

Gyrolab xP workstation

Product Information Sheet

D0012268/G

- Nanoliter-scale immunoassays generating high data quality
- Unattended runs, automated assay workflows
- Fast time to result: up to 112 data points in <1 hour, 560 data points in <5 hours
- New assays developed in days



Identity	Expected Conc. (µg)	Measured	R/S	Lab Conc. (µg)	Average Conc. (µg)	CV (µg)
Blank	0.00	0.0000	0.790			
Blank	0.00	0.0020	1.000			
Blank	0.00	0.0040	1.000			
Standard 1	0.750	0.0002	4.24	0.750	0.750	15.1
Standard 2	0.750	0.0009	8.20	0.750	0.750	15.1
Standard 3	0.750	0.0040	3.48	0.688	0.750	15.1
Standard 4	0.90	0.001	12.7	0.719	0.750	15.1
Standard 5	0.90	0.002	19.0	0.750	0.750	15.1
Standard 6	0.90	0.005	18.0	0.830	0.750	15.1
Standard 7	0.90	0.008	16.0	0.810	0.750	15.1
Standard 8	0.90	0.010	14.0	0.810	0.750	15.1
Standard 9	0.90	0.015	12.0	0.810	0.750	15.1
Standard 10	0.90	0.020	11.0	0.810	0.750	15.1
Standard 11	0.90	0.030	10.0	0.810	0.750	15.1
Standard 12	0.90	0.040	9.0	0.810	0.750	15.1
Standard 13	0.90	0.050	8.0	0.810	0.750	15.1
Standard 14	0.90	0.060	7.0	0.810	0.750	15.1
Standard 15	0.90	0.070	6.0	0.810	0.750	15.1
Standard 16	0.90	0.080	5.0	0.810	0.750	15.1
Standard 17	0.90	0.090	4.0	0.810	0.750	15.1
Standard 18	0.90	0.100	3.0	0.810	0.750	15.1
Standard 19	0.90	0.110	2.0	0.810	0.750	15.1
Standard 20	0.90	0.120	1.0	0.810	0.750	15.1
Standard 21	0.90	0.130	0.5	0.810	0.750	15.1
Standard 22	0.90	0.140	0.2	0.810	0.750	15.1
Standard 23	0.90	0.150	0.1	0.810	0.750	15.1
Standard 24	0.90	0.160	0.05	0.810	0.750	15.1
Standard 25	0.90	0.170	0.02	0.810	0.750	15.1
Standard 26	0.90	0.180	0.01	0.810	0.750	15.1
Standard 27	0.90	0.190	0.005	0.810	0.750	15.1
Standard 28	0.90	0.200	0.002	0.810	0.750	15.1
Standard 29	0.90	0.210	0.001	0.810	0.750	15.1
Standard 30	0.90	0.220	0.0005	0.810	0.750	15.1
Standard 31	0.90	0.230	0.0002	0.810	0.750	15.1
Standard 32	0.90	0.240	0.0001	0.810	0.750	15.1
Standard 33	0.90	0.250	0.00005	0.810	0.750	15.1
Standard 34	0.90	0.260	0.00002	0.810	0.750	15.1
Standard 35	0.90	0.270	0.00001	0.810	0.750	15.1
Standard 36	0.90	0.280	0.000005	0.810	0.750	15.1
Standard 37	0.90	0.290	0.000002	0.810	0.750	15.1
Standard 38	0.90	0.300	0.000001	0.810	0.750	15.1
Standard 39	0.90	0.310	0.0000005	0.810	0.750	15.1
Standard 40	0.90	0.320	0.0000002	0.810	0.750	15.1
Standard 41	0.90	0.330	0.0000001	0.810	0.750	15.1
Standard 42	0.90	0.340	0.00000005	0.810	0.750	15.1
Standard 43	0.90	0.350	0.00000002	0.810	0.750	15.1
Standard 44	0.90	0.360	0.00000001	0.810	0.750	15.1
Standard 45	0.90	0.370	0.000000005	0.810	0.750	15.1
Standard 46	0.90	0.380	0.000000002	0.810	0.750	15.1
Standard 47	0.90	0.390	0.000000001	0.810	0.750	15.1
Standard 48	0.90	0.400	0.0000000005	0.810	0.750	15.1
Standard 49	0.90	0.410	0.0000000002	0.810	0.750	15.1
Standard 50	0.90	0.420	0.0000000001	0.810	0.750	15.1
Standard 51	0.90	0.430	0.00000000005	0.810	0.750	15.1
Standard 52	0.90	0.440	0.00000000002	0.810	0.750	15.1
Standard 53	0.90	0.450	0.00000000001	0.810	0.750	15.1
Standard 54	0.90	0.460	0.000000000005	0.810	0.750	15.1
Standard 55	0.90	0.470	0.000000000002	0.810	0.750	15.1
Standard 56	0.90	0.480	0.000000000001	0.810	0.750	15.1
Standard 57	0.90	0.490	0.0000000000005	0.810	0.750	15.1
Standard 58	0.90	0.500	0.0000000000002	0.810	0.750	15.1
Standard 59	0.90	0.510	0.0000000000001	0.810	0.750	15.1
Standard 60	0.90	0.520	0.00000000000005	0.810	0.750	15.1
Standard 61	0.90	0.530	0.00000000000002	0.810	0.750	15.1
Standard 62	0.90	0.540	0.00000000000001	0.810	0.750	15.1
Standard 63	0.90	0.550	0.000000000000005	0.810	0.750	15.1
Standard 64	0.90	0.560	0.000000000000002	0.810	0.750	15.1
Standard 65	0.90	0.570	0.000000000000001	0.810	0.750	15.1
Standard 66	0.90	0.580	0.0000000000000005	0.810	0.750	15.1
Standard 67	0.90	0.590	0.0000000000000002	0.810	0.750	15.1
Standard 68	0.90	0.600	0.0000000000000001	0.810	0.750	15.1
Standard 69	0.90	0.610	0.00000000000000005	0.810	0.750	15.1
Standard 70	0.90	0.620	0.00000000000000002	0.810	0.750	15.1
Standard 71	0.90	0.630	0.00000000000000001	0.810	0.750	15.1
Standard 72	0.90	0.640	0.000000000000000005	0.810	0.750	15.1
Standard 73	0.90	0.650	0.000000000000000002	0.810	0.750	15.1
Standard 74	0.90	0.660	0.000000000000000001	0.810	0.750	15.1
Standard 75	0.90	0.670	0.0000000000000000005	0.810	0.750	15.1
Standard 76	0.90	0.680	0.0000000000000000002	0.810	0.750	15.1
Standard 77	0.90	0.690	0.0000000000000000001	0.810	0.750	15.1
Standard 78	0.90	0.700	0.00000000000000000005	0.810	0.750	15.1
Standard 79	0.90	0.710	0.00000000000000000002	0.810	0.750	15.1
Standard 80	0.90	0.720	0.00000000000000000001	0.810	0.750	15.1
Standard 81	0.90	0.730	0.000000000000000000005	0.810	0.750	15.1
Standard 82	0.90	0.740	0.000000000000000000002	0.810	0.750	15.1
Standard 83	0.90	0.750	0.000000000000000000001	0.810	0.750	15.1
Standard 84	0.90	0.760	0.0000000000000000000005	0.810	0.750	15.1
Standard 85	0.90	0.770	0.0000000000000000000002	0.810	0.750	15.1
Standard 86	0.90	0.780	0.0000000000000000000001	0.810	0.750	15.1
Standard 87	0.90	0.790	0.00000000000000000000005	0.810	0.750	15.1
Standard 88	0.90	0.800	0.00000000000000000000002	0.810	0.750	15.1
Standard 89	0.90	0.810	0.00000000000000000000001	0.810	0.750	15.1
Standard 90	0.90	0.820	0.000000000000000000000005	0.810	0.750	15.1
Standard 91	0.90	0.830	0.000000000000000000000002	0.810	0.750	15.1
Standard 92	0.90	0.840	0.000000000000000000000001	0.810	0.750	15.1
Standard 93	0.90	0.850	0.0000000000000000000000005	0.810	0.750	15.1
Standard 94	0.90	0.860	0.0000000000000000000000002	0.810	0.750	15.1
Standard 95	0.90	0.870	0.0000000000000000000000001	0.810	0.750	15.1
Standard 96	0.90	0.880	0.00000000000000000000000005	0.810	0.750	15.1
Standard 97	0.90	0.890	0.00000000000000000000000002	0.810	0.750	15.1
Standard 98	0.90	0.900	0.00000000000000000000000001	0.810	0.750	15.1
Standard 99	0.90	0.910	0.000000000000000000000000005	0.810	0.750	15.1
Standard 100	0.90	0.920	0.000000000000000000000000002	0.810	0.750	15.1
Standard 101	0.90	0.930	0.000000000000000000000000001	0.810	0.750	15.1
Standard 102	0.90	0.940	0.0000000000000000000000000005	0.810	0.750	15.1
Standard 103	0.90	0.950	0.0000000000000000000000000002	0.810	0.750	15.1
Standard 104	0.90	0.960	0.0000000000000000000000000001	0.810	0.750	15.1
Standard 105	0.90	0.970	0.00000000000000000000000000005	0.810	0.750	15.1
Standard 106	0.90	0.980	0.00000000000000000000000000002	0.810	0.750	15.1
Standard 107	0.90	0.990	0.00000000000000000000000000001	0.810	0.750	15.1
Standard 108	0.90	1.000	0.000000000000000000000000000005	0.810	0.750	15.1
Standard 109	0.90	1.010	0.000000000000000000000000000002	0.810	0.750	15.1
Standard 110	0.90	1.020	0.000000000000000000000000000001	0.810	0.750	15.1
Standard 111	0.90	1.030	0.0000000000000000000000000000005	0.810	0.750	15.1
Standard 112	0.90	1.040	0.0000000000000000000000000000002	0.810	0.750	15.1
Standard 113	0.90	1.050	0.0000000000000000000000000000001	0.810	0.750	15.1
Standard 114	0.90	1.060	0.00000000000000000000000000000005	0.810	0.750	15.1
Standard 115	0.90	1.070	0.00000000000000000000000000000002	0.810	0.750	15.1
Standard 116	0.90	1.080	0.00000000000000000000000000000001	0.810	0.750	15.1
Standard 117	0.90	1.090	0.000000000000000000000000000000005	0.810	0.750	15.1
Standard 118	0.90	1.100	0.000000000000000000000000000000002	0.810	0.750	15.1
Standard 119	0.90	1.110	0.000000000000000000000000000000001	0.810	0.750	15.1
Standard 120	0.90	1.120	0.0000000000000000000000000000000005	0.810	0.750	15.1
Standard 121	0.90	1.130	0.0000000000000000000000000000000002	0.810	0.750	15.1
Standard 122	0.90	1.140	0.0000000000000000000000000000000001	0.810	0.750	15.1
Standard 123	0.90	1.150	0.00000000000000000000000000000000005	0.810	0.750	15.1
Standard 124	0.90	1.160	0.00000000000000000000000000000000002	0.810	0.750	15.1
Standard 125	0.90	1.170	0.00000000000000000000000000000000001	0.810	0.750	15.1
Standard 126	0.90	1.180	0.000000000000000000000000000000000005	0.810	0.750	15.1
Standard 127	0.90	1.190	0.000000000000000000000000000000000002	0.810	0.750	15.1
Standard 128	0.90	1.200	0.000000000000000000000000000000000001	0.810	0.750	15.1
Standard 129	0.90	1.210	0.0000000000000000000000000000000000005	0.810	0.750	15.1
Standard 130	0.90	1.220	0.0000000000000000000000000000000000002	0.810	0.750	15.1
Standard 131	0.90	1.230	0.0000000000000000000000000000000000001	0.810	0.750	15.1
Standard 132	0.90	1.240	0.00000000000000000000000000000000000005	0.810	0.750	15.1
Standard 133	0.90	1.250	0.00000000000000000000000000000000000002	0.810	0.750	15.1
Standard 134	0.90	1.260	0.00000000000000000000000000000000000001	0.810	0.750	15.1
Standard 135	0.90	1.270	0.000000000000000000000000000000000000005	0.810	0.750	15.1
Standard 136	0.90	1.280	0.000000000000000000000000000000000000002	0.810	0.750	15.1
Standard 137	0.90	1.290	0.000000000			

Gyrolab xP workstation overview



Each Gyrolab workstation is delivered with:

Item	Content/Description
Gyrolab Control Unit	PC control unit with in-built electronics, monitor, keyboard, mouse and cable set, Windows Professional XP SP3 and all softwares pre-installed
Microsoft® Excel®	For data input in Microsoft Excel
USB-stick, 1 GB	For file transfer if required
Wash bottles and tubings	For storage and transfer of wash solutions and pump liquid
Degasser	For degassing of pump buffer
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 licence agreement) is responsible for ensuring that the number of users does not exceed the number of licences purchased. User records must be maintained and made available for inspection by Gyros upon request. Gyrolab software is supplied under license to the End-User and remains the property of Gyros Group. Gyrolab software is protected by copyright laws and international treaties.

Gyrolab Control

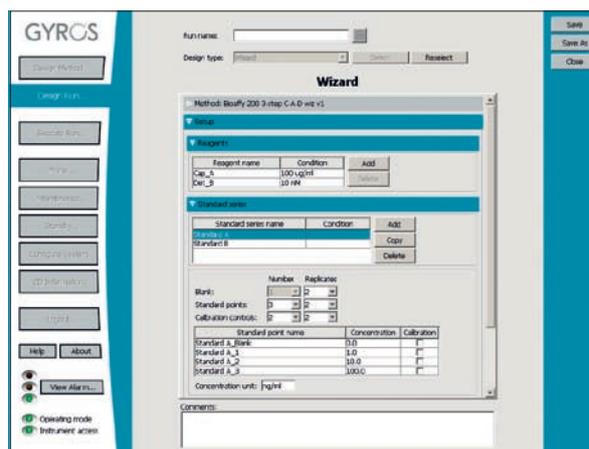
- Follow Gyrolab wizards to set-up and execute runs
- Run automated assays workflows, unattended
- Ensure 21 CFR Part 11 compliance
 - defined user access levels and passwords
 - logged audit trails

Gyrolab Control includes user-friendly wizards to facilitate set-up and execution of immunoassays for assay development or routine analysis. Template methods (assay protocols) enable control of all steps in an assay workflow, including sample and reagent transfer, wash and incubation steps, spinning of CD and fluorescence detection, for each type of CD. All instrument and software actions are logged within an audit trail.

Gyrolab Control in clinical and pre-clinical analysis

For users working with validation and analysis of clinical and pre-clinical samples the software can be integrated with a LIMS system through the Gyrolab LIMS interface software module.

Users analyzing raw data through their LIMS systems are advised to acquire a license for the Gyrolab Control Report module to automatically generate non-editable, raw data reports after each run.



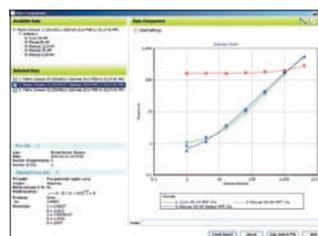
1. Select Gyrolab method (assay protocol)
2. Define capture reagents, detection reagents, standards and control samples
3. Select combination of reagents, standards and control samples for the experiment
4. Define unknown samples in Sample List
5. View automatically generated sample list and calculation of reagents consumption

Gyrolab Evaluator

- Store all data in specified project folders
- Control consistency in evaluation
 - lock analysis settings for each project
- Ensure 21 CFR Part 11 compliance
 - defined user access levels and passwords
 - logged audit trails

Gyrolab Evaluator enables all sample and run details, run data and analyses to be stored in specified project folders. Analytical parameters, such as curve fitting options and acceptance criteria, can be locked by an administrator 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 compared within and between runs. All software actions, such as changes in acceptance criteria or exclusion of data points, are logged within an audit trail.

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



Data comparison analysis



Quantification report

within the same project. Data comparison reports can be customized to include selected data tables and columns, with separate tables for each sample type

Extending the functionality of Gyrolab Evaluator

Users wishing to speed up assay development or quality control their data by viewing and comparing the binding profiles of data points during evaluation should acquire a license for the Gyrolab Viewer software module.

Users in bioprocess development and production can automatically calculate spike recovery when verifying accuracy of sample analysis by installation of the Gyrolab Serial Dilution Analysis module.

IQ/OQ validation support and PQ guidance

- **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 Gyros-certified service engineers using equipment calibrated to NIST traceable standards**



Products from Gyros 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 fully operational and set up for normal use, e.g. linked 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 3 to 4 days on site

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

Installation Qualification procedures cover:

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

Operational Qualification procedures cover:

- 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 contains 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 the establishment of acceptance criteria as well as inspection and testing of results with calibrated equipment, performed by trained, qualified end-users.

Re-validation

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

Gyrolab Functionality Check Kit

- **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



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

Compatible with workstations controlled by Gyrolab Control v 5.2 or higher, the Functionality Check Kit provides a ready to use, confirmatory test of instrument performance. The check is completed in a single run, taking only 20 minutes to perform and requires no additional training. An 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 workstation is maintained and handled according to recommendations, for example, that Preventive Maintenance is performed regularly and that user maintenance procedures have been followed.

Storage and shelf life

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.

Operational requirements for a Gyrolab workstation



Instrument dimensions (w × d × h)	120 × 60 × 90 cm (47 × 24 × 35 inch)
Bench dimensions (l × d)	2.20 × 0.62 m (84 × 25 inch)
Bench load	160 kg (352 lbs)
Overhead clearance	1.10 m (43 inch)
Ambient temperature/ambient relative humidity	+20°C to +28°C (68°F to 82°F)/ 20% to 80%, non-condensing
Mains voltage	100 to 240 V (US and Japan standard 15 A power outlet, EU standard 10 A outlet)
Power/Frequency	880 VA/50 to 60 Hz
Air supply	Pressure: >66 to <145 psi / >0.45 to <1 MPa / >4.5 to <10 bar Average flow rate at 0.45 MPa: 5.3 cfm / 150 NI/min / 2.5 NI/s Maximum flow rate (during 5 seconds period at 0.45 MPa): 10.9 cfm / 310 NI/min / 5.2 NI/s
Air quality	Particle size not exceeding 1 micron Oil content not exceeding 0.1 mg/m ³ Water content not exceeding 940 ppm
Air connection	A hose barb suitable for a hose with an inner diameter of 10 mm (0.39 inch) and outer diameter of 15 mm (0.59 inch). The point of connection should be within 3 m (10 feet) of the instrument.

Note: Place in a vibration-free location, away from direct sunlight and other heat sources. As specified above, the system periodically consumes compressed air which must be available throughout the run (up to 5 hours per run). Gyros recommend use of a compressor that continuously delivers compressed air. Additional information about compressor requirements and guidelines as well as tools and instructions on how to verify supply specifications can be provided.

Ordering information

To ensure that every user is able to benefit from the continual improvements in Gyrolab software, please contact your local Gyros representative to discuss your exact requirements.

For terms and conditions of purchase contact your Gyros representative.

Product	Content/Description	Product number
Gyrolab xP	Workstation with content as listed under Gyrolab xP workstation overview	P0004943
<i>Accessories</i>		
Gyrolab User Licences**	For five (5) additional 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 compatible with Gyrolab Control v 5.2 or higher. 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, operational and guidance for performance qualification. Gyros-certified engineer performs IQ/OQ.	P0003807
Instrument re-validation	Re-validation performed by a Gyros-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 and REXXIP buffers	Refer to product information sheet "Gyrolab CDs and REXXIP buffers"	D0012493
Additional Gyrolab software modules	Refer to product information sheet "Gyrolab software modules"	D0016374

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