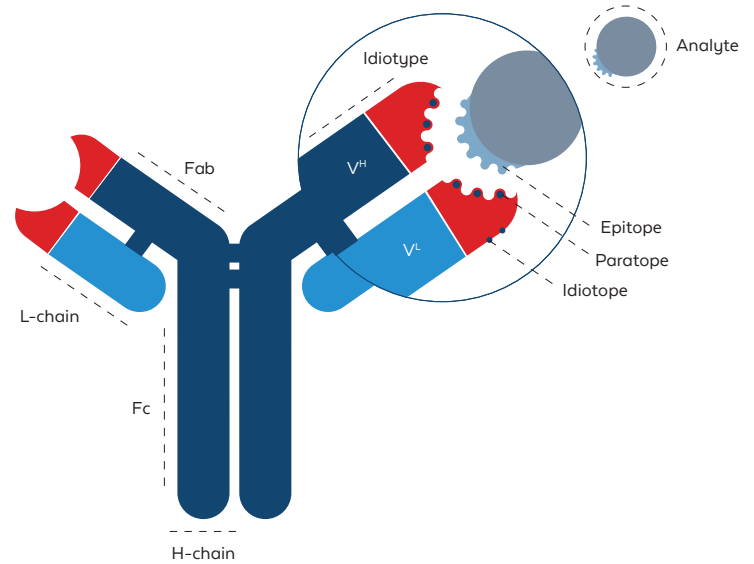


## ANTI-IDIOTYPIC ANTIBODY PRODUCTION SERVICE

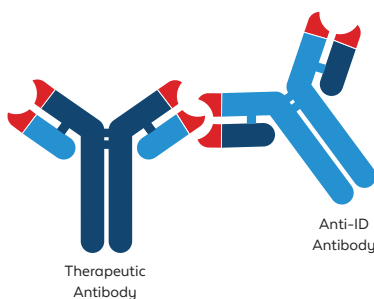
For more than twenty-five years, Rockland has been producing customized anti-idiotype (anti-ID) antibodies for the detection, identification, and analysis of therapeutic drugs to support pre-clinical and downstream clinical trials. Anti-ID antibodies can be produced as polyclonal or hybridoma-based monoclonal antibodies depending on the needs of your study. These fit-for-purpose antibodies can be generated in a variety of hosts for use in studies to identify, neutralize, block, and assess the properties of drug-to-analyte binding on the target therapeutic antibody.

The idiotope is the unique set of antigenic determinants found within the variable region of an antibody. The idiotope region constitutes the paratope—or the antigen binding site—where the epitope portion of the analyte is bound. Analytes can be protein targets or drugs. When a second antibody is generated that specifically binds to the idiotope region of the therapeutic antibody, the antibody is referred to as an anti-idiotype or anti-idiotypic antibody.



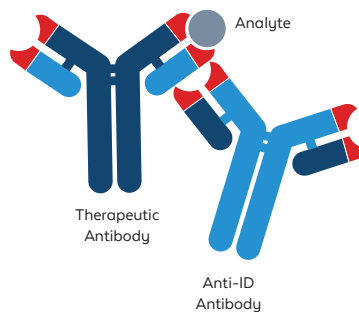
### TYPES OF ANTI-ID ANTIBODIES

Anti-ID antibodies can be produced using proprietary methods developed at Rockland to tailor the specificity of the antibody for your needs. Type I anti-ID antibodies bind the therapeutic antibody at or near the idiotope preventing the therapeutic antibody from binding its target. Consequently, type I anti-ID antibodies are useful for identification purposes and for neutralizing studies. Type II anti-ID antibodies detect therapeutic antibodies regardless of whether or not it's bound to its target and are non-inhibitory; therefore, not used for neutralization studies. Type III anti-ID antibodies only bind the therapeutic antibody when the therapeutic antibody is bound to its target and are most useful for pharmacodynamic (PD) and pharmacokinetic (PK) studies.



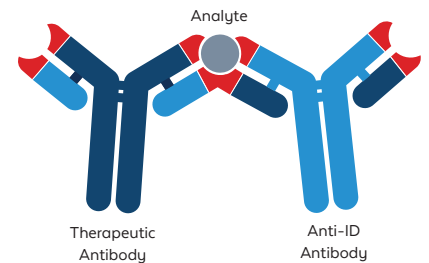
TYPE I

- Inhibitory/neutralizing
- Detects free antibody drug



TYPE II

- Not Inhibitory
- Detects total antibody drug (free, partially bound, fully bound)



TYPE III

- Antibody drug-to-target complex specific
- Detects bound antibody drug only

## UTILITY OF ANTI-ID ANTIBODIES

Anti-ID antibodies are used at various critical points of pre-clinical and clinical therapeutic drug development, evaluation, manufacturing, and release. Anti-ID antibodies are often used in immunoassays for evaluating PD, PK, and immunogenic properties of the antibody drug substance (DS) or drug product (DP). Additionally, they can be used to identify and differentiate particular antibody drugs manufactured on similar antibody architecture. Certain anti-ID antibodies can be used in basic Double Radial Immunodiffusion (DRID) testing to allow for identification of antibody drug substances throughout the manufacturing process.

