

# Gyrolab<sup>®</sup> ADA Solution

Product Information Sheet

D0016915/E

- **Reduces hands-on time**
  - Automates sample pretreatment and immunoassay workflow at nanoliter scale
- **Shortens overall run times**
  - Results can be obtained in as little as one hour
- **Saves precious reagents and samples**
  - 5 µL sample and 2 µl reagent is sufficient for duplicates
- **Streamlines workflows from assay development through screening to confirmation**
  - Enabled using Gyrolab ADA protocol and dedicated Gyrolab ADA Software
  - Rexpip ADA buffer to facilitate assay development
  - Higher sample throughput

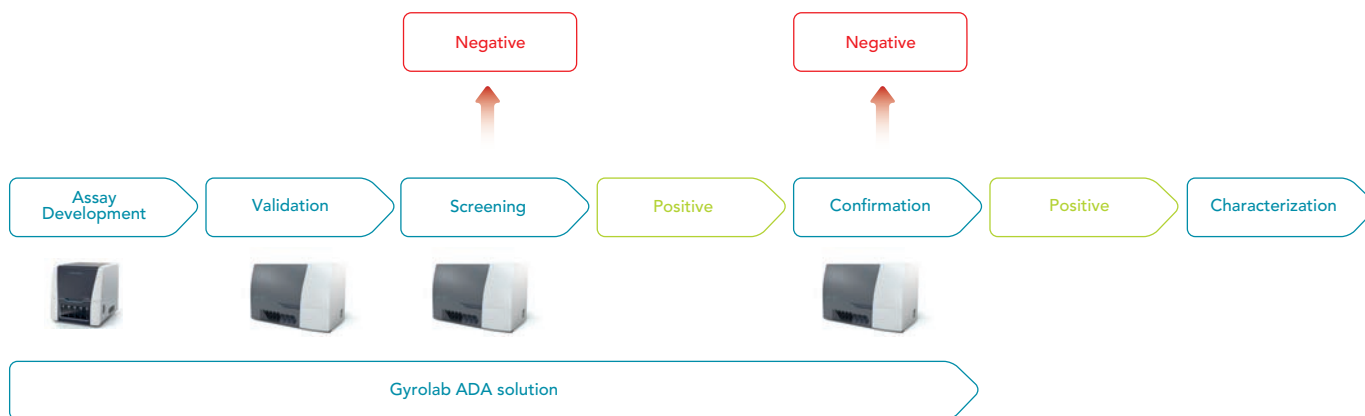


## Streamlined workflow from development to confirmation

Immunogenicity testing is a regulatory requirement as part of the safety assessment of biotherapeutic submissions. Anti-Drug Antibodies (ADA) immunoassays for biotherapeutics are complex and require lengthy protocols to maximize drug tolerance, minimize drug interference and establish equilibrium, such as overnight incubations and acid sample pre-treatment. Gyrolab ADA solution provides a nanoliter-scale method for automated acid pre-treatment all in a Gyrolab<sup>®</sup> Mixing CD with 96 microstructures or this flexible

solution can be also used without acid dissociation. Working at nanoliter-scale reduces processing times and minimizes sample/reagent consumption.

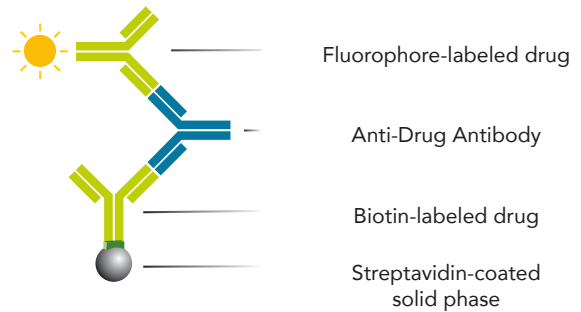
Dedicated, Gyrolab ADA software, designed for 21 CFR Part 11 compliance, facilitates data analysis for either screening or confirmation. Gyrolab ADA assays exhibit high drug tolerance and deliver sensitivity and consistent performance providing quality data.



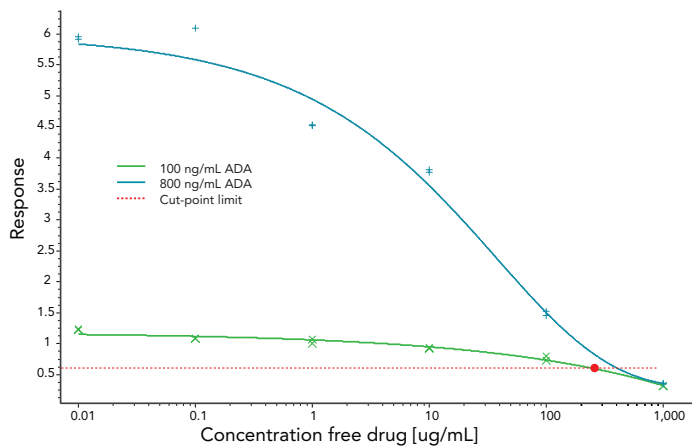
# Time-efficient drug-tolerant ADA analyses run automatically in a Gyrolab instrument

Gyrolab ADA solution provides an efficient way of optimizing ADA analysis. A homogeneous bridging assay format (Figure 1) detects ADA's of all isotypes. In addition, the assay format is species independent, which means that it can be used for both pre-clinical and clinical studies.

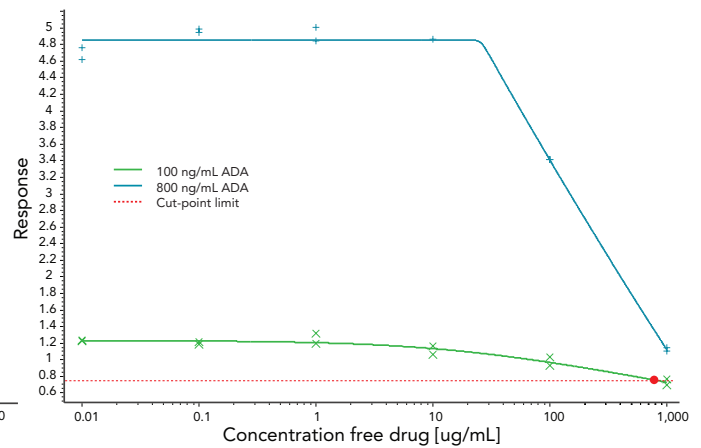
Assays can be performed using a Gyrolab Bioaffy 200 CD, an overnight incubation is then recommended to maximize free drug tolerance. In addition, Gyrolab Mixing CD 96 can be used to improve the drug tolerance of the assay by incorporating automated acid dissociation, as shown in Figures 2 and 3. Using the automated acid dissociation method will reduce the hands-on time and shorten the time to result.



**Figure 1.** Homogeneous bridging assay format with Gyrolab ADA solution.

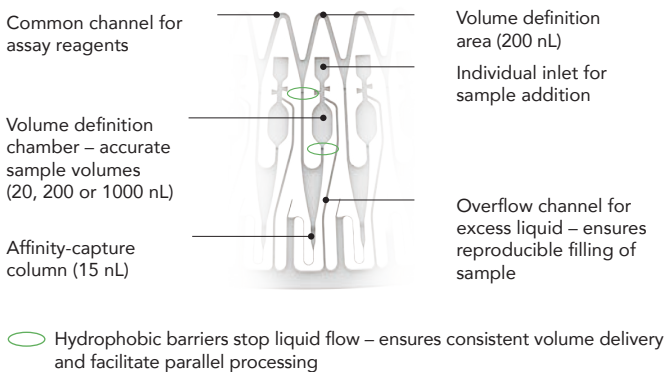


**Figure 2.** ADA analysis without acid dissociation, using Gyrolab Bioaffy 200 CD and overnight incubation. In this example 100 ng/mL ADA has a drug tolerance limit of 241  $\mu\text{g/mL}$  free drug (marked with ●). For higher drug tolerance it may be necessary to include acid dissociation in the assay.



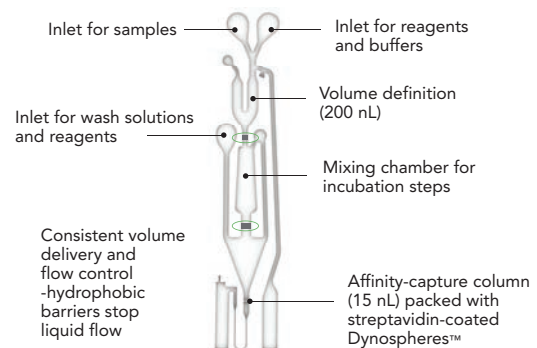
**Figure 3.** Modifying the assay to include acid dissociation, using Gyrolab Mixing CD 96 increases the tolerance of the assay to free drug, making it possible to measure ADA in the presence of drug concentrations above 241  $\mu\text{g/mL}$ . In this example 100 ng/mL ADA has a drug tolerance limit of 747  $\mu\text{g/mL}$  free drug (marked with ●).

## Gyrolab Bioaffy 200 CD



**Figure 4.** Microstructure of Gyrolab Bioaffy 200 CD. One microstructure - one data point.

## Gyrolab Mixing CD 96



**Figure 5.** Automated acid dissociation takes place in the mixing chambers of Gyrolab Mixing CD 96.

# Gyrolab ADA Software

## Streamlined assay development and implementation to validation, screening and confirmatory analysis

The Gyrolab ADA Software module guides you through the ADA analysis workflow from assay development and validation to screening and confirmatory analysis.

The 21 CFR Part 11 compliant Gyrolab ADA module becomes an intrinsic part of the Gyrolab Control and Gyrolab Evaluator software used to control runs and evaluate data from the Gyrolab system.

Key features of Gyrolab ADA software include:

- quantification (Figure 6)
- screening analysis (Figure 7)
- confirmatory analysis (Figure 8)

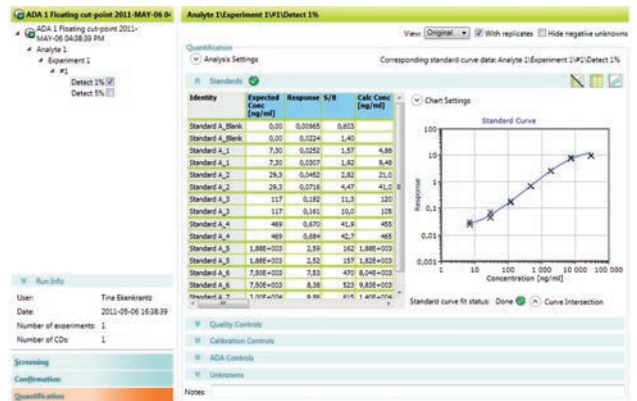


Figure 6. Quantification during assay development and validation to optimize assay conditions and establish acceptance criteria.

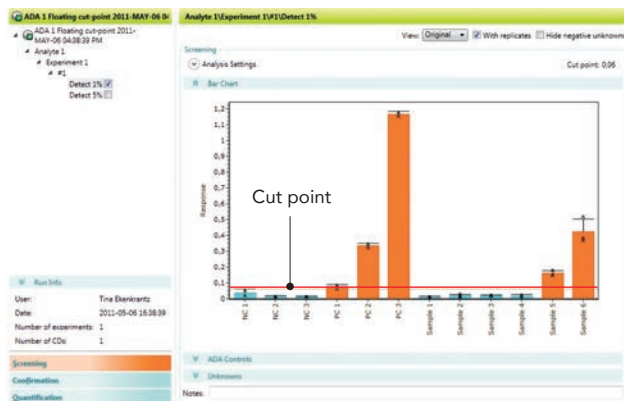


Figure 7. Screening analysis: Results displayed according to user-defined acceptance criteria and screening cut point. Software supports floating cut point calculations.

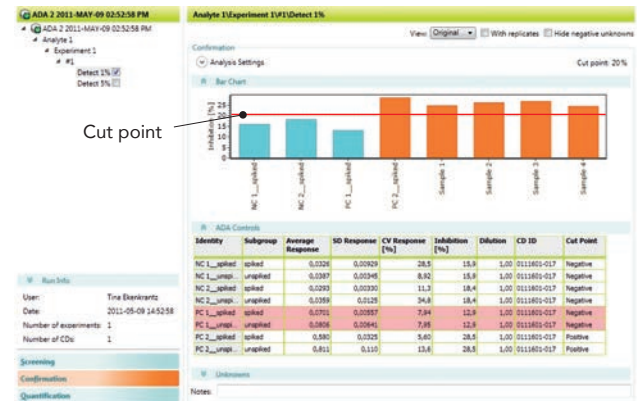


Figure 8. Confirmatory analysis: Results displayed according to user-defined acceptance criteria and confirmatory cut point. Samples outside the acceptance criteria are highlighted in the data table.

# Rexxip ADA

## Rexxip ADA is optimized for best assay performance

Rexxip buffers are designed to ensure that every sample enters and flows optimally through the microfluidic channels in a Gyrolab CD. Using the optimal buffer minimizes the risk of non-specific binding and can enhance binding between analyte and reagent, contributing towards improved assay performance. Rexxip ADA is fully compatible with acid dissociation and neutralization buffers.



Figure 9. Rexxip ADA: for dilution of samples and controls when using Gyrolab Mixing CD 96.

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## Technical information

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Gyrolab CD type	Number of microstructures	Sample pretreatment	ADA assay format
Gyrolab Mixing CD 96	96	Automated in CD	Homogeneous bridging
Gyrolab Bioaffy 200	112	Overnight incubation	Homogeneous bridging

### Storage of Gyrolab CDs

Refrigerate at +4 °C to +8°C, unopened package.

Shelf life (unopened package): Minimum 12 months after delivery.

Storage (opened package): CDs must be used within one week of opening. Return partially used CDs to the original CD box and pouch. Re-seal. Store dark, dry and at room temperature.

Note: Partially-used CDs can be re-used. To guarantee optimal performance, Gyros Protein Technologies recommends using a new CD for each run.

### Chemical compatibility of Gyrolab CDs

Streptavidin-coated particles and surfaces within CD microstructures are stable in buffers pH 2-10.

Compatible with the following solutions: 0.2% Tween 20, 40% methanol, 30% dimethyl sulfoxide (DMSO), 30% 2-propanol, 0.01% Triton X-100, 0.1% SDS.

### Storage of REXXIP buffers

Refrigerate at +4°C to +8°C. Do not freeze.

Shelf life (unopened package): see product label.

Shelf life (opened package): <3 months if contamination is avoided by use of adequate pipetting routines.

Contamination will reduce shelf life.

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## Ordering information

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Product number	Product name
P0020520	Gyrolab xPand
P0020300	Gyrolab xPlore
P0020455	Gyrolab Mixing CD 96
P0004180	Gyrolab Bioaffy 200
P0020027	REXXIP ADA buffer
P0020025	Gyrolab ADA Software*

\* included in Gyrolab xPand

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