



Gyrolab® Kits and Solutions

Designed for **best results**

GYROS PROTEIN
Technologies



Automated. Nanoliter-scale. Market validated.

Trusted around the world

A majority of the world's leading biopharmaceutical companies and CROs use Gyrolab® immunoassay technology. Many have multiple systems. It's not hard to see why.

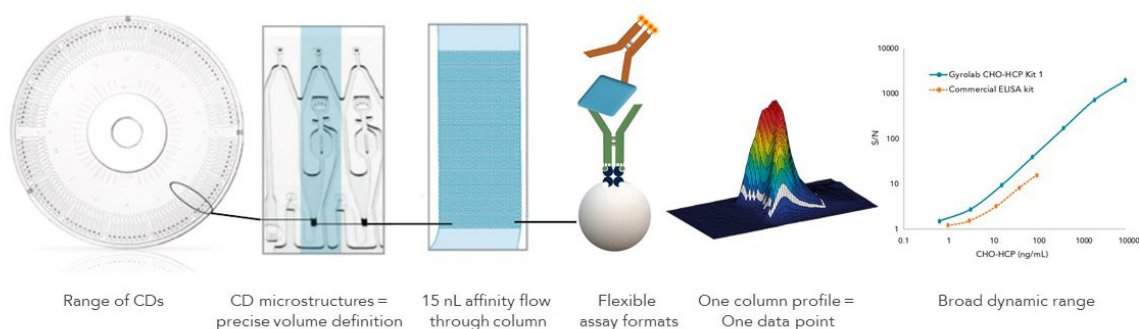
Gyrolab system is regarded as a must-have technology to accelerate biopharmaceutical development and production. Gyrolab delivers the performance needed for time critical workflows, including rapid assay development, handling small sample and reagent volumes, and the ability to measure over a broad dynamic range with minimal matrix interference.

The Gyrolab system of hardware, software and consumables is constantly developing to meet the demands of applications such as cell line development, bioanalysis for bioprocessing, and pre-clinical PK/TK studies. You can use this open platform to set up assays with your own reagents together with Gyrolab CDs and Rexpip buffers. Alternatively, you can exploit the benefits of optimized ready to use kits that contain everything you need and also avoid method development.

This brochure presents the high quality Gyrolab consumables that will ensure the best results, whether you are developing your own assays or using our kits.

Gyrolab® CD's

Gyrolab® Bioaffy™ CDs are key components of the open Gyrolab platform, and a selection of CDs meets the needs for developing immunoassays in a range of formats, over a broad range of concentrations and for a variety of matrices. Gyrolab immunoassays are easily transferred between sites and data meets the needs for processes requiring regulatory approval. The high performance of Gyrolab technology has made it an established format used by the majority of biopharma companies and contract research organizations (CROs) worldwide.

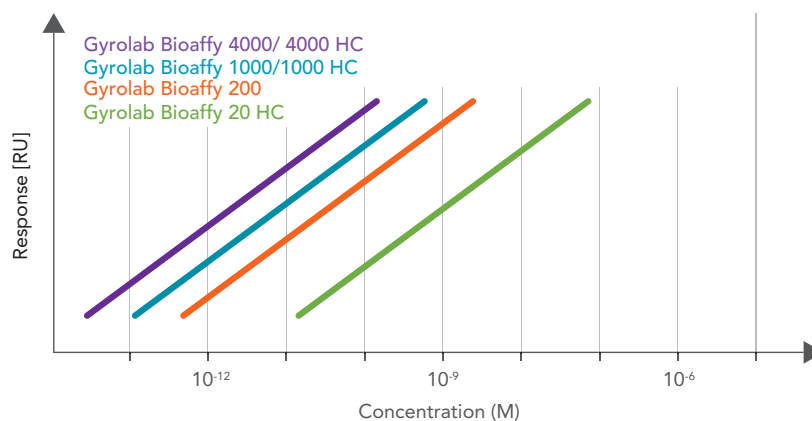


Selection of CD

Several parameters influence the choice of Gyrolab Bioaffy CD, such as the required dynamic range, analyte concentration, quality of reagents and assay format. For most applications, the Gyrolab Bioaffy 200 CD can be used as a starting point. For highest sensitivity, Gyrolab Bioaffy 1000 or Gyrolab Bioaffy 4000 are the CDs of choice. The porous particles included in Gyrolab Bioaffy 20 HC, Gyrolab 1000 HC CD and Gyrolab 4000 HC CD provide higher binding capacity. Gyrolab Bioaffy 20 HC is suitable when samples contain high analyte concentrations while Gyrolab Bioaffy 1000 HC CD and Gyrolab Bioaffy 4000 HC CD have demonstrated improved performance when capture reagents have low affinity binding to the analyte.

Gyrolab Mixing CD 96 can be used to integrate sample preparation steps that may include an acid dissociation step when analyzing anti-drug antibodies, or steps involving equilibration or enzymatic reactions.

Recommendations are to perform CD selection experiments prior to assay development to identify the CD for the required assay performance.



Automated nanoliter-scale immunoassays

Gyrolab technology simplifies immunoassay workflows in a CD format by eliminating incubations and shortening run times. Centrifugal force, capillary action and hydrophobic barriers precisely control the parallel processing of up to 112 data points per CD.

Analytes can be measured over a broad dynamic range, reproducibility is exceptional, and repeats are kept to a minimum. The automated workflow saves you time, sample and reagents.

Hydrophobic breaks

ensure consistent volume delivery

Overflow channel

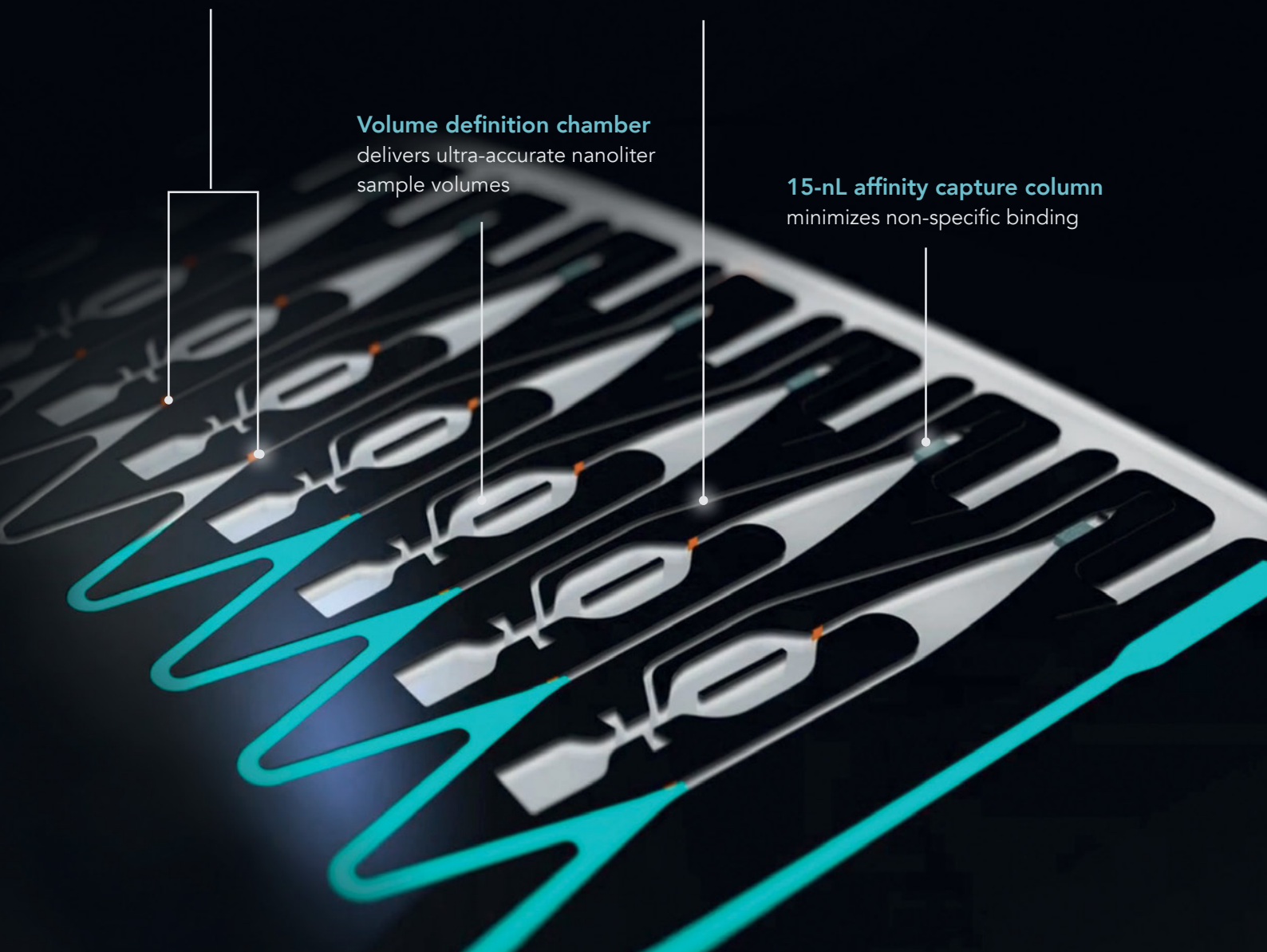
reduces need for pipetting accuracy

Volume definition chamber

delivers ultra-accurate nanoliter sample volumes

15-nL affinity capture column

minimizes non-specific binding



Ordering Information

Product Number	CD	Sample volume (nL)	Data points	Particle	Sensitivity*	Application**
P0004424	Gyrolab Bioaffy 20 HC	20	112	Porous	1X	Higher binding capacity for higher concentrations e.g. IgG titer, TK
P0004180	Gyrolab Bioaffy 200	200	112	Solid	10X	Standard CD for any application e.g. PK
P0004253	Gyrolab Bioaffy 1000	1000	96	Solid	50X	Applications requiring higher sensitivity e.g. PK, biomarker
P0020245	Gyrolab Bioaffy 1000 HC	1000	96	Porous	50X	High binding capacity e.g. Low affinity reagents
P0020705	Gyrolab Bioaffy 4000	4000	96	Solid	200X	Applications requiring highest sensitivity e.g. PK, biomarkers
P0020805	Gyrolab Bioaffy 4000 HC	4000	96	Porous	200X	Low affinity reagents. Potentially higher sensitivity than Bioaffy 1000 HC CD
P0020455	Gyrolab Mixing CD 96	200	96	Solid	N/A	Applications requiring Sample pre-treatment e.g. acid dissociation

*Achievable sensitivity depends on application.

**For guidance only.

Storage of Gyrolab CDs

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

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

Opened CD package

CDs must be used within one week of opening. Return partially used CDs to original CD pouch. Re-seal the pouch with the zipper. Store dark, dry and at room temperature.

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



INSIDE GYROLAB BIOAFFY CD

Toolboxes

Gyrolab Bioaffy Assay Toolboxes provide support for users who wish to develop assays with process-specific reagents based on components of the ready-to-use Gyrolab kits. Gyrolab Bioaffy Assay Toolboxes include Gyrolab Bioaffy CD, wash buffers, sample dilution buffer, plates, foils and instructions for use. As the toolboxes have been designed to enable the development of assays with your own reagents, additional optimization involving choice of sample dilution buffers and/or other components may be required depending on the nature of the assay.

Ordering Information

Prod. No	Product Name	Description
Gyrolab Bioaffy Toolboxes (for use in Biorprocessing/Cell and Gene Therapy)		
P0020667	Gyrolab Bioaffy 1000 HC Assay Toolbox	Includes 1 CD and all buffers and consumables to generate 96 data points.
P0020668	Gyrolab Bioaffy 1000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.
P0020852	Gyrolab Bioaffy 4000 HC Assay Toolbox	Includes 1 CD and all buffers and consumables to generate 96 data points.
P0020853	Gyrolab Bioaffy 4000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.



Gyrolab® Ready-to-Use Kits and Solutions

Countless uses. Convenient set-up. Gyrolab quality.

Gyrolab® ready-to-use kits and solutions provide plug-and-play miniaturized immunoassays for use on all Gyrolab systems. From bioanalysis of pre-clinical and clinical samples to downstream bioprocessing of biotherapeutics, it's all at your fingertips in easy to use Gyrolab kits.

Bioprocess Titer/Impurities (mAb Therapeutics)

As a result of increasing workloads it is even more critical to increase efficiency and productivity for titer and impurity bioanalytics in supporting multiple programs with limited resources. Current plate-based, manual methods such as enzyme-linked immunosorbent assays (ELISAs) create bottlenecks in critical workflows because of throughput constraints, repeat testing, or longer assay times. The Gyrolab automated immunoassay platform can generate high-quality analytical data with high throughput using nanoliter volumes for more rapid and efficient titer and impurity immunoassays.

Ordering Information

Prod. No	Product Name	Description
Determination of human IgG concentrations in cell line development		
P0020381	Gyrolab hulG Kit – Low Titer	Reagents and consumables to generate 96 datapoints (1 CD). Standard is not included.
P0020382	Gyrolab hulG Kit – High Titer	Reagents and consumables to generate 112 datapoints (1 CD). Standard is not included.
P0020379	Gyrolab hulG Standard (IgG1)	4 mg/mL, 50 µL.
Determination of leached Protein A		
P0020456	Gyrolab Protein A Kit for MabSelect SuRe™ Ligand	Reagents and consumables for 96 datapoints (1 CD).
Determination of CHO-HCP impurity levels		
CHO HCP 3G Solution for Gyrolab		
G550-1	CHO HCP 3G Assay Reagent Set for Gyrolab (Order from Cygnus Technologies)	Includes anti-CHO HCP capture and detection reagents and CHO HCP antigen concentrate. Sufficient quantities to generate 96 data points (1 CD).
P0020667	Gyrolab Bioaffy 1000 HC Assay Toolbox	Includes 1 CD, buffers and consumables to generate 96 data points.
P0020668	Gyrolab Bioaffy 1000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.
P0020670	Gyrolab HCP Sample Dilution Buffer	Extra sample dilution buffer for Gyrolab Bioaffy 1000 HC Assay Toolbox.



Bioprocess Titer/Impurities (mAb Therapeutics) cont.

Ordering Information

Determination of E. coli HCP impurity levels		
P0020625	Gyrolab E. coli HCP Kit	Reagents and consumables to generate 96 datapoints (1 CD).
P0020629	Gyrolab E. coli HCP CD50 Kit	Reagents and consumables to generate 4800 datapoints (50 CD's). Made to order.
P0020647	Gyrolab E. coli Sample Dilution Buffer	Sample dilution buffer, 25 mL.
P0020637	Gyrolab E. coli HCP Standard	2500 ng/mL, 50 µL. For spiking experiments.
E.coli HCP 2G Solution for Gyrolab		
G1020	E.coli HCP 2G Assay Reagent Set for Gyrolab (Order from Cygnus Technologies)	Includes anti-E.coli HCP capture and detection reagents and E.coli HCP antigen concentrate. Sufficient quantities to generate 96 datapoints (1 CD).
P0020667	Gyrolab Bioaffy 1000 HC Assay Toolbox	Includes 1 CD, buffers and consumables to generate 96 data points.
P0020668	Gyrolab Bioaffy 1000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.
P0020670	Gyrolab HCP Sample Dilution Buffer	Extra sample dilution buffer for Gyrolab Bioaffy 1000 HC Assay Toolbox.

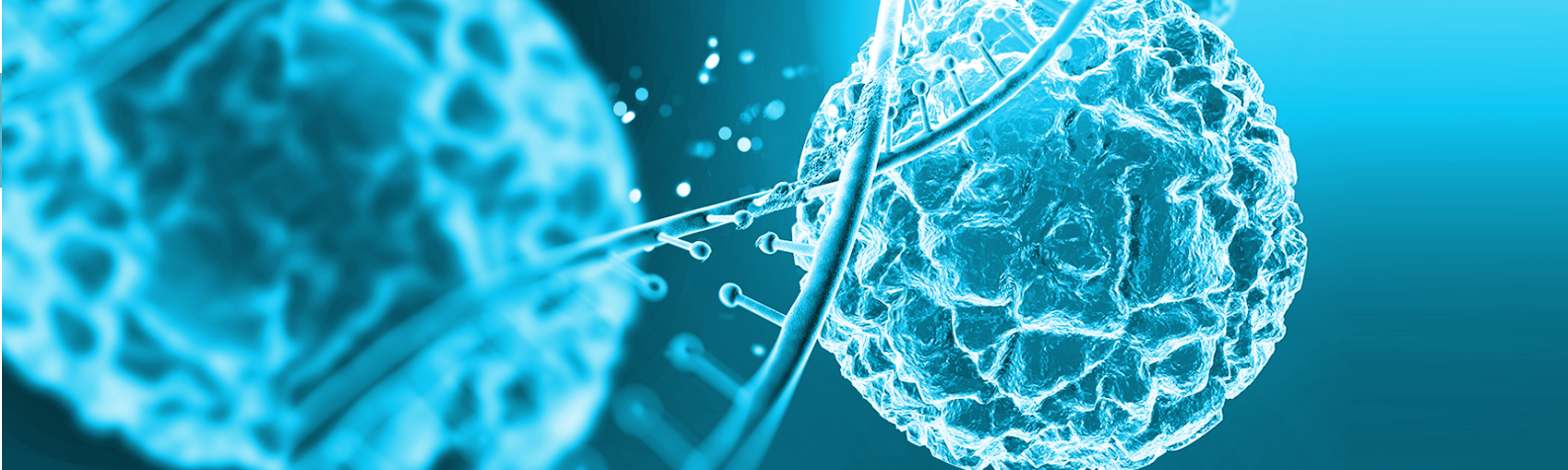
Bioprocessing Titer/Impurities (Cell and Gene Therapy)

Immunoassays are an essential bioanalysis tool used throughout cell and gene therapy development and manufacturing to evaluate viral vector titer and impurity measurement and monitoring.

Gyrolab automated microfluidic, nanoliter-scale immunoassay Kits and Solutions dramatically shorten time to results to one hour, reduce sample volumes, and improve data quality for AAV- and lentivirus-based gene therapy immunoassays during development, and are ideally suited for compressed cell and gene therapy development timelines.

Ordering Information

Prod. No	Product Name	Description
Titer determination for Cell and Gene Therapy		
P0020659	Gyrolab p24 Kit	Reagents and consumables to generate 96 data points.
P0020665	Gyrolab p24 CD50 Kit	Reagents and consumables to generate 4800 data points (50 CDs). Made to order.
P0020664	Gyrolab p24 Standard	1250 ng/mL, 400 μ L. For spiking experiments.
P0020674	Gyrolab p24 Sample Dilution Buffer	Extra sample dilution buffer, 25 mL.
P0020695	Gyrolab AAVX Titer Kit	Reagents and consumables to generate 96 datapoints.
P0020697	Gyrolab AAVX Titer CD50 Kit	Reagents and consumables to generate 4800 datapoints (50 CDs).
P0020699	Gyrolab AAVX Titer Sample Dilution Buffer	Sample dilution buffer, 25 mL.
P0020747	Gyrolab AAV9 Titer Kit	Reagents and consumables to generate 96 datapoints.
P0020749	Gyrolab AAV9 Titer CD50 Kit	Reagents and consumables to generate 4800 datapoints (50 CDs).
P0020751	Gyrolab AAV9 Titer Sample Dilution Buffer	Sample dilution buffer, 25 mL.



Bioprocessing Titer/Impurities (Cell and Gene Therapy) cont.

Ordering Information

Prod. No	Product Name	Description
Determination of impurities for Cell and Gene Therapy		
HEK 293 HCP Solution for Gyrolab		
G650S-1	HEK 293 HCP Assay Reagent Set for Gyrolab (Order from Cygnus Technologies)	Includes anti-HEK 293 HCP capture and detection reagents and HEK 293 HCP antigen concentrate. Sufficient quantities to generate 96 data points (1 CD).
P0020667	Gyrolab Bioaffy 1000 HC Assay Toolbox	Includes 1 CD and all buffers and consumables to generate 96 data points.
P0020668	Gyrolab Bioaffy 1000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.
P0020670	Gyrolab HCP Sample Dilution Buffer	Extra sample dilution buffer for Gyrolab Bioaffy 1000 HC Assay Toolbox.
EndonucleaseGTP® Solution for Gyrolab		
G960	EndonucleaseGTP Assay Reagent Set for Gyrolab (Order from Cygnus Technologies)	Includes anti-endonuclease capture and detection reagents and endonuclease standard. Sufficient quantities to generate 96 data points (1 CD).
P0020667	Gyrolab Bioaffy 1000 HC Assay Toolbox	Includes 1 CD and all buffers and consumables to generate 96 data points.
P0020668	Gyrolab Bioaffy 1000 HC Assay Toolbox CD50	Includes 50 CDs, buffers and consumables to generate 4800 datapoints.
P0020670	Gyrolab HCP Sample Dilution Buffer	Extra sample dilution buffer for Gyrolab Bioaffy 1000 HC Assay Toolbox.

Pharmacokinetics (PK)/Toxicokinetics (TK)



Pharmacokinetic (PK) and toxicokinetic (TK) bioanalysis presents challenges at all stages of development to monitor the safety and efficacy of biologics. Early in development, there is a need to support multiple therapeutic candidates and multiple programs. Preclinical development is subject to aggressive timelines and large sample numbers in a variety of species with limited volumes for both samples and reagents. Gyrolab Generic PK and TK Kits are ready-to-use solutions for use with all IgG-based therapeutics in non-human species to accelerate preclinical evaluation.

Ordering Information

Prod. No	Product Name	Description
Gyrolab 2G Generic PK Kit		
P0020969	Gyrolab 2G Generic PK Type E Kit ¹	Kit Reagents, Gyrolab Bioaffy 1000 HC CD and accessories to generate 96 datapoints (1 CD).
P0020970	Gyrolab 2G Generic PK Type F Kit ^{1,2}	Kit Reagents, Gyrolab Bioaffy 1000 HC CD and accessories to generate 96 datapoints (1 CD).
P0020971	Gyrolab 2G Generic PK CD50 Type E Kit ^{1,3}	Kit Reagents, Gyrolab Bioaffy 1000 HC CDs and accessories to generate 4800 datapoints (50 CDs).
P0020972	Gyrolab 2G Generic PK CD50 Type F Kit ^{1,2,3}	Includes Kit Reagents, Gyrolab Bioaffy 1000 HC CDs and accessories to generate 4800 datapoints (50 CDs).
P0020957	Gyrolab 2G Generic PK Type E Kit Reagents ¹	Includes ready-to-use capture and detect reagents, sample dilution and wash buffers to generate 96 datapoints (for 1 CD).
P0020958	Gyrolab 2G Generic PK Type F Kit Reagents ^{1,2}	Includes ready-to-use capture and detect reagents, sample dilution and wash buffers to generate 96 datapoints (for 1 CD).
Gyrolab Generic PK Kit		
P0020499	Gyrolab Generic PK Kit ¹	Reagents and consumables to generate 96 data points (1 CD). Includes two Sample Dilution Buffers (Type E and Type F) for selection of most optimal buffer.
P0020617	Gyrolab Generic PK CD50 Type E Kit ^{1,3}	Reagents and consumables to generate 4800 datapoints (50 CDs).
P0020619	Gyrolab Generic PK CD50 Type F Kit ^{1,2,3}	Reagents and consumables for 4800 datapoints (50 CDs).
P0020641	Gyrolab Generic PK Kit Reagent E (10 x 100 mL) ³	Sample Dilution Buffer, 10 X 100 mL.
P0020642	Gyrolab Generic PK Kit Reagent F (10 x 100 mL) ²	Sample Dilution Buffer, 10 X 100 mL.
Gyrolab Generic TK Kit		
P0020500	Gyrolab Generic TK Kit ¹	Reagents and consumables to generate 96 datapoints (1 CD). Includes two Sample Dilution Buffers (Type E and Type F) for selection of most optimal buffer.

¹Standard is not included

²Primarily for molecules with pI > 8

³Made to order

Gyrolab biomarker kits are optimized for use on all Gyrolab systems, offer improved assay performance, and fulfill all top key requirements to meet the biomarker assay development challenges during drug development programs and regulatory studies.

Ordering Information

Prod. No	Product Name	Description
Gyrolab Human Cytokine Kit Reagents*		
P0020821	Gyrolab Human IL-10 Kit Reagents	Includes capture and detect reagents, standard, sample dilution buffer and wash buffer required to generate 96 datapoints.
P0020822	Gyrolab Human IL-4 Kit Reagents	Includes capture and detect reagents, standard, sample dilution buffer and wash buffer required to generate 96 datapoints.
P0020823	Gyrolab Human IL-6 Kit Reagents	Includes capture and detect reagents, standard, sample dilution buffer and wash buffer required to generate 96 datapoints.
P0020824	Gyrolab Human IFN-gamma Kit Reagents	Includes capture and detect reagents, standard, sample dilution buffer and wash buffer required to generate 96 datapoints.
P0020825	Gyrolab Human TNF-alpha Kit Reagents	Includes capture and detect reagents, standard, sample dilution buffer and wash buffer required to generate 96 datapoints.
P0020826	Gyrolab Human IL-10 Standard	25 600 pg/mL, 200 µL. For spiking experiments.
P0020827	Gyrolab Human IL-4 Standard	16 000 pg/mL, 200 µL. For spiking experiments.
P0020828	Gyrolab Human IL-6 Standard	28 800 pg/mL, 200 µL. For spiking experiments.
P0020829	Gyrolab Human IFN-gamma Standard	16 000 pg/mL, 200 µL. For spiking experiments.
P0020830	Gyrolab Human TNF-alpha Standard	1 µg/mL, 200 µL. For spiking experiments.
P0020831	Gyrolab Biomarker Sample Dilution Buffer 1	Sample dilution buffer, 25 mL.

*Gyrolab Kit Reagents do not include CDs; these should be ordered separately.

Immunogenicity

Assessment of anti-drug antibodies (ADAs) is commonly screened during biotherapeutic candidate selection, and is a fundamental requirement during preclinical or clinical studies. The Gyrolab Generic Cyno ADA Kit Reagents are a ready-to-use and time-saving solution for ADA screening with measurement of ADA complexes in cynomolgus monkey serum. Additionally, the Gyrolab platform provides a solution for drug-specific ADA assays, automating the measurement of ADA using sandwich assays and acid dissociation, streamlining the process and improving efficiency in preclinical or clinical studies.

Ordering Information

Prod. No	Product Name	Description
For immunogenicity assessment in non-human species (cyno)		
P0020965	Gyrolab Generic Cyno ADA Kit Reagents Bundle	Includes capture and detect reagents, Rexpix H sample dilution buffer, and Gyrolab Assay Wash Buffer Duo to generate 480 datapoints (5 CDs). CDs not included.
P0020867	Gyrolab Generic Cyno ADA Positive Control	50 000 ng/mL, 50 µL. Cyno ADA positive control.
For drug-specific ADA assays in preclinical or clinical studies		
Gyrolab ADA Solution		
P0020455	Gyrolab Mixing CD 96	Applications requiring sample pre-treatment e.g., acid dissociation prior. 96 datapoints.
P0020027	Rexpix ADA buffer	25 mL. For dilution of samples and controls when using Gyrolab Mixing CD 96.
P0020025	Gyrolab ADA Software	Enables confirmatory analysis by displaying results according to your acceptance criteria and confirmatory cut point. Samples falling outside of acceptance criteria are automatically highlighted
P0004180	Gyrolab Bioaffy 200 CD	Alternative to Gyrolab Mixing CD 96 when using a homogenous, bridging format using overnight incubation.

Rexxip Buffers



Rexxip buffers are designed to ensure that every sample enters and flows optimally through the microfluidic channels of a Gyrolab CD. Using the optimal buffer can enhance binding between analyte and reagent and minimize the risk of non-specific binding.

- Save time to assay development
- Maximize immunoassay performance
- Compatible with a variety of molecules with different analytical properties

Rexxip Buffer Selection Guide

PRIMARY USE	ADDITIVES	BUFFER							
		A / A-max	AN / AN-max	H / H-max	HN / HN-max	HX / HX-max	F	CCS	ADA
Detection reagent buffer							•		
Recommended buffer if none of the below conditions apply		•							
Hydrophobic analyte						•	•		
Human and nonhuman primate samples (e.g. serum and plasma)									
Positively charged analyte, pI≥8					•				
Analyte with pI<8				•	*	•	**		
Animal samples (nonprimate)									
Positively charged analyte, pI≥8			•						
Cell culture samples with high protein concentration. Analyte is a therapeutic protein.									
Positively charged analyte, pI≥8			•						
Analyte with pI<8								•	
Anti-drug antibody samples									
Acidic conditions									•

*) First option, **) Second option

Salt: Increased ionic strength

Neutr: Reagents to neutralize heterophilic antibodies, e.g. HAMA

Det: Detergent

Rexxip max buffers are designed for sample dilutions 1:2.

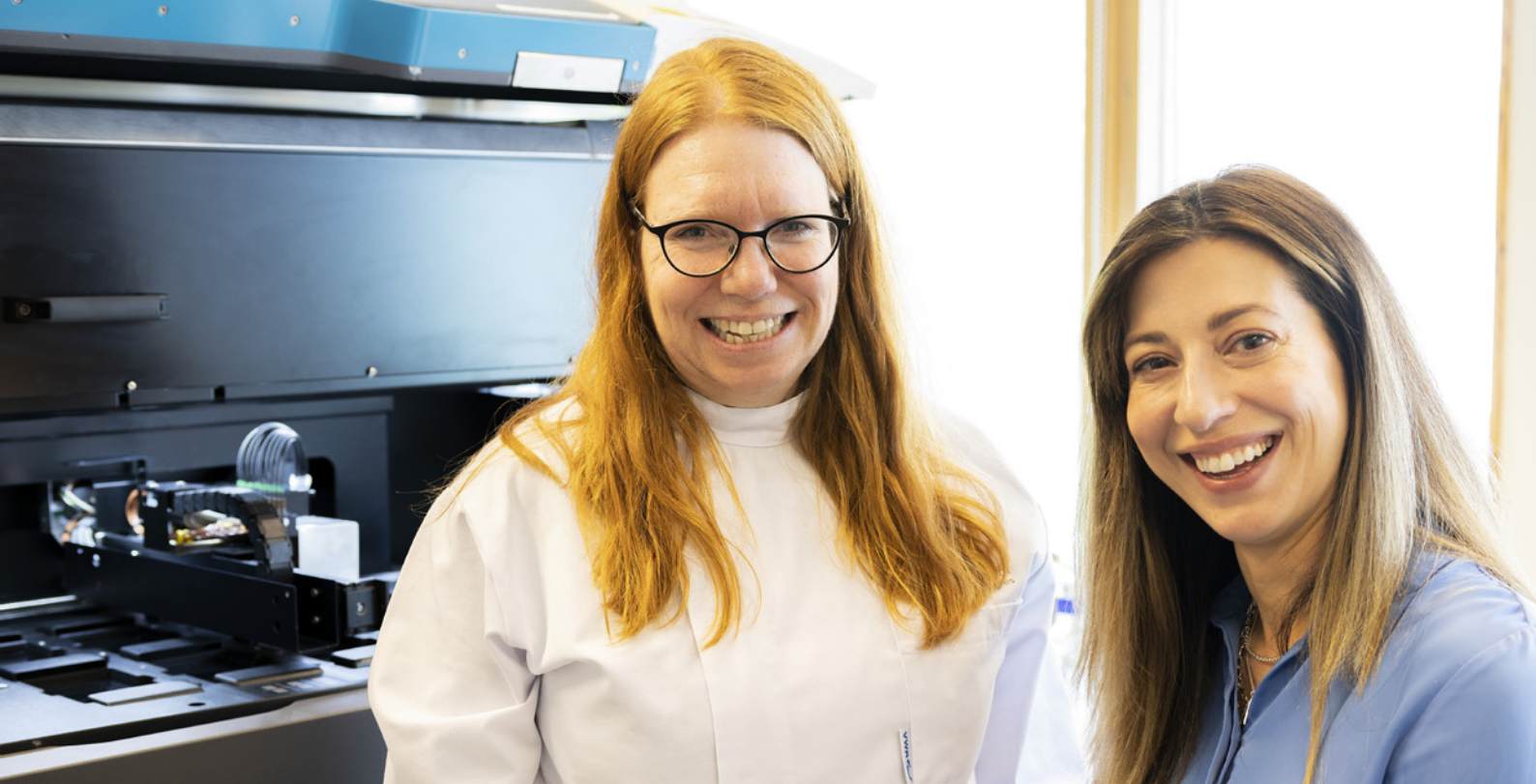
Regular Rexxip buffers should be used for sample dilutions > 1:2.

Ordering Information

Product No.	Product Name	Volume
P0004820	Rexxip A	25 mL
P0004821	Rexxip A-max	25 mL
P0004822	Rexxip H	25 mL
P0004823	Rexxip H-max	25 mL
P0004994	Rexxip AN	25 mL
P0004995	Rexxip AN-max	25 mL
P0020033	Rexxip HX	25 mL
P0020034	Rexxip HX-max	25 mL
P0004996	Rexxip HN	25 mL
P0004997	Rexxip HN-max	25 mL
P0004824	Rexxip CCS	25 mL
P0004825	Rexxip F	10 mL
P0020027	Rexxip ADA	25 mL
P0020851	Rexxip Scouting Pack	25 mL*
P0020096	Gyrolab Wash Buffer pH 11	10 × 10 g

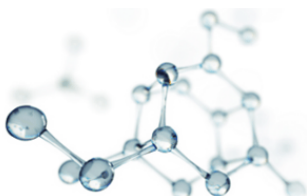
*5 mL of each of the following buffers: Rexxip A, AN, H, HN, HX

Certain Rexxip buffers are also available in 10 x 100 mL (1L). Please contact your local sales representative for more information.



Can't find what you are looking for?

Utilize commercially available or your own proprietary reagents in combination with the Gyrolab Customized Assay Services to develop an assay/kit tailored to your specific needs!



Biomolecule Labeling

Conjugating biomolecules with biotin or Alexa Fluor® 647 fluorophore is a key step to developing a robust Gyrolab immunoassay. Gyros Protein Technologies will provide a high level of experience to produce a biotin- or Alexa Fluor 647-conjugated biomolecule for use as capture or detection reagent in Gyrolab assays.



Gyrolab Custom Assay Services

If a ready-to-use assay is needed for your biologic development program, we can provide a fully qualified assay using a rigorous assay development process. We ensure the best assay conditions and assay performance for your Gyrolab immunoassay, and our efficient assay development service can expedite time to assay validation for your biotherapeutic development program.



Custom kit development

Gyros Protein Technologies offers the convenience of the development and manufacturing of custom kits for your assay needs. Custom assay kits are a convenient, ready-to-use solution that combines the reliable performance of Gyrolab Kits with customized solutions for your lab.

Learn more at <https://www.gyrosproteintechnologies.com/immunoassays/services>

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