

Gyrolab® Generic Cyno ADA Kit Reagents

For the detection of circulating immune complexes of human IgG in complex with cynomolgus monkey (cyno) anti-human IgG

Product Information Sheet

D0043728/A

- Accelerate biotherapeutic candidate evaluation in preclinical studies
- Eliminate the need for drug-specific assay development
- Eliminate the need for acid dissociation of immune complexes prior to detection
- Provide a sensitive, drug-tolerant assay for detection of anti-human ADAs
- Automate ADA complex detection with an 80 minute run time



Introduction

Biopharmaceutical drugs may elicit immune responses that can have serious adverse effects, including reduced efficacy and safety. Detecting and monitoring anti-drug antibodies (ADA) is therefore essential throughout drug development. During the discovery stage, multiple drug candidates are often evaluated in parallel using a small number of animals and the development of drug-specific ADA assays for each candidate can be impractical. Gyros Protein Technologies has therefore developed a generic ADA kit reagent set that detects human IgG in complex with cyno anti-human IgG without the need for additional sample treatment steps. The generic ADA assay uses the same capture and detect reagents regardless of the drug candidate being evaluated.

This approach streamlines preclinical development using cynomolgus monkey models by greatly reducing the time that would be required to establish assays to evaluate multiple drug candidates. The generic ADA kit reagents can be readily used in conjunction with pharmacokinetics and toxicity studies to give insights into unexpected clearance profiles together with safety or efficacy issues caused by formation of immune complexes.

Gyrolab Generic ADA Kit Reagents contain ready-to-use reagents (capture and detection) for five CD runs (480 data points). While the kit reagents have been optimized to be used in combination with Gyrolab® Bioaffy™ 1000 CD, other Gyrolab CD types can be used to customize the technical performance to meet the needs of the application.

Gyrolab Generic Cyno ADA Kit Reagents increase productivity in preclinical studies:

- Ready-to-use solutions that offer convenience and expedited analytical solutions by removing the need for labeling of reagents, assay development or optimization across molecules
- Automation generates 96 data points within 80 minutes without manual intervention, reducing variability due to errors and speeding up workflows
- Robust, reproducible, and reliable data generated from nanoliter sample volumes enables ADA assessment in the same animal/sample as in PK/TK, PD, or safety studies

The Gyrolab solution

Gyrolab Generic Cyno ADA Kit Reagents have been developed to quantify drug-ADA immune complexes in preclinical samples. The sandwich immunoassay is run on a Gyrolab Bioaffy 1000 CD and detects complexes between human IgG-based therapeutics and cyno anti-human IgG ADAs based on the same sandwich assay principle (Figure 1). The biotinylated anti-human IgG antibody is automatically introduced into microstructures in the Gyrolab Bioaffy CD and captured on streptavidin-coated beads in the flow-through affinity columns. Samples containing immune complexes are then introduced into the microstructures and are captured by the immobilized anti-human IgG antibody. Bound immune complexes are then detected using an anti-cyno IgG antibody labeled with Alexa Fluor® 647. Positive control consists of human monoclonal IgG covalently bound with cyno IgG. Results are evaluated using Gyrolab Evaluator or exported to a LIMS. All Gyrolab software programs are designed for 21 CFR Part 11 compliance, ensuring that assays can be developed and transferred in regulated environments.

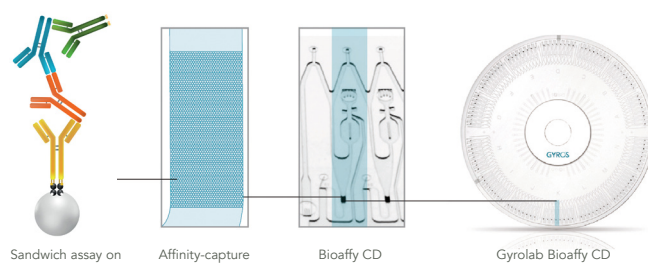


Figure 1. Sandwich immunoassay format on a Gyrolab Bioaffy 1000 CD

Assay performance

Gyrolab Generic Cyno ADA Kit Reagents

Broad dynamic range

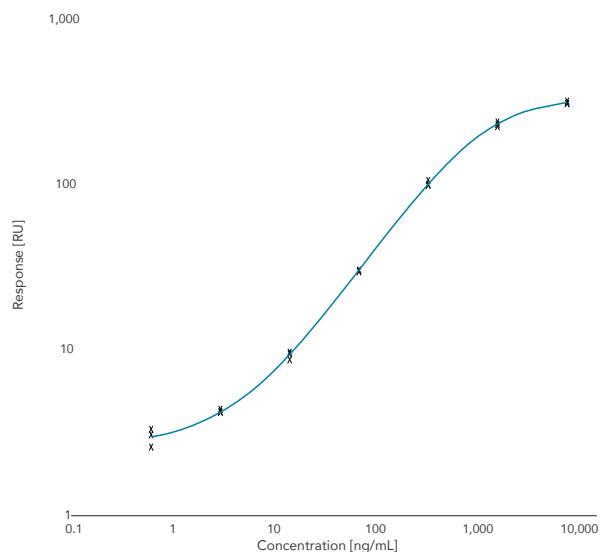


Figure 2. Generic cyno ADA standard curve. A typical example of detection of serially diluted Positive Control in 10% cyno serum in REXXIP H from a Gyrolab run using the Gyrolab Generic Cyno ADA Kit Reagents and the Gyrolab Bioaffy 1000 CD. Each standard sample was analyzed in triplicate.

Accuracy and precision

Intra- and inter-run precision were determined for three cyno ADA QC samples with different concentrations of Positive Control in REXXIP H. The data is summarized in Table 1 and shows high intra- and inter-run accuracy and precision.

Table 1. Intra- and inter-run precision data for QC samples of Positive Control in REXXIP H covering the assay working range. The QC samples were run in triplicate in six separate runs by two different operators over more than two days.

Sample	Nominal conc. (ng/mL)	Average measured conc. (ng/mL)	Intra-run CV (%)	Inter-run CV (%)
HQC	1000	1010	2.2-6.0	4.7
MQC	100	106	2.0-7.5	5.6
LQC	3.20	3.4	2.6-9.9	7.1

Ordering Information

Product Number	Product name	Description
P0020965	Gyrolab Generic Cyno ADA Kit Reagents Bundle	Includes kit reagents, sample dilution and wash buffers to generate 480 datapoints (5 CDs).
P0020867	Gyrolab Generic Cyno ADA Positive Control	Cyno ADA Positive Control, 50 000 ng/mL, 50 µL.
P0004253	Gyrolab Bioaffy 1000 CD	1000 nL, 96 datapoints.

Gyrolab Generic Cyno ADA Kit Reagents Bundle (0020965) Contents

P0020865	Gyrolab Generic Cyno ADA Kit Reagents	Includes capture and detect reagents to generate 480 datapoints (5 CDs).
P0004822	Rexxip H	25 mL, 1 x standard formulation, agents to neutralize heterophilic antibodies.
P0020669	Gyrolab Assay Wash Buffer Duo	Wash buffer 1 and 2 (2 vials x 2 mL).

All products above can also be purchased separately as stand-alone products.

Gyrolab Generic Cyno ADA Kit Reagents (P0020865) Contents

Each kit reagent contains reagents for generation of 480 datapoints

Capture Reagent: Biotinylated anti-human IgG antibody, ready-to-use solution

Detection Reagent: Alexa Fluor™ 647 labelled anti-cyno IgG antibody, ready-to-use solution

Storage conditions

Gyrolab Generic Cyno ADA Kit Reagents are shipped refrigerated and can be stored up to 3 months at +4 to +8°C. Positive controls are shipped refrigerated and should be stored at -20°C.

Shelf life: See Instruction For Use (IFUs) provided with the products.

Related products

Scan the QR-code to learn more about our other ready-to-use kits and solutions for different applications:



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