



GenScript

Make Research Easy

In Vitro Diagnostics

Target
Identification



Assay Design
&
Optimization



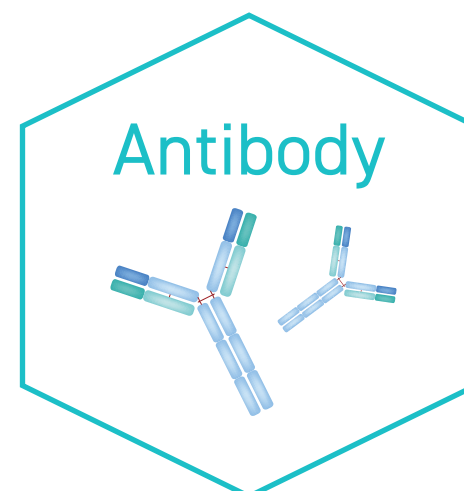
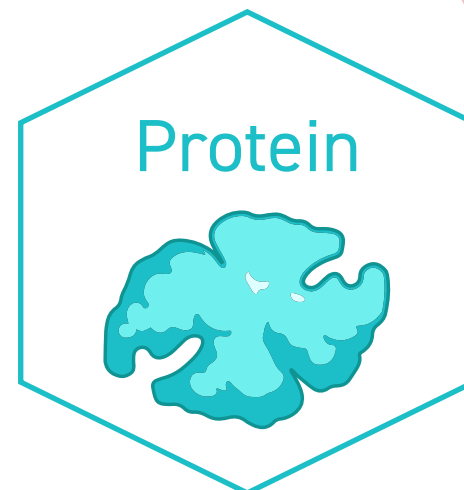
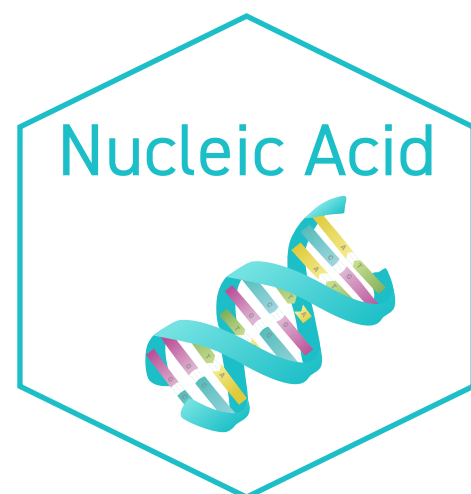
Assay Production
&
Quality Control

01

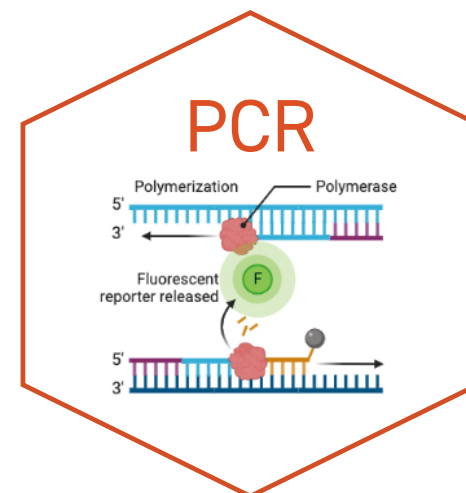
Target Identification

IVD development generally starts with selecting a disease or condition to target and identifying potential biomarkers associated with it.

- Clinical utility
- Cross-reactivity
- Reproducibility
- Stability
- Sensitivity
- Specificity



Optimization ensures that the assay is sensitive, specific, and robust enough to accurately detect the biomarker. This involves fine-tuning the assay parameters, such as reagent concentrations, incubation times, and detection methods.



02

Assay Design & Optimization

03

Assay Production

Rigorous quality control measures are the foundation of assay reliability, reproducibility, and consistency.

- Raw material qualification
- In-process testing
- Final product testing
- Regulatory requirements

Quality Control

- ISO 9001:2015
- ISO 13485





Overcome barriers in assay development

