Gyrolab® CDs

Product Information Sheet D0012493/I

- **Reduce consumption of precious samples and costly reagents**
- **Minimize dilution steps and repeat runs**
- **Generate highly reproducible data**
- **Ensure minimal matrix effects**
- **Shorten processing times**
- **Meet the needs of many immunoassay applications**

An established way to automate a wide range of immunoassays

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 (Figure 1), 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.

Gyrolab CD-based immunoassays are widely used in many applications, including:

- Pharmacokinetics/toxicokinetics studies
- Pharmacodynamics and biomarker monitoring
- Immunogenicity testing
- Affinity determination
- Product titer quantitation
- Impurity testing

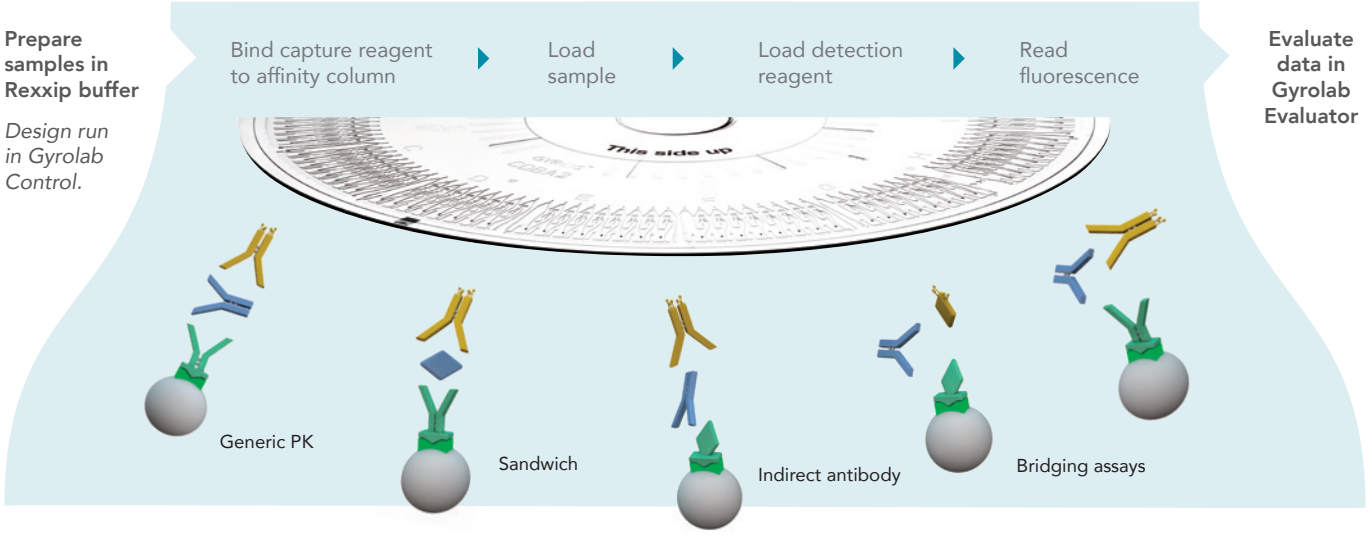

Figure 1. Samples are processed simultaneously in parallel in the Gyrolab Bioaffy CD, with every step controlled through an automated method. The fully automated addition of reagents and samples is defined in methods and protocols and controlled by user-friendly software that also evaluates the data. Gyrolab system can be used for a range of immunoassay formats.

GYROS PROTEIN Technologies

Gyrolab CD-based immunoassays boost productivity

A Gyrolab Bioaffy CD for every application

Gyrolab Bioaffy CDs differ primarily in the volume of sample volume processed, which determines the sensitivity of the assay (Figure 2). Many assays can be run using Gyrolab Bioaffy 200 which processes 200 nL. For highest sensitivity, Gyrolab Bioaffy 1000 or Gyrolab Bioaffy 4000 are the CDs of choice.

Gyrolab Mixing CD 96 integrates a sample preparation step into the in-CD workflow. A mixing chamber enables e. g. inclusion of an acid dissociation step when analyzing anti-drug (ADA) antibodies. Using Gyrolab Mixing CD 96 to integrate these steps reduces assay complexity and risk of error from additional manual steps and also shortens turnaround time.

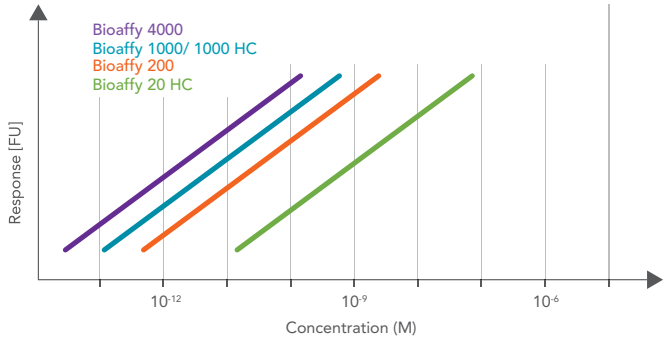

Figure 2. The sample volume defined in the CD determines sensitivity.

Save time and reduce consumption

Automation at nanoliter-scale reduces overall processing time and the fast reactions eliminate lengthy incubation steps required by conventional assay formats. For example, Gyrolab assays can generate 96 data points in one hour in an unattended run in contrast to ELISA which has a turnaround time of up to five hours and requires several manual interventions. The small volumes also minimize the consumption of precious samples and reagents.

A broad dynamic range

The precision microfluidics in Gyrolab Bioaffy CD ensure tight control over the assay workflow and the high binding capacity in the flow-through columns ensures a broad dynamic range. The result is a higher reproducibility over a broader dynamic range than that achieved using other technologies (see Figure 3).

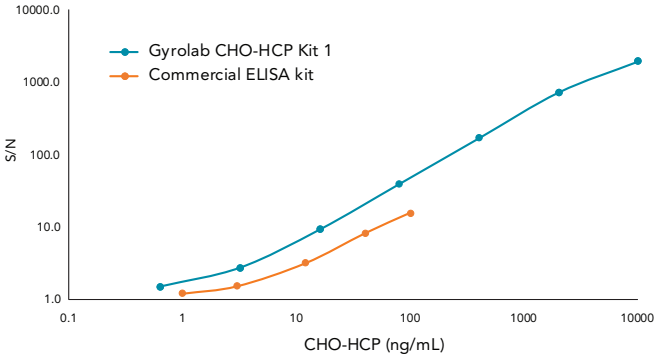

Figure 3. A Gyrolab assay of CHO-HCP extends two logs beyond the dynamic range of a conventional ELISA, ensuring that more samples are in range and fewer need to be diluted.

Minimal matrix effects

The flow-through format of the CD minimizes contact times between the interactants, which greatly reduces the matrix interference that can be an issue in conventional assay formats. This maximizes the success rate of assays based on matrices as diverse as serum (see Figure 4) and bioprocess samples.

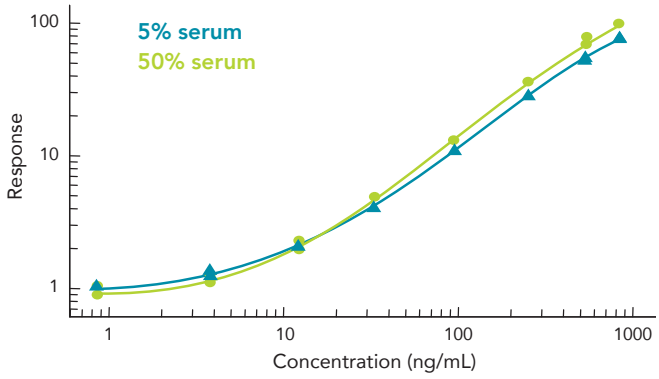

Figure 4. The flow-through format of the CD means that this drug could be measured equally well in 5% and 50% serum.

High precision

The unique properties and precision of Gyrolab Bioaffy CDs ensure very low intra- and inter-CD assay variation. Figure 5 shows five standard curves from an indirect antibody assay in 5% human serum run on five CD's from three CD batches in a single automated run. An inter-CD precision of <8% coefficient of variation was established from five QC samples in quadruplicate run on five CDs.

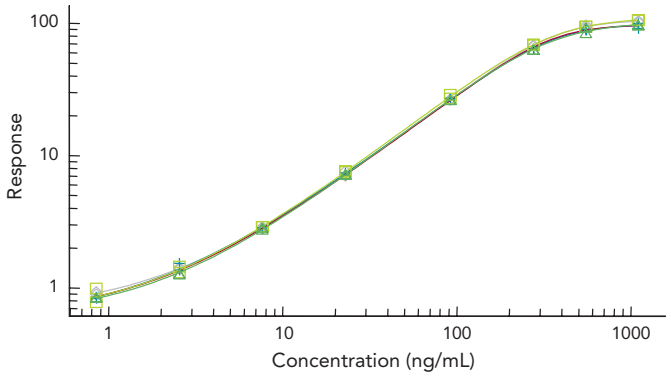

Figure 5. Five standard curves from a five CD run from three batches of Gyrolab Bioaffy 200 CD during an in-house validation of a clinical PK assay of commercially available biotherapeutic antibody.

Robust sample preparation with optimized Rexxip buffers

Rexxip buffers have been optimized to deliver high immunoassay performance in the Gyrolab Bioaffy CDs. Rexxip buffers ensure compatibility with samples containing a variety of molecules with different analytical properties.

Advanced quality control and troubleshooting

Unique to Gyrolab systems, Gyrolab Viewer software enables continuous monitoring of the fluorescence of individual structures in Gyrolab Bioaffy CDs to provide a quality check for each data point (Figure 6). This helps in spotting outliers and troubleshooting.

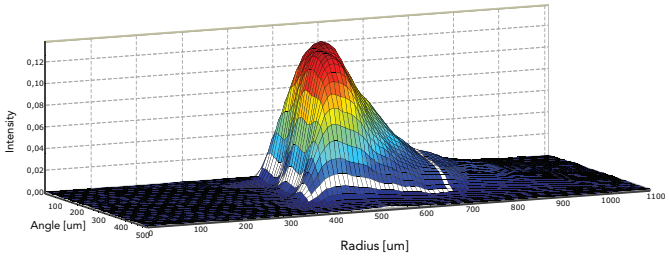

Figure 6. The affinity column profile accessible in the Gyrolab Viewer software provides a quality check of each datapoint, which is a unique feature of the CD-based technology used in Gyrolab systems.

Tiny CD technology

Nanoliter-scale affinity flow-through technology powers up immunoassays

Gyrolab CD is at the heart of the Gyrolab system, which enables immunoassays to be run in an affinity-column format using streptavidin-coated beads at nanoliter-scale (Figure 7).

The proprietary CD technology is engineered with highly reproducible microfluidic structures that ensure high-precision volume definition and tight control over the workflow (see Figure 8). Precise, and automated control of centrifugal forces and capillary actions steer liquid flow through the microfluidic structures within the CD. Integration in Gyrolab systems enables parallel processing of 96 or 112 microstructures coupled with laser-induced fluorescence detection.

The flow-through affinity micro-column format eliminates incubations and minimizes matrix interference. The nanoliter-scale format saves reagents and samples. The result is cost-effective and highly reproducible data over broad dynamic ranges.

Gyrolab Bioaffy CDs combined with Gyrolab systems reduce hands-on time and shorten processing times compared with many other platforms, leading to a considerable boost in productivity.

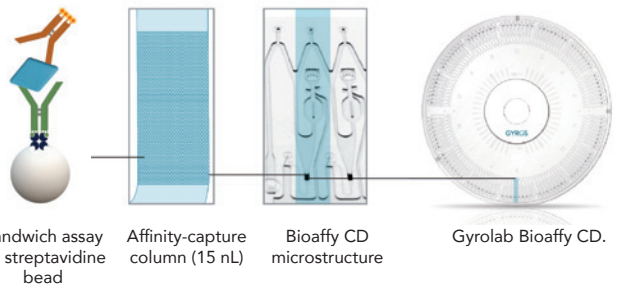

Figure 7. Gyrolab Bioaffy CDs enable immunoassays to be run on affinity capture columns at nanoliter-scale.

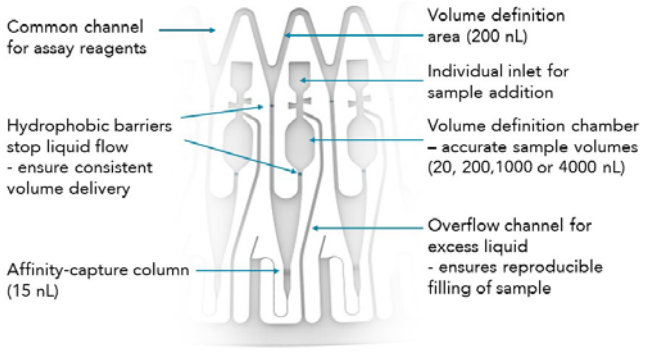

Figure 8. One microstructure – one data point – no cross-talk.

Gyrolab Bioaffy CD selection and specifications

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 has demonstrated improved performance when capture reagents have low affinity binding to the analyte.

Product No	CD	Sample volume (nL)	Data points	Particle	Sensitivity[1]	Application[2]
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
P0020455	Gyrolab Mixing CD 96	200	96	Solid	N/A	Applications requiring Sample pre-treatment e.g. acid dissociation

[1]Achievable sensitivity depends on application.

[2]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.

Storage (opened package)[3]: CDs must be used within one week of opening. Return partially used CDs to original CD box and pouch. Re-seal. Store dark, dry and at room temperature.

[3]Partially-used CDs can be run again. 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 micro-structures are stable in buffers pH 2-10.

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