

# Gyrolab xPlore™

## Product Information Sheet

D0023564/E

- Nanoliter-scale immunoassays generating high data quality
- Automated assay workflows
- Multiple samples run in parallel in a single CD
- Fast time to result: up to 112 data points in <1 hour
- New assays developed in days

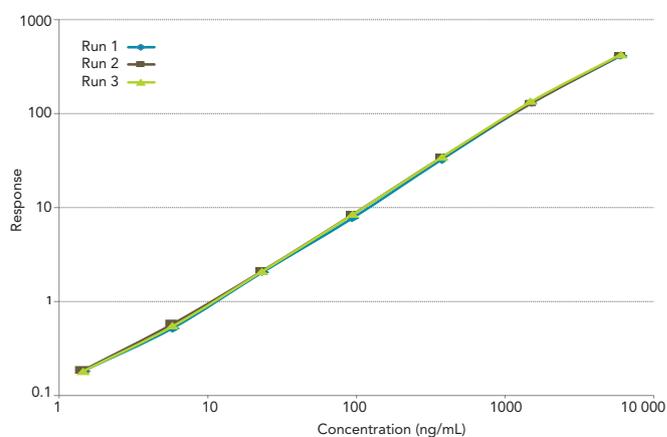


## Automated high performance immunoassays throughout biopharma development

Gyrolab xPlore™ runs nanoliter-scale immunoassays in a Compact Disk (CD) format, quickly and with low sample and reagent consumption, all with exceptional reproducibility. Gyrolab xPlore single-CD system is a cost-effective tool to automate immunoassays in discovery and preclinical R&D, bioprocessing and regulated bioanalysis. Regulatory compliance in GxP environments is supported by Gyrolab Functionality Check Kit to check system performance, a comprehensive IQ/OQ validation, QSR (21 CFR part 11) compliance, and a PQ guidance package.

A range of consumables is available to support the versatility of Gyrolab xPlore, including CDs for different applications and assays, and buffers to optimize performance. Assays can be developed using your own reagents, or kits from Gyros Protein Technologies. A range of software modules and methods ensure optimal performance, data analysis and reporting.

In every phase of biopharma product development, Gyrolab xPlore gives you and your team the agility to develop immunoassays more quickly and increase data quality with reduced hands-on time, reliably and precisely.



Gyrolab xPlore delivers high precision immunoassay data with great reproducibility. The figure shows standard curves from three separate runs.

## Gyrolab xPlore Overview



### Gyrolab xPlore is delivered with:

| Item                              | Content/Description   |
|-----------------------------------|---|
| USB-stick, 1 GB                   | For file transfer if required   |
| Wash bottles and tubing           | For storage and transfer of wash solutions and pump liquid  |
| Start-up kit                      | For sample handling: including microplates (25), microplate foils (50), microplate foil adapter (1)                             |
| User, Instrument and Quick Guides | Detailed instruction manuals and fast start-up  |
| Gyrolab Control                   | Software that controls processing of Gyrolab CDs. Includes template methods (assay protocols) for each type of CD.              |
| Gyrolab Evaluator                 | Software for analysis of immunoassay data   |
| Gyrolab User Licenses*            | Software license for four (4) users   |
| 12 months warranty                | Covers instrument installation and verification, defects in materials and workmanship, and repairs associated with the warranty |

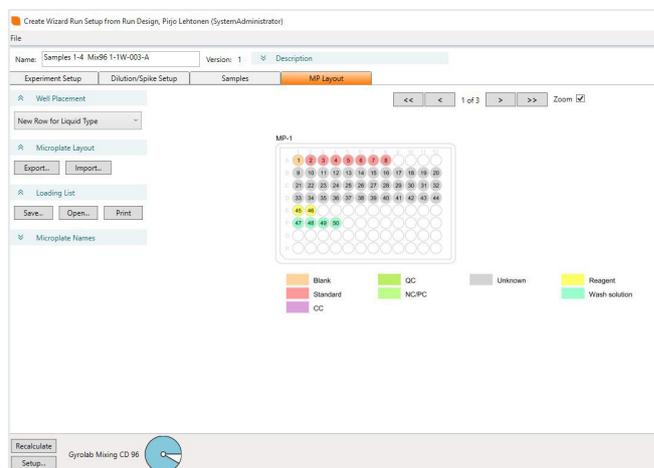
\*The End-User (as specified in the original Software End User license agreement) is responsible for ensuring that the number of users does not exceed the number of licenses purchased. User records must be maintained and made available for inspection by Gyros Protein Technologies upon request. Gyrolab software is supplied under license to the End-User and remains the property of Gyros Protein Technologies Group. Gyrolab software is protected by copyright laws and international treaties.

## Gyrolab Manager

- **Plan and set up runs at your desk while the instrument is running**
- **Mix and match assays according to your needs**
- **Designed for 21 CFR Part 11 compliance**
  - defined user access levels and passwords
  - logged audit trails
- **Advanced settings:**
  - spike recovery and sample dilution linearity studies
  - mapping of which samples are going to be processed for which experiments

Gyrolab Manager helps you maximize productivity at your desk. You can plan your experiments away from the lab and run any combination of experiments you wish. Run designs are stored in user-defined folders, allowing you to organize information according to your needs.

The advanced Dilution/Spike functionality provides a high level of flexibility and enables you to set-up advanced analyte concentration determinations, for example when testing assay accuracy and sensitivity by spike recovery studies or analyzing sample dilution linearity.



Gyrolab Manager simplifies the setup of experiments at your desktop.

## Workflow:

1. Create a Run Design by defining Gyrolab methods, reagents, standards and control samples for the experiments
2. Create a Run Setup by adding samples to the experiments
3. View automatically generated loading list and arrange microplate layout

Optional settings include:

- a. Define spike recovery and sample dilution series
- b. Specify mapping of sample set to experiments

## Gyrolab Control

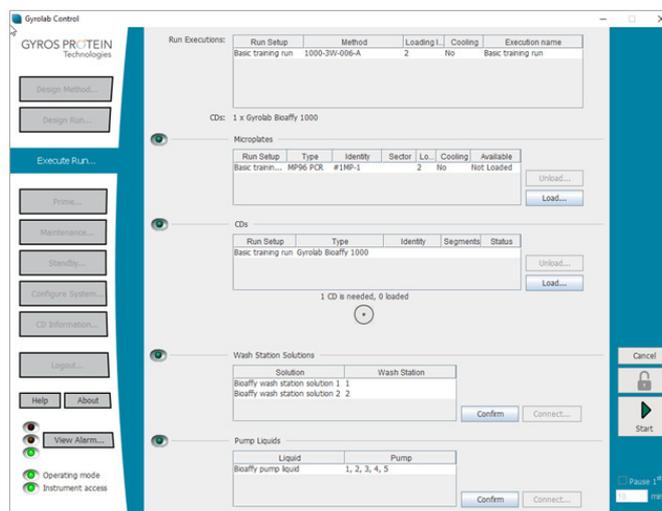
- Gyrolab Control software to execute runs
- Run automated assays workflows, unattended
- Designed for 21 CFR Part 11 compliance

Gyrolab Control is used to execute immunoassays for assay development or routine analysis. Gyrolab methods enable control of all steps in an assay workflow, including sample and reagent transfer, wash and incubation steps, spinning the CD and fluorescence detection, for each type of CD. Gyrolab Control executes the runs, which may have been created by different users with Gyrolab Manager. All instrument and software actions are logged in an audit trail.

### Gyrolab Control in pre-clinical and clinical analysis

Users working with validation and analysis of clinical and pre-clinical samples can integrate with a LIMS through Gyrolab LIMS interface software module.

Users analyzing raw data through their LIMS can use Gyrolab Control Report module to automatically generate non-editable raw data reports after each run.



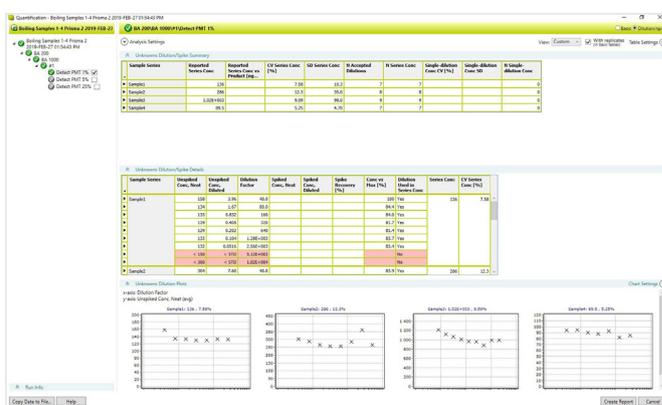
Gyrolab Control is used to execute runs.

## Gyrolab Evaluator

- Store all data in specified project folders
- Control consistency in evaluation
  - lock analysis settings for each project
- Designed for 21 CFR Part 11 compliance

Gyrolab Evaluator enables all sample and run details, run data and analyses to be stored in specified project folders. The administrator can lock analytical parameters, such as curve-fitting options and acceptance criteria, to ensure consistency between different users during data evaluation. Samples from different experiments within a single run can be analyzed and quantified in a single step and data can be compared within and between runs. All software actions, such as changes in acceptance criteria or exclusion of data points, are logged in an audit trail.

The advanced features in Gyrolab Evaluator, include visualizing dilution linearity and spike recovery data. Summarizing and plotting the dilution series enables assay qualification acceptance criteria to be set based on parameters defined by the user, such as maximum values or levels of variation, according to guidelines.



Gyrolab Evaluator software is used to analyze data and generate reports.

Quantification reports, including curve fit information, details on standard curves, control samples and unknowns can be generated for one or more samples from the same run or within the same project. Data comparison reports can be customized to include selected data tables and columns, with separate tables for each sample type.

## Operational requirements for Gyrolab xPlore



|   |   |
|---|---|
| Instrument dimensions (w × d × h)             | 54 × 58 × 64 cm (21 × 23 × 25 in)   |
| Instrument weight                             | 80 kg (176 lb)  |
| Bench dimensions (l × d)                      | 125 × 60 cm (50 × 24 in), Bench depth: 60 cm (with open space behind), 65 cm (with wall behind) |
| Bench load                                    | 90 kg (198 lb)  |
| Overhead clearance                            | 100 cm (40 in)  |
| Ambient temperature/ambient relative humidity | +20°C to +28°C (68°F to 82°F)/ 20% to 80%, non-condensing                                       |
| Mains voltage                                 | 100 - 240 VAC, +/- 10%. US and JP standard 15 A power outlet, Europe standard 10 A outlet       |
| Power/Frequency                               | 500 W/50 to 60 Hz   |
| Power outlet                                  | The instrument shall be connected to a grounded power outlet.                                   |

### Note:

- Place in a vibration-free location, away from direct sunlight and other heat sources.
- Gyrolab xPlore will produce small amounts of liquid waste. A waste tube (2 m long) will be supplied which can be directed to a waste reservoir or a drainage facility.
- If the system database is to be run over the local area network (LAN), a suitable network connection should be available in the proximity of the system.
- The operator needs 1 m (40 in) workspace in front of the Gyrolab xPlore workbench.
- Do not install the instrument in a location with risk for explosion or fire hazard.
- If hazardous chemicals are being used with the instrument, forced ventilation shall be provided for the work area.
- The instrument is IP class 20 and a Class 1 Laser Product.

## PC requirements

Gyrolab xPlore requires an external computer (PC) on which the User Interface and database are installed. The external PC, including monitor, keyboard, mouse, Microsoft Excel and Adobe Acrobat Reader, is either supplied by the Gyrolab user or purchased from Gyros Protein Technologies. Configuration guidelines are provided by Gyros Protein Technologies (D0022621).

|                   |  |
|-------------------|--|
| Operating system  | Windows 7 x64 - Professional, Enterprise, and Ultimate editions – English<br>or<br>Windows 10 x64 – Professional and Enterprise editions – English   |
| CPU               | 64 bits processor, 1.8 GHz or higher<br>Processor: AMD64, and Intel EM64T  |
| RAM               | Minimum 4 GB   |
| Hard drive size   | Recommended 500 GB or more (C: partition)<br><i>The data is stored in an application-specific Oracle Database installed by a Gyrolab-certified service engineer.<br/>Data generated from processing one CD is approximately 15 MB.</i> |
| USB port          | USB 2 or 3 interface, minimum four ports.<br><i>The software communicates with the instrument via one USB port. The other three are intended for the mouse, the keyboard, and a USB device.</i>  |
| DVD reader        | The DVD reader is required to install software upgrades.   |
| Screen Resolution | Recommended 1366 X 768   |

## *IQ/OQ validation support and PQ guidance*

- Provides time-saving support for on-site qualification and validation
- Certifies instrument functionality and performance within published specifications
- Includes certificates and records to fulfill GxP, FDA and EMEA requirements
- IQ/OQ performed by lab-certified service engineers using equipment calibrated to NIST traceable standards



Products from Gyros Protein Technologies are quality controlled and validated prior to delivery according to clearly defined processes. After delivery, the IQ/OQ/PQ support package extends this validation process to enable on-site qualification and validation for those instruments that are used in GxP environments.

### *Installation Qualification/Operational Qualification Process*

Prior to IQ/OQ, certain criteria must be fulfilled:

- Documentation must be customized to match the user’s workflow and approved for use.
- The instrument should be installed and fully operational, and set up for normal use, such as connected to a network, if applicable.
- A Preventive Maintenance (PM) check is strongly recommended and becomes mandatory if more than 6 months have elapsed since installation or the previous PM check.

### *The IQ/OQ process takes approx. 2 days on site*

During this time the user will monitor and approve every step of the IQ/OQ performed by the lab-certified service engineer as outlined below.

Installation Qualification procedures cover verification of:

- Site qualification and environmental conditions
- Configuration and calibration
- Calibration certificates of all equipment used during validation
- Configuration and documentation of computer hardware and software

Operational Qualification procedures cover verification of:

- Computer hardware and software functionality
- Instrument functionality
- System operation

Upon conclusion of all procedures, the user will approve the complete IQ and OQ documentation.

### *Performance Qualification*

The PQ guidance package includes recommended procedures to help the user validate instrument performance. After IQ/OQ the user is required to test and verify that specifications are met for the specific application and end-user handling i.e. a performance qualification. This process will require establishing acceptance criteria as well as inspecting and testing results with calibrated equipment, performed by trained, qualified end-users.

### *Re-validation*

IQ/OQ documentation must be updated to ensure that an instrument remains in a validated state after repair, upgrade or relocation. All IQ/OQ and re-validation services are performed by lab-certified engineers.

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## Gyrolab Functionality Check Kit

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- Ensure high quality results
- Support GLP/GMP and quality assurance requirements
- Verify instrument performance within 20 minutes
  - checks liquid transfer from microplate to CD
  - checks spinner functionality
  - checks detection functionality
  - checks software and database connection

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### Storage and shelf life

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|   |  |
|---|--|
| Unopened kit (CD and reagents)            | Refrigerate at +4°C to +8°C. Do not freeze.  |
| Shelf life unopened kit (CD and reagents) | Specified on product label.  |
| Opened reagents                           | Store at room temperature. Discard after 12 hours.   |
| CD after completion of first run          | Return CD to original CD box and pouch, re-seal and store at room temperature. Discard after 12 hours. |

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Designed for one time use, the kit enables a repeat check in the event that the first check is unsuccessful.

The Functionality Check Kit provides a ready-to-use confirmatory test of instrument performance. The check is completed in a single run, takes only 20 minutes to perform and requires no additional training. The automatically generated report is stored within the database, detailing results. Routine runs can be started immediately after a successful check.

It is assumed that the instrument is maintained and handled according to recommendations, for example, that Preventive Maintenance is performed regularly and that user maintenance procedures have been followed.

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## Ordering information

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To ensure that you are able to benefit from the continual improvements in Gyrolab software, please contact your local Gyros Protein Technologies representative to discuss your exact requirements.

For terms and conditions of purchase contact your Gyros Protein Technologies representative.

| Product                                   | Content/Description   | Product number |
|---|---|----------------|
| Gyrolab xPlore                            | System with content as listed under Gyrolab xPlore overview   | P0020300       |
| Gyrolab xPlore installation               | Instrument installation performed by a lab-certified engineer.  | P0020304       |
| <i>Accessories</i>                        |   |                |
| Gyrolab User Licences                     | Grants an unlimited number of Gyrolab software users  | P0004955       |
| Microplate foil adapter                   | One (1) adapter for transfer of microplate foil to microplates  | P0003697       |
| <i>Performance and validation support</i> |   |                |
| Gyrolab Functionality Check Kit           | A confirmatory test of instrument performance. Includes Functionality Check CD (1), reagent (1500 µL), wash buffer (1500 µL), microplates and foils (2 of each), instruction for use (1).           | P0005002       |
| IQ/OQ validation support and PQ guidance  | Documented collection of procedures and test protocols for on-site installation and operational qualification, and guidance for performance qualification. A lab-certified engineer performs IQ/OQ. | P0020291       |
| Instrument re-validation                  | Re-validation performed by a lab-certified engineer after modification of a validated instrument e.g. repair, update, upgrade or relocation (travel and parts billed separately).                   | P0004979       |
| <i>Consumables</i>                        |   |                |
| Microplate foil                           | Pack of 50  | P0003313       |
| PCR Plate 96                              | Pack of 25  | P0004861       |
| Gyrolab CDs                               | Refer to product information sheet "Gyrolab CDs"  | D0012493       |
| Rexxip buffers                            | Refer to product information sheet "Rexxip buffers"   | D0021887       |
| Additional Gyrolab software modules       | Refer to product information sheet "Gyrolab software modules"   | D0016374       |

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