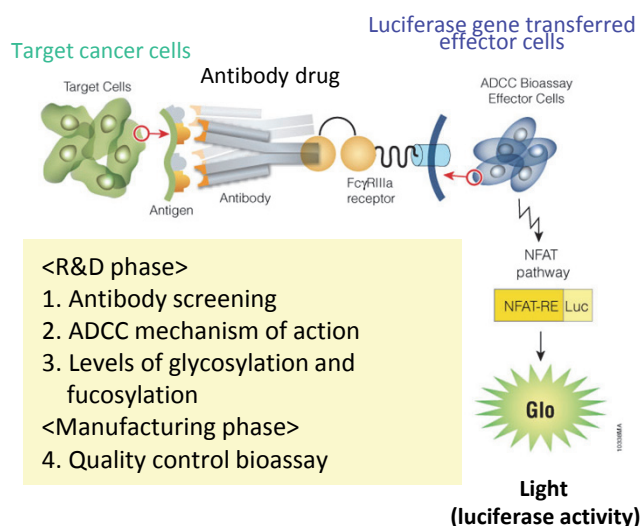


Cell-based assay —Luciferase reporter bioassay—

ADCC luciferase reporter bioassay is bioluminescence test for antibody-dependent cell-mediated cytotoxicity. This assay shows ADCC activity with luminescence intensity. With excellent reproducibility, this assay is helpful for quality assurance, bioequivalence study, and neutralization assay for antibody drugs.

ADCC activity assay



<R&D phase>

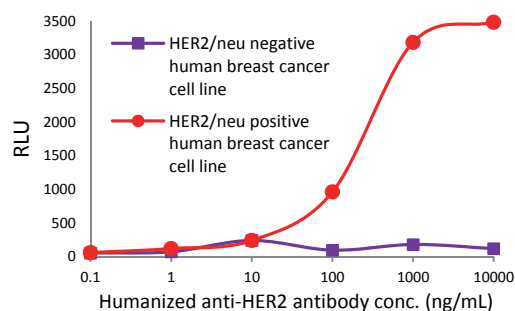
1. Antibody screening
2. ADCC mechanism of action
3. Levels of glycosylation and fucosylation

<Manufacturing phase>

4. Quality control bioassay

Under license from US. PROMEGA Corporation
www.promega.com

ADCC activity is one of major efficacies of antibody drugs. Instead of fresh lymphocyte from healthy donors, stable cell line where luciferase gene and human FcγRIIIa gene are transferred to NFAT downstream is used as effector cells for this assay. This assay is helpful for screening antibodies with ADCC activity and finding possible binding affinity between Fc region of antibody drugs and Fc receptor of effector cells.

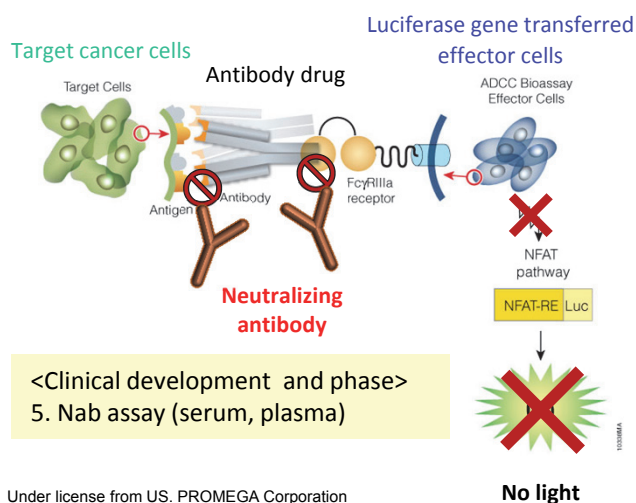


Nab assay

Neutralizing antibodies interfere with binding of an antibody drug to cell surface antigen and effector cells to neutralize pharmacologic action.

FDA Draft Guidance* recommends cell-based Nab assay.

*Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products, Guidance for Industry, Draft Guidance, FDA; April 2016

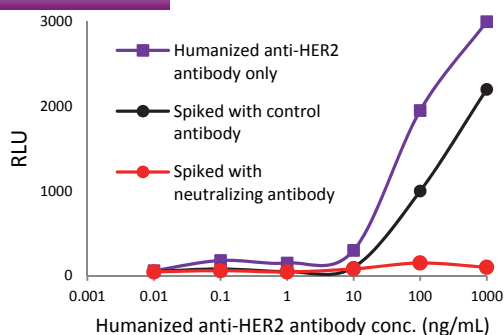


<Clinical development and phase>

5. Nab assay (serum, plasma)

Under license from US. PROMEGA Corporation
www.promega.com

Example 1



Example 2

