# A Fully Automated Workflow for Gyrolab Assays

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## ABSTRACT

We describe a fully automated workflow for Gyrolab immunoassays based on sequence files from Watson™ LIMS, sample preparation with Hamilton STAR™ liquid handlers, and sample analysis in the Gyrolab® xPand. Data evaluation is performed in Watson™ LIMS. This workflow enables seamless traceability through barcode recognition in the liquid handler and guarantees an immunoassay setup according to ICH M10, which is not supported by default in regular Gyrolab workflows. The workflow is completed with documentation in our electronic lab notebook, Labnotes™.

## INTRODUCTION

The Gyrolab is an automated, open platform for developing immunoassays in a dedicated microfluidic disk. Capillary action and centrifugal force promote the delivery of reagents and samples to a nanocolumn (Fig 1). The flow-through format shortens the contact time between samples and binding sites. This typically reduces matrix effects and improves assay selectivity.

With minimal sample volumes, it generates data in just one hour with a wide dynamic range. This platform significantly reduces assay development time from weeks to days, accelerates critical development times, and conserves valuable samples and reagents.

When planning analytical runs with the Gyrolab software package, a special software algorithm plans the distribution of calibrators, quality control samples, and unknown samples on the 96-well plates so that each sample type is applied in a separate row on the plate. This distribution is not only prone to errors during sample transfer to the plate but also contradicts the requirements of ICH M10 (1), which stipulate that unknown samples must be surrounded by quality control samples.

We therefore sought an efficient solution to ensure sample processing typical for immunoassays. The goal was to plan the runs in Watson™ LIMS (as is customary in our laboratory) and export a worklist from there that could be used for both the Gyrolab® xPand and an upstream Hamilton Liquid Handler.

Below we describe our solution, which has proven particularly efficient in our laboratory for high-throughput analyses and, of course, also features computerized system validation according to the requirements of FDA 21CFR Part 11, enabling operation in regulated laboratory environments (2–5).

**Figure 1:** Gyrolab microfluidic disk in detail: Capillary action and centrifugal force deliver the reagents and samples to a nanocolumn.

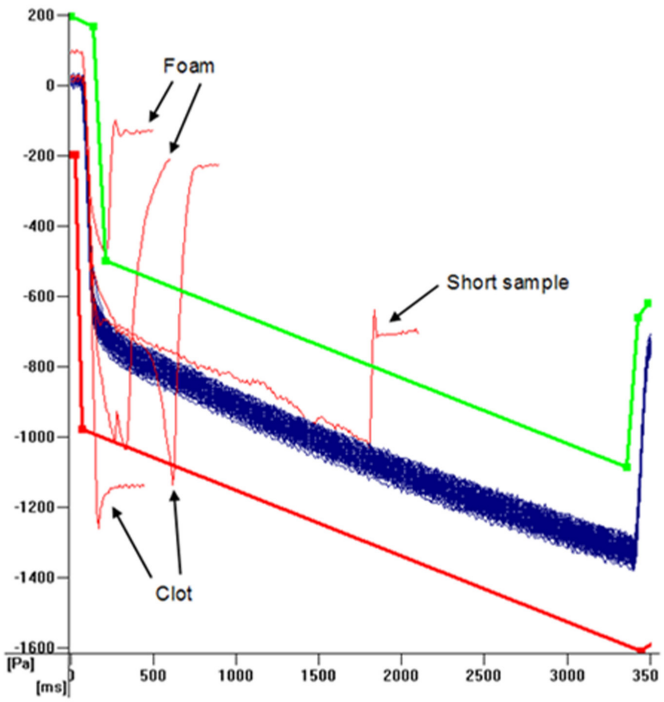
## SYSTEM AND WORKFLOW DESCRIPTION

Celerion uses Watson™ LIMS (version 7.6.1) to plan and evaluate analytical runs. One analytical run comprises 96 positions with calibrators, quality control samples, and unknown samples. Because Gyrolab technology is clearly an immunoassay, it requires two independent sets of quality control samples surrounding the unknown samples. This cannot be achieved when planning with the Gyrolab Manager software. Surprisingly, a special algorithm in the software distributes calibrators, controls, and unknowns into separate rows, which, when applied to sample distribution to the plate(s) before loading them to the Gyrolab, contradicts the typical immunoassay setup described above.

However, the Gyrolab software offers the ability to work with sequence files, which can be exported from LIMS after runs have been planned according to ICH M10.

Additionally, LIMS-derived worklist files are used to control the Hamilton STAR™. This compares the barcodes on the cryovials in the deck with the sample IDs and sequence specified in the worklist. A key strength of this liquid handler is the ability to monitor pressure curves during liquid transfer and report any errors in an automatically generated report file. Figure 2 shows a graphical example of these pressure curves and possible errors during liquid transfer.

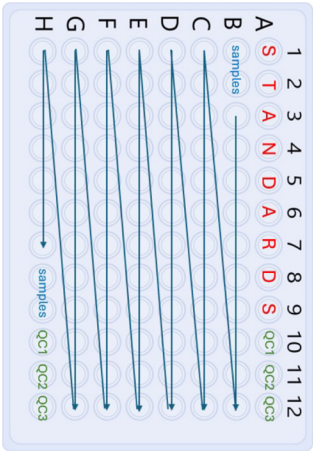
**Figure 2:** Example of Hamilton pressure curves with errors during liquid transfer.




The Gyrolab® xPand can process up to six 96-well V-bottom polypropylene plates, with one plate reserved for antibodies and reagents. The plates are arranged in landscape orientation and processing occurs row by row.

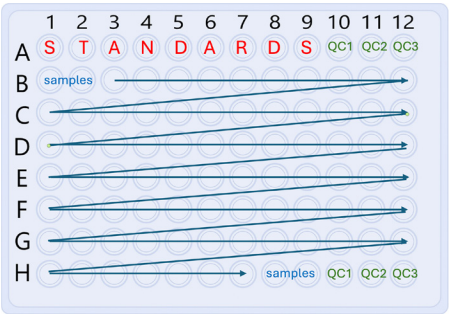
This must be considered when dispensing samples onto the plate. We were able to achieve efficient dispensing of standards, 1st QC set, unknown samples, and 2nd QC set by loading the plates onto the Hamilton in portrait orientation (i.e., rotated 90° for processing on the Gyrolab), ensuring simultaneous aspiration and dispensing of the samples. Loading the plates directly in landscape orientation would have resulted in the "dancing" needle phenomenon upon dispensing onto the plate, with a correspondingly long residence time of the matrix in the pipette tips and the risk of drying out before dispensing. The Hamilton pipetting scheme is shown in Fig. 3a.

**Figure 3a:** Portrait pipetting orientation on the Hamilton STAR for Gyrolab usage.



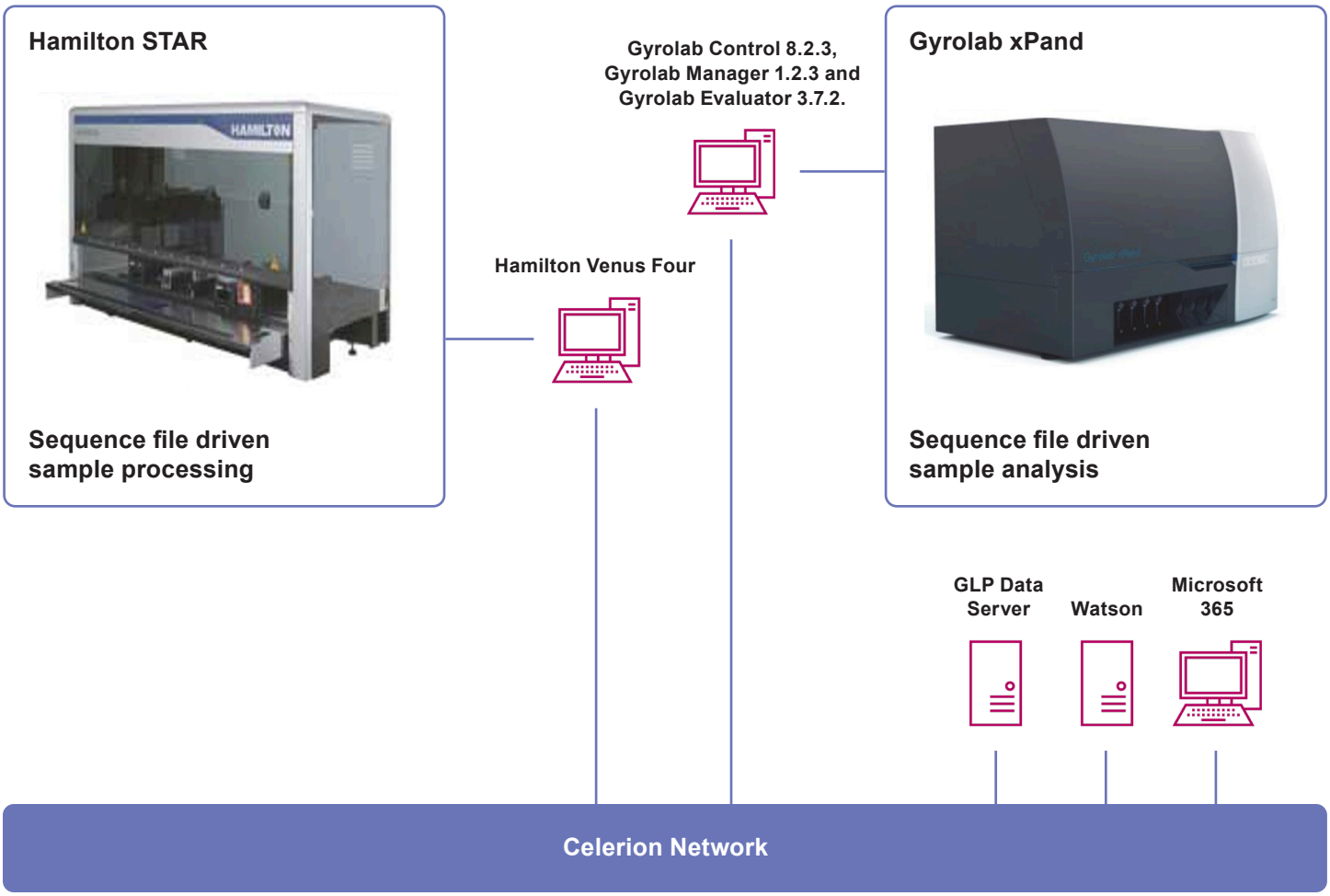

After liquid transfer on the Hamilton (which takes approximately 2h for three consecutive runs), the plates are loaded into the Gyrolab in landscape format, together with one additional plate containing the antibodies and reagents as calculated in the Gyrolab software. Then, the runs are processed according to the Watson™ LIMS sequence files (see Fig. 3b). After the measurement, the Gyrolab software inserts the raw data into the corresponding columns of the sequence files, which are automatically saved to a protected location on the GLP data server.

**Figure 3b:** Landscape processing orientation on Gyrolab® xPand.



From there, the upload into Watson™ LIMS can easily take place, where the data assessment is performed. For details on the system, see the diagram in Fig. 4

**Figure 4:** System diagram of the Hamilton STAR–Gyrolab® xPand Tandem in the Celerion LBS Laboratory.




## SUMMARY

We have developed a workflow for Gyrolab that is fast and highly efficient, meeting the ICH M10 requirements for conducting immunoassays. By staggering work on the Hamilton front end and the Gyrolab, we can achieve very high throughput with minimal personnel expenditure, especially since while a measurement is running on the Gyrolab® xPand, another set of plates can be prepared on the Hamilton, which can then be measured overnight. The usage of LIMS derived worklist and sequence files guaranties highest standards of data integrity.

In summary, Celerion now offers the Gyrolab platform for preclinical and clinical testing at the highest levels of quality and quantity.

## REFERENCES

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