

Gyrolab® Generic Rodent ADA Kit Reagents

For the detection of circulating immune complexes of human IgG in complex with rodent anti-human IgG.

[Product Information Sheet](#)

D0048541/A

The Gyrolab® Generic Rodent ADA assay:

- Accelerates biotherapeutic candidate evaluation in preclinical studies
- Eliminates the need for drug-specific assay development
- Is validated for use with mouse and rat samples
- Eliminates the need for acid dissociation of immune complexes prior to detection
- Provides a sensitive, drug-tolerant assay for detection of circulating anti-human ADA complexes
- 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 humanized antibody 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 assay that detects human IgG in complex with rodent 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 and is validated for use with mouse and rat samples. The detection reagent has also been proven to detect guinea pig and Syrian hamster IgG. This approach streamlines preclinical development using rodent models by greatly reducing the time that would be required to establish assays to evaluate multiple drug candidates. The Gyrolab Generic Rodent ADA Assay 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 Rodent ADA Kit Reagents increase productivity in preclinical studies:

- Ready-to-use assay offers convenience and expedited analytical solutions by removing the need for labeling of reagents, assay development or optimization across molecules
- Validated for use in multiple rodent species to reduce development time and allowing for use in multiple studies across the preclinical program without additional assay development
- Robust, reproducible, and reliable data generated from nanoliter sample volumes enables ADA assessment in the same samples as PK/TK or PD
- Automated Gyrolab assay generates 96 data points within 80 minutes without manual intervention, reducing variability due to errors and speeding up workflows

The Gyrolab solution

Gyrolab Generic Rodent ADA Kit Reagents have been developed to quantify drug-ADA immune complexes in preclinical samples. This sandwich immunoassay is run on the Gyrolab Bioaffy 1000 CD and detects complexes between human IgG and rodent IgG as shown in Figure 1. The biotinylated anti-human IgG antibody fragment (F(ab')₂) is automatically introduced into a microstructure in the Gyrolab Bioaffy CD and captured on streptavidin-coated beads in the flow-through affinity column. Samples containing immune complexes are introduced into the microstructures and captured by the immobilized capture reagent. Bound immune complexes are then detected using an anti-rodent IgG antibody labeled with Alexa Fluor™ 647. The supplementary Gyrolab Generic Mouse ADA Positive Control sample consists of human monoclonal IgG covalently bound with mouse 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.

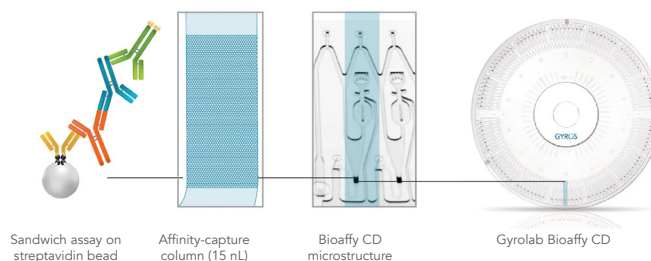


Figure 1. Sandwich immunoassay format on a Gyrolab Bioaffy 1000 CD.

Assay performance

Gyrolab Generic Rodent ADA Kit Reagents

Performance has been evaluated using the Gyrolab Generic Mouse ADA Positive Control to determine sensitivity and precision. Assay attributes such as sensitivity and drug tolerance will need to be assessed prior to use, using matrix representative of the intended test animals. It is not typically required to run a dilution series on all runs once assay performance has been established, instead appropriately set Positive Control concentrations may be used to assess run to run assay performance.

Sensitivity assessment

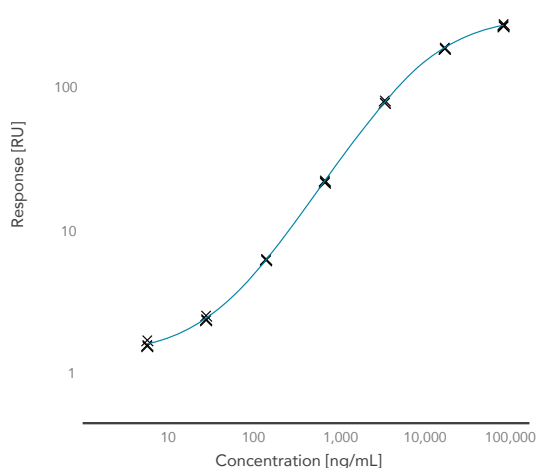


Figure 2. An example of serially diluted Gyrolab Generic Mouse ADA Positive Control from a Gyrolab run to determine assay sensitivity in matrix. Concentrations shown are neat serum concentrations, run in 10% mouse serum with REXXIP H. Each sample was analyzed in triplicate.

Positive Control precision

Intra- and inter-run precision were determined for three PC samples with different concentrations of Gyrolab Generic Mouse ADA Positive Control in 10% mouse serum with REXXIP H. The data is summarized in Table 1 and shows intra- and inter-run precision with low %CV.

Table 1. Intra- and inter-run precision data for PC samples of Gyrolab Generic Mouse Positive Control in 10% mouse serum with REXXIP H covering the assay working range. CV values are calculated on response and concentrations shown are neat concentrations. The PC samples were run in triplicate in six separate runs by two different operators over two days.

Sample	Nominal conc. (ng/mL)	Intra-run CV (%)	Inter-run CV (%)
HPC	10,000	0.9 – 5.0	5.1
MPC	1,000	0.3 – 7.1	5.8
LPC	100	0.3 – 8.0	7.2

Ordering Information

Product Number	Product name	Description
P0021054	Gyrolab Generic Rodent ADA Kit Reagents Bundle	Includes kit reagents, sample dilution and wash buffers to generate 480 data points (5 CDs).
P0021055	Gyrolab Generic Mouse ADA Positive Control	Mouse ADA Positive Control, 50,000 ng/mL, 50 µL.
P0004253	Gyrolab Bioaffy 1000 CD	1000 nL, 96 data points.

Gyrolab Generic Rodent ADA Kit Reagents Bundle (P0021054) Contents

P0021053	Gyrolab Generic Rodent ADA Kit Reagents	Includes capture and detect reagents to generate 480 data points (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 Rodent ADA Kit Reagents (P0021053) Contents

Each Kit Reagents product contains ready-to-use capture and detection reagents for generation of 480 data points:

Capture Reagent, Biotinylated anti-human IgG antibody fragment (F(ab')₂), ready-to-use solution

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

Storage conditions

Gyrolab Generic Rodent ADA Kit Reagents are shipped refrigerated and should be stored at +4 to +8°C.

Shelf life: See product label for shelf life details

Related products

Scan the QR-code to learn more about our other ready-to-use kits used in Bioanalysis.



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