

Gyrolab® Bioaffy™ CD and Gyrolab Mixing CD 96

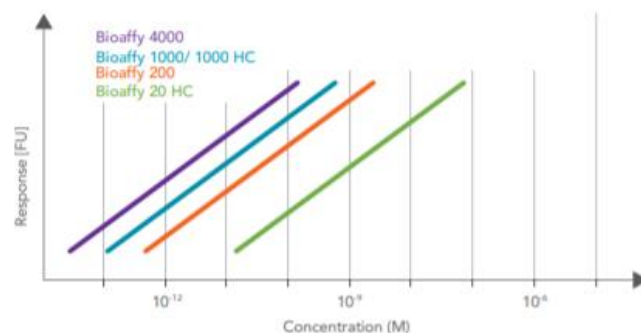
Product number	Product Name
P0004424	Gyrolab Bioaffy 20 HC
P0004180	Gyrolab Bioaffy 200
P0004253	Gyrolab Bioaffy 1000
P0020245	Gyrolab Bioaffy 1000 HC
P0020705	Gyrolab Bioaffy 4000
P0020455	Gyrolab Mixing CD 96

1. Product description

1.1. Gyrolab Bioaffy CD

Gyrolab® Bioaffy™ CDs are available in several versions differing primarily in volume of sample that is analyzed. Selecting the correct CD for a specific immunoassay is influenced by several parameters including the required dynamic range, the analyte concentration as well as the quality of reagents and the assay format.

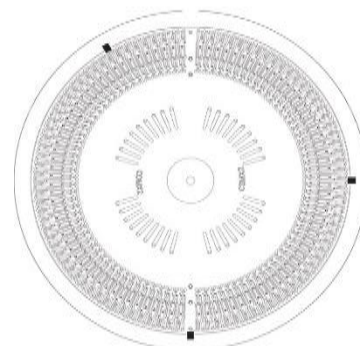
In general, the sample volume chamber in the CD determines the sensitivity of the assay. Many assays can be run using Gyrolab Bioaffy 200. If sensitivity is critical then Gyrolab Bioaffy 1000 or Gyrolab Bioaffy 4000 is the CD of choice since it can process 1000 or 4000 nL of sample. The porous particles included in Gyrolab Bioaffy 20 HC and Gyrolab Bioaffy 1000 HC CD allows for higher binding capacity. Gyrolab Bioaffy 20 HC is suitable when samples contain high analyte concentrations, such as IgG in cell culture samples. Gyrolab Bioaffy 1000 HC has demonstrated improved performance when capture reagents displays low affinity binding to the analyte.



Recommendations are to perform CD selection experiments prior to assay development to identify the CD for the required assay performance. The figure indicates typical concentration ranges for each Bioaffy CD.

1.2. Gyrolab Mixing CD 96

The detection of ADAs is a prime example of integrating sample pretreatment into the nanoliter-scale immunoassay workflow of Gyrolab Mixing CD 96. Addition of a mixing chamber allows for greater flexibility in assay workflows requiring additional incubations for equilibration, acid treatment or enzymatic reactions to occur. These additional assay steps typically add complexity and time to existing assays, while the Gyrolab Mixing CD 96 not only integrates sample pretreatment, but also shortens assay and incubation times with its nanoliter-scale workflows. Compatible with solutions of pH 2-10.



2. Methods for running Gyrolab CDs

Gyrolab CDs are run in Gyrolab Systems according predefined Gyrolab Methods. A Gyrolab Method can be defined as the instrument instructions to perform the automated "assay protocol". Parameters for transfers of liquids (samples, reagents, washes) and spin sequences are preprogrammed in the Gyrolab Method. Different methods depending on selected CD and assay design are available for download on www.gyrosproteintechnologies.com/gyrolab-user-zone.

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3. CD Selection

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 extended sensitivity e.g. biomarkers
P0020455	Gyrolab Mixing CD 96	200	96	Solid	N/A	Possibility to include sample pre-treatment e.g. acid dissociation in ADA or Pro A applications

*Achievable sensitivity depends on application.

**For guidance only. Recommendations are to perform CD selection experiments prior to assay development.

Gyrolab® Bioaffy™ CD and Gyrolab Mixing CD

4. Safety

Gyrolab Mixing CD and Gyrolab Bioaffy CDs are for research use only. Not for use in diagnostic procedures. Removal of a CD from a Gyrolab system after analysis as well as storage and disposal of a used CD must be according to applicable safety instructions. Samples and reagents may to some extent remain both inside and outside the CD after analysis. This circumstance must be included in the risk analysis of any hazardous samples and reagents.

5. Storage

Shelf Life

Minimum 12 months upon delivery

Unopened CD package

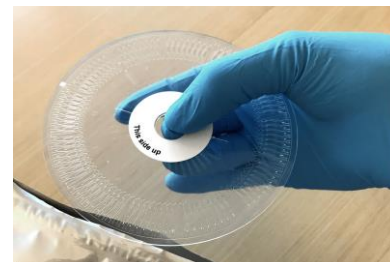
Refrigerate at +4 to +8°C, pouch unopened.

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.

6. Instructions

- Before use, equilibrate the CD in room temperature for at least 30 minutes in the unopened aluminum pouch.
- Complete the preparation of samples and reagents.
- Using protective gloves, open the CD pouch and carefully remove the CD from its pouch as demonstrated in the image. Do not touch the outer portion of the CD that contain the micro-structures. Load the CD together with samples and reagents directly in Gyrolab system. Protect the CD from sunlight or extended illumination by indoor lighting since this may affect data quality. Re-seal. Store dark, dry and at room temperature.



7. Certificates of analysis

Certificates of analysis are available at www.gyrosproteintechnologies.com

8. Disposal procedures

Gyrolab CDs should be disposed of in accordance with federal, state and local environmental control regulations. The user is responsible for waste disposal and for providing suitable waste containers. Packaging material can be disposed of through combustion for energy recovery.