

Gyrolab® Functionality Check

Gyrolab® Functionality Check is a confirmatory test of instrument performance. The check is completed in a single run taking approximately 20 minutes to perform and requires no additional user training. An automatically generated report is stored in the database including detailed results of instrument functions. Regular routine runs can be started immediately after a successful check. The check verifies instrument functionality such as:

- liquid transfer from the microplate to the CD including foil penetration, needle wash, spin and detection
- detection module including response level and position of the LIF
- software and database connection

Gyrolab Functionality Check Kit (Product Number P0005002) includes sufficient reagents to run a functionality check twice in one day i.e. the check can be repeated after following a recommended trouble shooting procedure to re-verify instrument performance after a failed result.

Prerequisites for running a Functionality Check:

- Software Gyrolab Control version 5.2 or above.
- Maintenance and handling of Gyrolab instrument according to Gyros Protein Technologies recommendations e.g. Preventive Maintenance has been performed regularly and that user maintenance procedures have been followed, see Gyrolab User Guide.

Kit contents

Products included in the kit are listed in below.

Component	Number of items	Volume (µl)
Gyrolab Functionality Check CD	1	N.a.
Reagent	1	1500
Wash buffer	1	1500
Microplate and foil	2 of each	N.a.
Instruction For Use	1	N.a.

Storage and Handling

Before use

Place the kit in room temperature for a minimum of 30 minutes.

Unopened kit components

Refrigerate at +4 to +8 °C. Do not freeze.

Opened kit components

- Gyrolab Functionality Check CD:
 - After completion of the first run return CD to the original CD pouch, re-seal e.g. with adhesive tape and store CD in room temperature for one day. Discard after 12 hours.
- Reagents:
 - Store in room temperature. Discard after 12 hours.

Safety

For research use only.

Certificate of analysis

A certificate of analysis is available upon request.

Recommended frequency

Perform Gyrolab Functionality Check regularly to verify instrument performance. For instruments in regular use Gyros Protein Technologies recommend that a functionality check is performed at least on a *monthly* basis or *after every 20 CD*. Alternative frequencies of Gyrolab Functionality Check should be determined by the operator taking into account instrument usage and/or local regulations and Standard Operating Procedures. Always perform a Gyrolab Functionality Check if it is suspected that the instrument is malfunctioning.

Procedure

Overall procedure

1. Prepare Gyrolab instrument
2. Prepare kit components
3. Run Gyrolab Functionality Check
4. Evaluate

1. Prepare Gyrolab instrument

Regular instrument preparation routines are applicable, see Gyrolab User Guide.

1.1 Switch on the instrument in advance:

- 1.1.1 Switch on Gyrolab instruments GW10045, GW10066 and higher 30 minutes before starting a check.
- 1.1.2 Switch on all other Gyrolab instruments 3 hours before starting a check.

1.2 Prime the instrument and check syringes for air bubbles, remove as necessary, (see Gyrolab User Guide version P0004354/D or later for instructions):

- 1.2.1 Fill 250 ml Bioaffy Pump Liquid in the bottle for the syringe pumps.
- 1.2.2 Fill 500 ml Bioaffy Wash Station Solution 1 in the wash station bottle.
- 1.2.3 Bioaffy Pump Liquid and Bioaffy Wash Station Solution 1; 15 mM phosphate buffer, 150 mM NaCl, 0.02% NaN₃, 0.01% Tween 20.

2. Prepare kit components

- 2.1 Before use, place the kit in room temperature for 30 minutes. Leave the CD in the unopened pouch.
- 2.2 Gently rotate or vortex the Reagent tube (brown cap).
- 2.3 Prepare the microplate according to Table 2. Apply microplate foil to the microplate.
- 2.4 Centrifuge microplate (4000 x g for two minutes) to eliminate bubbles and ensure that liquids are at the bottom of the wells.

Table 2. Description of reagent placement in microplate

Component	Microplate well	Volume/well
Reagent (brown cap)	A1-A10	10 µl
Reagent (brown cap)	B1-B10	50 µl
Wash buffer (clear cap)	C1-C2	50 µl

Gyrolab® Functionality Check

3. Run Gyrolab Functionality Check

For detailed instructions regarding start of a run, refer to Gyrolab User Guide version P0004354/D or later.

- 3.1 Select **Maintenance...** in the Main menu.
- 3.2 Choose the tab **Check** and select the run **Gyrolab Functionality Check v2**. Click **OK**.
- 3.3 Enter the **acceptance criteria for the detector response** as printed on the CD pouch.
- 3.4 Enter or browse **settings for the Report copy** or select **Use default settings**. The original report for the run will always be stored in Gyrolab Database. Click **OK**.
- 3.5 Load the instrument with Gyrolab Functionality Check CD.
- 3.6 For Gyrolab xPand; If the cooling is to be tested, enable cooling by checking the box*.
- 3.7 **Confirm** Wash Station Solutions and Pump Liquids.
- 3.8 Load the prepared microplate.
- 3.9 Click **Start**. The run will take approximately 20 minutes.
- 3.10 Click **Finish** when the run is complete and unload the CD and microplate.
- 3.11 Click **View report** or click **OK** to return to the Main menu.

* **Note:** Cooling will not appear in the report but there will be a warning if the cooling does not reach 2–8 degrees Celsius within 15 minutes, which is the acceptance criteria for cooling.

4. Evaluate

View the report in connection to the completed run, see 3.10, or open the report from Gyrolab Database or from the destination as specified in 3.4.

Result summary in the report indicates Passed or Failed for the complete functionality check.

The result of the individual tested functions; liquid handling, detector response and position, are presented in detail in the report indicating Passed/Failed information.

Troubleshooting

The report includes results for liquid handling and detection functions. Other instrument-related failures will appear as alarms during and/or after a check. For any alarm that occurs during the check, contact Gyros Protein Technologies. If the functionality check fails; go through each step in the troubleshooting list below, verify, correct and re-run the check. If the check still fails, contact Gyros Protein Technologies.

Table 3 Troubleshooting after a failed functionality check

Failed result:
Has Preventive Maintenance been performed on a regular basis as well as maintenance routines described in Gyrolab User Guide version P0004354/D or later?
Was handling and preparation of the instrument, CD and reagent performed according to the instruction for use?
Liquid Handling failure:
Prior to the Check was the instrument primed according to the instruction?
Was degasser turned on?
Check that the buffer level in the syringe pump bottle is higher than the top of filters.
Check that the microplate was loaded in the correct direction and correct loading position in the microplate carousel.
Check that all liquids in the microplate were correctly loaded according to the instruction.
Check that the microplate foil was penetrated according to the well identities in Table 2.
Check that there are no air bubbles in the microplate wells.

Gyrolab[®] Functionality Check

Prime the instrument (select all syringe and wash pumps) and ensure that: <ul style="list-style-type: none">○ All syringe pumps are functioning and:<ul style="list-style-type: none">○ No air bubbles visible in syringes.○ No leakage from syringes.○ Wash pumps are functioning.
Detector failure:
Verify that the instrument was turned on in advance before starting the Gyrolab Functionality Check according to the Instruction For Use.