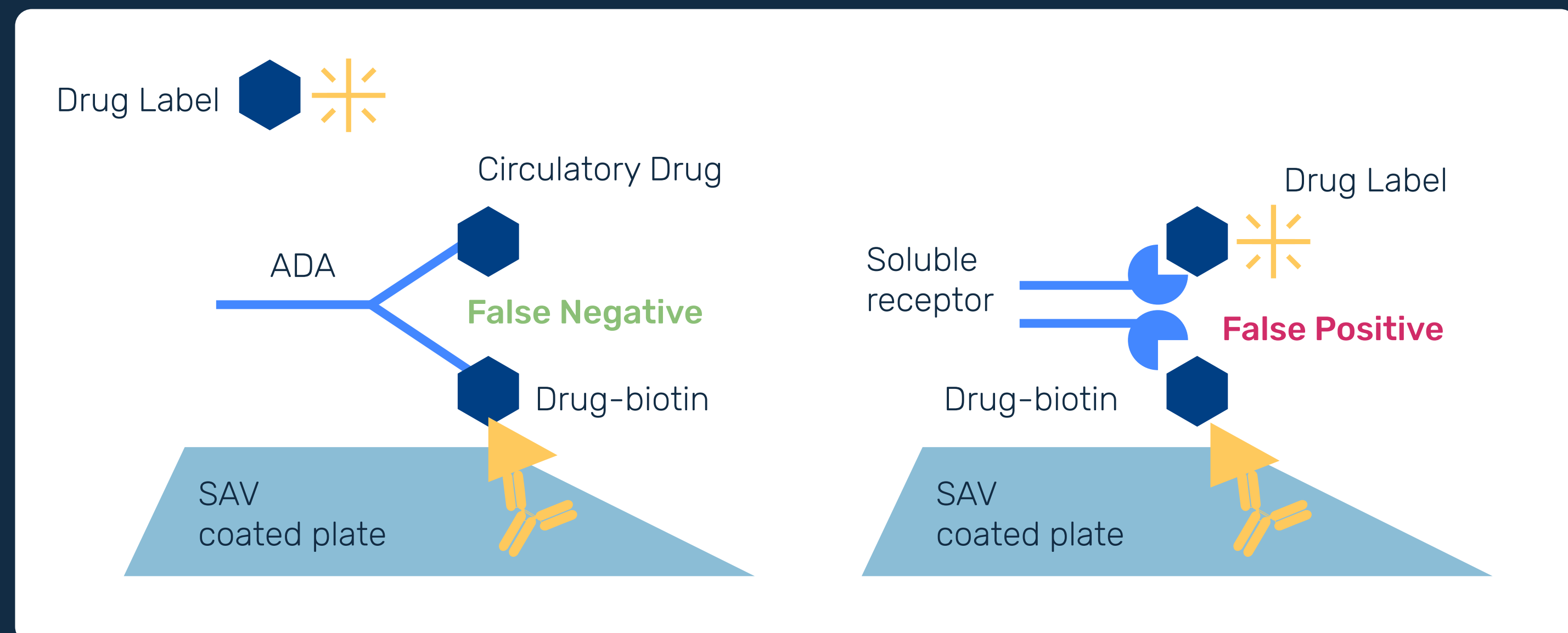
What are ADAs?

- ADAs are produced by the patient's immune system after dosing with drugs.
- ADAs can lead to enhanced drug clearance and/or block drug binding to target, both of which can result in reduced efficacy. In rare instances the ADAs can trigger adverse safety events such as anaphylaxis.



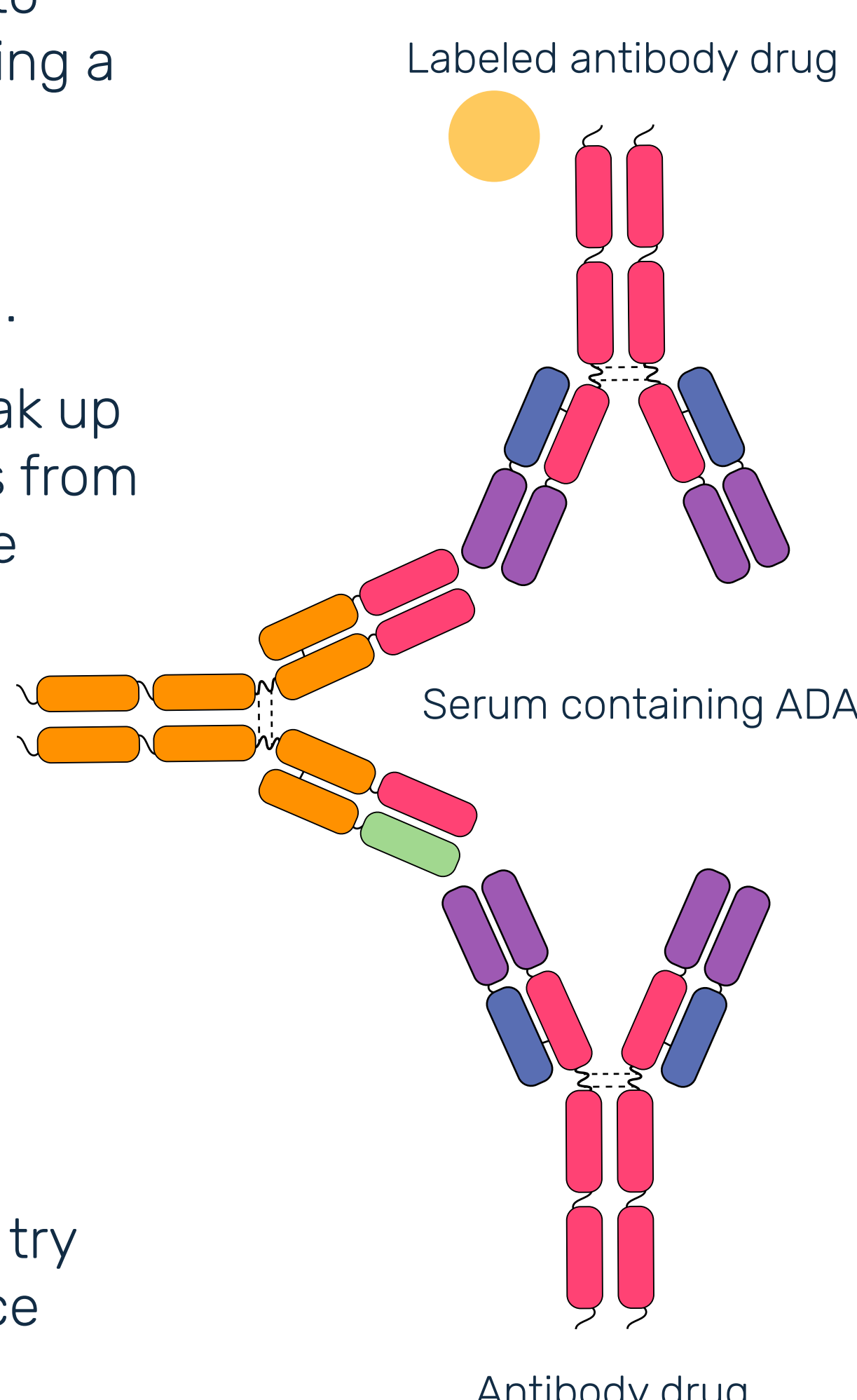
Why is drug tolerance an important factor in ADA assays?

- ADA assays are an important bioanalytical tool; these assays need to be sensitive, robust and reliable.
- Circulating drug can interfere in the ADA assay resulting in false negative results.
- There are several tips and tricks that bioanalytical scientists can employ to improve the drug tolerance of the ADA assays.



Tips and tricks to improve drug tolerance in ADA assays

- A starting step to improve drug tolerance is to increase the incubation time in the assay using a homogenous bridging format.
- If that does not achieve the required drug tolerance, sample pretreatment can be used.
- Sample pretreatment often uses acid to break up the drug/ADA complexes, isolating the ADAs from the sample and then running them in the bridging assay. There are multiple methods that involve acid dissociation including:
 - 1. ACE** (affinity capture and elution)
 - 2. SPEAD** (solid phase extraction with acid dissociation)
 - 3. BEAD** (biotin-drug extraction and acid dissociation)
- Each ADA assay is unique so it is possible to try multiple methods of improving drug tolerance before settling upon the final format.



This infographic has been created as part of a Bioanalysis Zone feature in association with BioAgilytix.