



**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.*

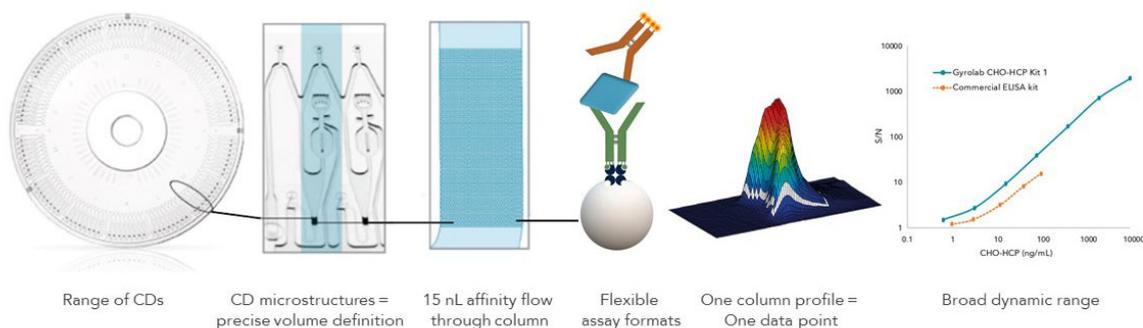
Gyrolab system is regarded as a must-have technology to accelerate biopharmaceutical development and production. Gyrolab delivers the performance needed for time critical workflows, including rapid assay development, handling small sample and reagent volumes, and the ability to measure over a broad dynamic 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 REXXIP 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 and Gyrolab 1000 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

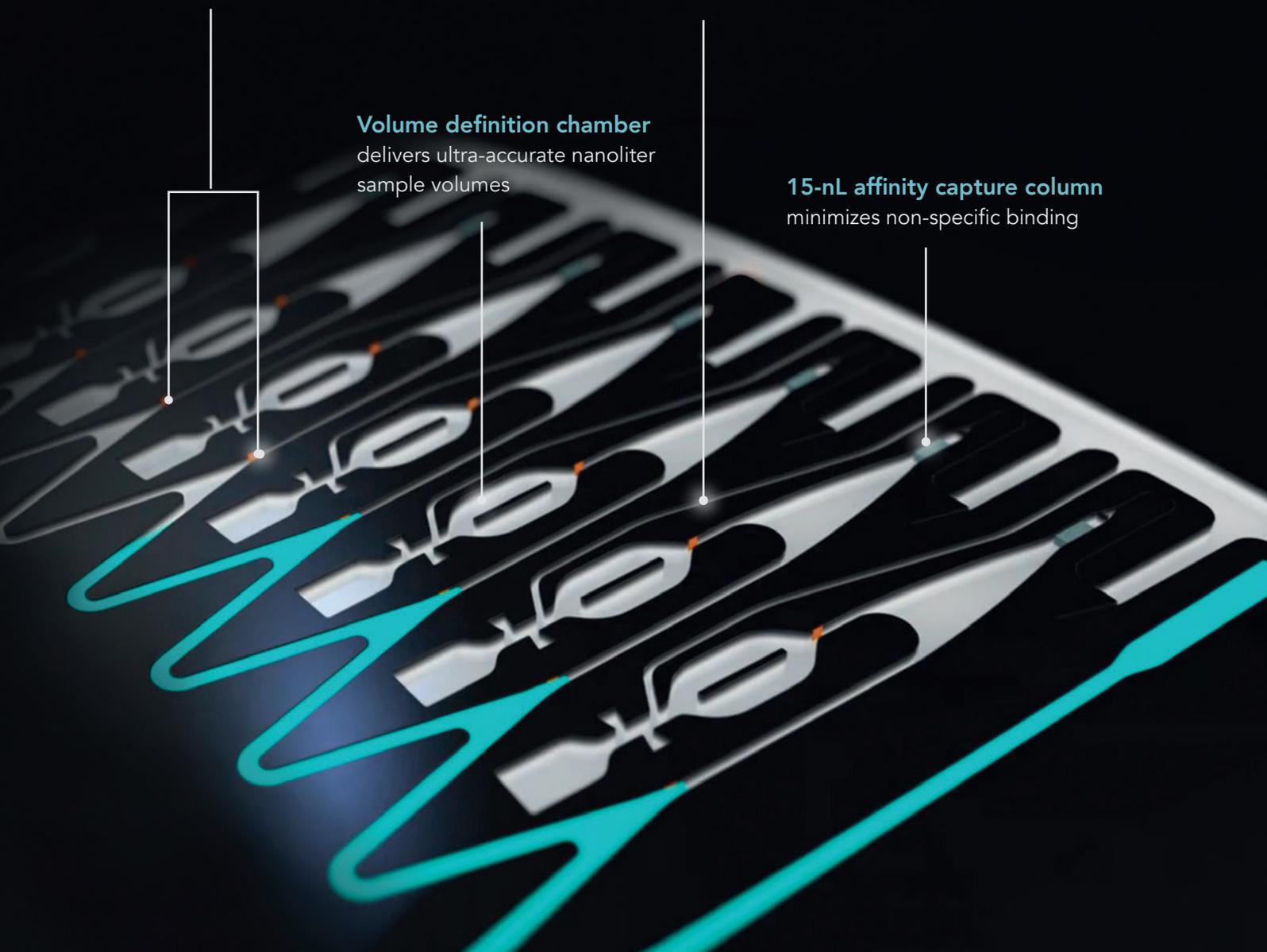
reduces need for pipetting accuracy

### 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

# Gyrolab® Ready-to-Use Kits and Solutions

Gyrolab® ready to use kits are optimized for fully automated analysis in Gyrolab Systems and provide fast turn-around, reproducibility and consistency of analysis without the need for assay development. Gyrolab ready to use kits contain sufficient reagents, CDs, buffers and consumables required for the indicated number of datapoints. The CD50 configurations of the kits are manufactured upon order and contain everything needed for 50 CD runs (50 x 96 data points). The CD50 reagents are conveniently supplied in volumes sufficient for 5 single CD runs in 10 bags to save storage space.



## Ordering Information

Prod. No	Product Name	Description
<b>Determination of human IgG concentrations in cell line development</b>		
P0020381	Gyrolab hulG Kit – Low Titer	Reagents and consumables for 96 datapoints (1 CD). Standard is not included.
P0020382	Gyrolab hulG Kit – High Titer	Reagents and consumables for 112 datapoints (1 CD). Standard is not included.
P0020379	Gyrolab hulG Standard (IgG1)	4 mg/mL, 50 µL.
<b>Determination of leached Protein A</b>		
P0020456	Gyrolab Protein A Kit for MabSelect SuRe™ Ligand	Reagents and consumables for 96 datapoints (1 CD).
<b>Determination of CHO-HCP impurity levels</b>		
<b>CHO HCP 3G Solution for Gyrolab</b>		
G550-1	CHO HCP 3G Assay Reagent Set for Gyrolab (Order from Cygnus Technologies)	Contains 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.
<b>Determination of E. coli HCP impurity levels</b>		
P0020625	Gyrolab E. coli HCP Kit	96 datapoints (1 CD).
P0020629	Gyrolab E. coli HCP CD50 Kit	Reagents and consumables for 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.
<b>For PK (pharmacokinetic) studies of human IgG in non-human species</b>		
P0020499	Gyrolab Generic PK Kit	Reagents and consumables for 96 datapoints (1 CD). Standard is not included. Includes two Sample Dilution Buffers (Type E and Type F) for selection of most optimal buffer.
P0020617	Gyrolab Generic PK CD50 Type E Kit	Reagents and consumables for 4800 datapoints (50 CDs). Standard is not included. Made to order.
P0020619	Gyrolab Generic PK CD50 Type F Kit	Reagents and consumables for 4800 datapoints (50 CDs). Standard is not included. Made to order.
P0020641	Gyrolab Generic PK Kit Reagent E (10 x 100 mL)	Sample Dilution Buffer, 10 X 100 mL. Made to order.
P0020642	Gyrolab Generic PK Kit Reagent F (10 x 100 mL)	Sample Dilution Buffer, 10 X 100 mL. Made to order.

Prod. No	Product Name	Description
<b>For TK (toxicokinetic) studies of human IgG in non-human species</b>		
P0020500	Gyrolab Generic TK Kit	Reagents and consumables for 96 datapoints (1 CD). Standard is not included. Includes two Sample Dilution Buffers (Type E and Type F) for selection of most optimal buffer.
<b>Titer determination for Cell and Gene Therapy</b>		
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 µL. 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.
<b>Determination of impurities for Cell and Gene Therapy</b>		
<b>HEK 293 HCP Solution for Gyrolab</b>		
G650S-1	HEK 293 HCP Assay Reagent Set for Gyrolab ( <a href="#">Order from Cygnus Technologies</a> )	Contains 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.
<b>EndonucleaseGTP® Solution for Gyrolab</b>		
G960	EndonucleaseGTP Assay Reagent Set for Gyrolab ( <a href="#">Order from Cygnus Technologies</a> )	Contains 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.
<b>Gyrolab Bioaffy Toolboxes (for use in Biorprocessing/Cell and Gene Therapy)</b>		
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.

Prod. No	Product Name	Description
<b>Gyrolab Human Cytokine Kit Reagents*</b>		
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.

## Gyrolab® Assay Protocols

Gyrolab systems are supported by an increasing range of ready-to-use kits and these open platforms are also recognized for their ability to enable the rapid in-house development and evaluation of high performance immunoassays. To accelerate access to robust immunoassays to a higher level, in addition we have prepared a number of protocols that have been rigorously tested to increase productivity while maintaining high quality requirements. New protocols will be added on a continuous basis.

Please visit [www.gyrosproteintechnologies.com/gyrolab-assays](http://www.gyrosproteintechnologies.com/gyrolab-assays)

**Gyrolab Assays**  
**Insulin Impurity Assay**

**INTRODUCTION**  
We have developed a three-step sandwich Gyrolab Assay to determine insulin in biological samples. The assay has a broad analytical range with an approximate LOD of 20 µg/mL, LOQ of 25 µg/mL, and ULOD of 15 000 µg/mL. Use of this protocol on Gyrolab systems will reduce time to market and increase productivity while maintaining quality requirements.

**ASSAY DESIGN**  
The assay was set up as a three-step sandwich immunoassay using human insulin (h-insulin) antibody capture and a different anti-human insulin (h-insulin) antibody as a detection antibody. Insulin (h-insulin) was used as a standard material.

**ASSAY PERFORMANCE**  
**Dynamic range, accuracy and precision**  
A robust linear standard curve (Figure 1) was generated over three runs, achieving an assay range from 20 µg/mL to 15 000 µg/mL (Table 1). The Limit of Detection (LOD) was determined as a concentration corresponding to at least two standard deviations above the assay blank.

**Table 1. Estimated Assay Range, based on three runs**

Assay Range	LOD (µg/mL)	LOQ (µg/mL)	ULOQ (µg/mL)
20 - 15 000	~20	25	15 000

**Table 2. Accuracy and precision data of 100 samples, in number of uses**

QC	Expected Conc. (µg/mL)	Average Measured Value (µg/mL)	CV (%)	Average CV (%)	Average Time (min)
LOD	20	25	1.0	0.7	15
LOQ	25	26	1.0	0.8	15
IPC	10 000	10 000	0.5	0.8	15
ULOQ	15 000	14 000	0.9	0.8	15

**Figure 1. Typical standard curve**

# 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	BUFFER							
	A / A-max	AN / AN-max	H / H-max	HN / HN-max	HX / HX-max	F	CCS	ADA
ADDITIVES	SALT	NEUTR	SALT NEUTR	NEUTR DET	DET			DET
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 x 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.

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