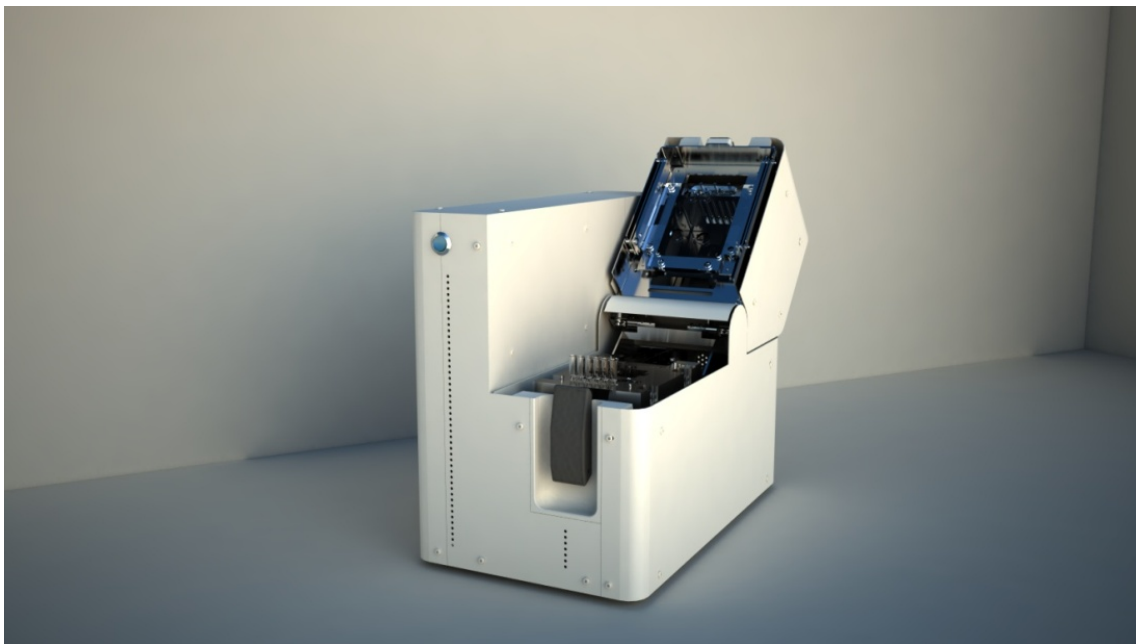


mLab4all

A Point of Care development platform for the implementation of analytical devices based on microfluidics, for the multi-parametric diagnosis of diseases.

The instruments implemented through the **mLab4All** platform share the following characteristics:

- *act as devices at the point-of-care in the clinical-analytical laboratory or in the rooms of a general practitioner*
- *perform complex multi-parameter analyses and supply the physician with a clear diagnosis based on the device derived information*
- *control the requirements, timing, reagents of the assay, and the interfaces to the Hospital Information System (HIS) and Electronic Patient Records (EPR)*
- *tests are performed after a drop of blood is added on one or more disposable microsystems, inserted into slots of the instrument, containing all of the assays, reagents, and sensors needed*



The hardware components of the instruments implemented through the **mLab4All** are partitioned in two groups, namely

1. the processing unit and
2. the microchip hosting unit

These two units can be thought of as two boxes that can be connected to form the final instrument. If a user wishes to expand the instrument and carry out more than one test simultaneously, they may purchase additional microchip hosting units and connect them to the main processing unit (while also expanding some of the electronics of the processing unit).

The **processing unit** is a complete PCI-board PC. The main processing unit of the instrument hosts the software application featuring the user interface and has the responsibility to kick-off the experiments, host the communication modules and control all possible peripherals, such as barcode readers, external storage etc.

The **chip hosting unit** provides for two or more separate slots, where test may be carried out in parallel. These slots host a chip (microsystem) of standard dimensions (e.g. titerplate format), where blood is inserted. Sample analysis requires a number of different steps (cell and plasma

separation, DNA amplification, primer fishing and hybridisation), thus the chip hosting unit accommodates all necessary components in order to perform all of them.

The **microsystems** contain all of the assays, reagents, and sensors needed for a test to be performed; in particular, they share the following characteristics:

- *they are made out of polymer that is biocompatible, easy to process, and inexpensive. The material is transparent and shows minimal non-specific adsorption of proteins, DNA, RNA, or other reagents. Barcode identification of the biochips allows for complete trace from production lot to medical diagnosis and facilitates relevant activities in the field of quality management.*
- *their footprint has the same outer dimensions (for all microsystems)*
- *the position of all interfaces between microsystem and instrument are shared by the different types of microsystem, even if one of the microsystems may be less complex and require less interfacing*
- *microfluidic microsystems are disposable, include all required reagents, and are able to handle the waste adequately. They are sealed systems avoiding the risk of potential contamination of the environment by samples or hazardous components of the on-chip solutions.*

The software environment of the instruments implemented through the **mLab4All**, namely the **Data Manager Application**, is hosted on the processing unit and allows for three groups of actors to interact with the instrument:

1. Administrators:
 - *for maintenance purposes,*
 - *with rights to edit protocols and configuration files using special tools*
2. Experimenters:
 - *with rights to edit protocol and modify parameters using special tools*
 - *for accessing the complete set of analysis tools*
 - *for detailed progress monitoring by displaying the complete set of steps and elements on the device*
 - *with the ability to export data and analysis results in more details*
 - *for uploading in central database*
3. Medical Experts:
 - *using a simple interface*
 - *for initiating and monitoring progress of the experiments*
 - *for having access to concise results reports*
 - *with an ability to export reports and/or upload the results in the central database*