

ChipGenie® edition Dx

One for all – A universal diagnostic platform

The ChipGenie® edition Dx system delivers a universal point-of-care diagnostic platform. It enables molecular, immunological and clinical chemistry assays for different sample matrices such as sputum, plasma, urine, soil and air. It is the one for all platform for users in multifaceted diagnostic fields.

The system concept

The ChipGenie® edition Dx platform is an integrated system covering the detection and identification of biological pathogens in a bleed-to-read fashion. Realized as lab-on-a-chip system, a consumable cartridge, the lab-on-a-chip, and the respective instrument constitute the ChipGenie® edition Dx system, leaving only the sample introduction as a hands-on-action for the user.

ChipGenie® edition Dx – Starting point for customization

The platform is customized according to your specific needs: The instrument will be equipped with the detection/sensor technology of choice and the chip can be designed for the respective assay panel, target samples and user-scenarios.

Assay categories

- Molecular assays
- Immunoassays
- Clinical chemistry assays
- Cell-based assays

Sample matrices

- Liquids
- Body fluids (blood, saliva, sputum, urine)
- Swabs
- Soil
- Air

Detection technologies

- Fluorescence
- Colorimetry
- Electrochemistry
- Special sensor technologies

Use-case scenarios

- One time use of the cartridge
- Permanent sampling

Confirmation within the same device

Option of reconfirming assays for one target combined on one lab-on-a-chip device

System Elements – Consumable and Instrument

The consumable – Lab-on-a-Chip

The assay-specific consumable cartridge defines all system operations. In order to minimize hands-on activities and a fully automated processing of all diagnostic assay steps, the consumable is a fully equipped lab: All reagents are integrated on the device either in a dry or liquid form. Sample preparation modules are included and on-board valves and pumps enable a complete operation of the consumable by the ChipGenie® edition Dx instrument.

Assay categories – Cartridge family

The platform is designed to allow for molecular, immunological, cell-based and clinical chemistry assays. These different assay categories and their varying sample preparation methods and assay steps require dedicated lab-on-a-chip devices. For example, cartridges for immunoassays may include a plasma generation unit, chips for molecular assays, a DNA extraction unit or reverse transcription, whereas cell-based assays can include concentration modules.

The expanding cartridge family addresses more and more different diagnostic tasks, designed according to the requirements of the ChipGenie® edition Dx platform concept in order to be operated with a common instrument platform.



ChipGenie® Dx cartridge – clinical assay with PCR read-out



ChipGenie® Dx cartridge – immunoassay



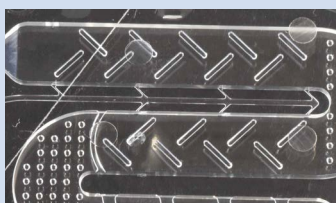
ChipGenie® Dx cartridge – molecular assay (DNA-based)

Platform Functionalities

In order to cope with the variety of process steps necessary to serve the full spectrum of diagnostic assays, a comprehensive set of functional elements form our microfluidic toolbox. A wide range of reagent integration technologies complements the microfluidic building blocks.

Microfluidic building blocks

Microfluidic building blocks are functional units with specific functions such as mixing, droplet generation or valving. Having such design components validated and available greatly simplifies the development of new microfluidic cartridge designs, for examples see below.



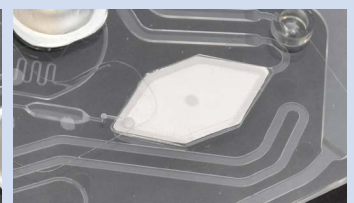
Mixing unit



PCR chambers



Valves



Membrane

Reagent integration

Only a full set of reagent integration technologies allow for the realization of lab-on-a-chip systems having embedded all necessary reagents. This includes e.g. liquid reagents in blisters, dry reagents implemented by lyophilization or spotted probes for hybridization assays.



Liquid reagents stored in blisters



Liquid storage in reagent tanks



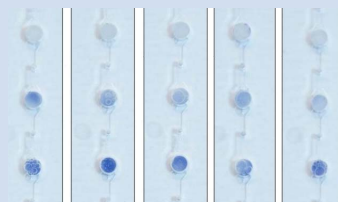
Lyophilized PCR master mix



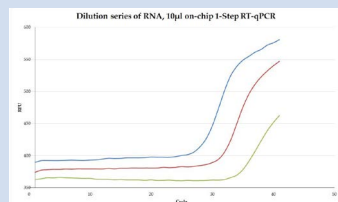
Spotted probes for hybridization

Detection technologies

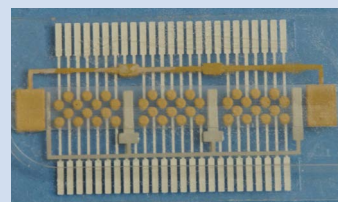
Various detection technologies can be used. Fluorescence, colorimetry or electrochemistry are options as well as special sensor technologies.



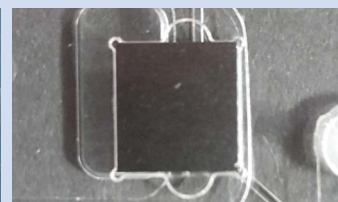
Colorimetric Immunoassay



Fluorescence detection



Electrochemical detection



Silicon photonic sensors

Procedure – Your Sample’s Path through the Cartridge

The cartridge replicates all steps carried out in a conventional lab – on a miniature footprint and without any manual interaction. Embedded liquid reservoirs like blisters or the syringe pump allow for the fluid management together with integrated turning valves and exact volume metering. All of this happens without any fluidic interface to the instrument, thereby avoiding contamination risks.

Assay steps along with fluidic processing and respective actuation are shown for one of our molecular assay platforms.



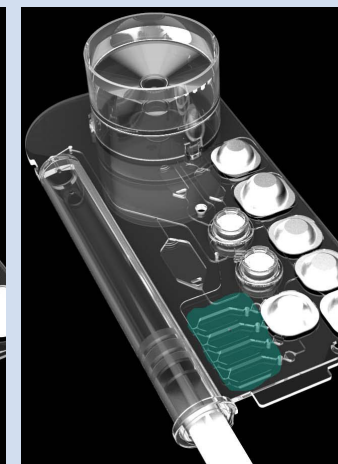
Sample preparation



Metering of the sample and incubation with assay reagents on chip



Washing with embedded reagents



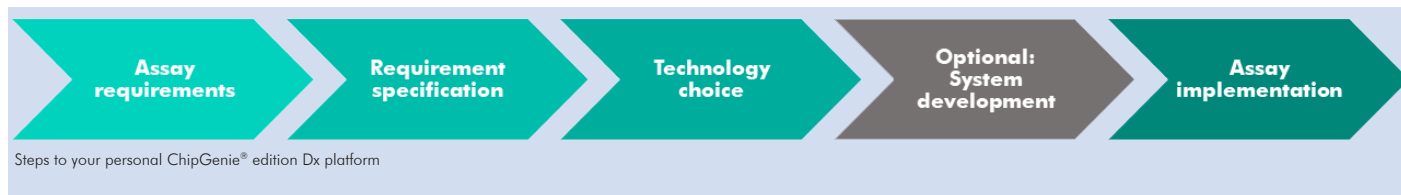
Detection

Service Range and Required Development

This system is designed as an open platform, allowing our partners to choose the desired detection technology and assay steps in combination with their assay portfolio to be implemented on the cartridge.

Your personal ChipGenie® edition Dx – The development process

Defining your personal ChipGenie® edition Dx platform starts with your assay description followed by the requirement specification and the common definition of the technologies to be implemented. Based on this, the choice of the platform configuration is made and assay implementation or further technological development begins. Common technical validation follows and for the subsequent clinical validation, a network of university clinics is at hand to assist our customers with this service for the product validation, all under the guidance of a certified ISO 13485 quality management system.



Configuration choice

The development varies according to the requested configuration. For some of the configurations, a cartridge platform as well as the instrument with all necessary functions can be used and the adaption work refers to the transfer of the customer assay only. Due to the variety of different technological options and ways for assay implementation, hardware developments are frequently necessary. The open concept of the instrument platform enables seamless integration of further functional elements in order to meet our customers' needs to deliver the full performance required for the respective application.

microfluidic ChipShop – Full Service Provider

microfluidic ChipShop offers a unique technology portfolio comprising consumables, instrument and assay implementation and is your partner from the first idea to volume fabrication.

Fully equipped application laboratories as well as close collaboration with university clinics allow for a smooth transition from the laboratory to partners for external testing and validation together with our customers.

Design-your-Platform Workshops

Do you want to configure your lab-on-a-chip? With our Design-your-Lab Workshops we assist you in creating your custom cartridge once you wish to get started with our open-platform concept.

