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Advanced Technologies for Industry – Product Watch

Nano-enabled microsystems for bio analysis

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Section 1

1. Background and objectives of the report

Background

The Product Watch Reports have been developed in the framework of the 'Advanced Technologies for Industry' project and serve to identify and analyse 15 promising advanced technology (AT)-based products and their value chains, with an assessment of the strengths and weaknesses of the EU positioning.

Promising AT-based products can be defined as "*enabling products for the development of goods and services enhancing their overall commercial and social value; embedded by constituent parts that are based on AR/VR, Big Data & Analytics, Blockchain, Cloud, Artificial Intelligence, the Internet of Things (IoT), Mobility, Robotics, Security & Connectivity, Nanotechnology, Micro-nanoelectronics, Industrial Biotechnology, Advanced Materials and/or Photonics; and, but not limited to, produced by Advanced Manufacturing Technologies*".

1.1 Background of this report

In the past decades there have been rapid developments of microfluidic technologies in various areas for different applications. One important technology trend has been the miniaturisation of microfluidic systems, especially for analytical purposes, to scale down the volume of samples and reagents, effectively cutting down on the time, costs and efforts in sample preparation and analyses enabled by significant progress in the fields of microelectronics as well as miniaturisation analysis and transducers. These developments contributed to improvements in the integration of laboratory systems onto one single chip.[1] A range of analytical procedures that used to be manually handled in laboratories can now be substituted by integrated technologies, commonly termed as lab-on-a-chip (LOC).[2] In the following, the report will focus on the LOC technology as a key platform technology essential for any nano-enabled microsystem for bio-analysis device or application.[3] The microfluidics is a core technology of LOC that comes into contact with the sample to be analysed. Along with microfluidics, LOC technology integrates nano- and micro-technology, such as photonics, magnetics, electronics, photoacoustics and micromechanics.

LOC technology holds the potential to dramatically improve the speed, efficiency and cost of many bio-chemical diagnostics procedures providing a paradigm shift for bio-analyses.[4] Therefore, technology receives a lot of interest from governments and industry investing more in this technology. The most significant current and potential advantages of the LOC-based technologies are:[5]

- **High parallelisation/multiplexity**: thanks to its capacity for integrating microchannels, LOC technology enables a large number of analyses to be performed simultaneously on the same chip;
- **Cost efficiency**: parallelisation significantly reduces the cost of analysis. Additionally, technology requires low sample and costly reagent demand. For medical and other diagnostic applications, LOC has the potential to drastically reduce diagnostic costs and the cost of diagnostic infrastructure;
- **Ease of use and compactness**: LOC devices are extra small in size (just a few square centimetres) and thus significantly more compact than conventional analytical devices. Diagnostics using lab-on-a-chip require a lot less handling and complex operations and can be performed on site and to monitor health at home or in different environments or locations, e.g. for air and water monitoring;
- **Diagnostic speed**: LOC considerably speeds up doing analyses and related operations;

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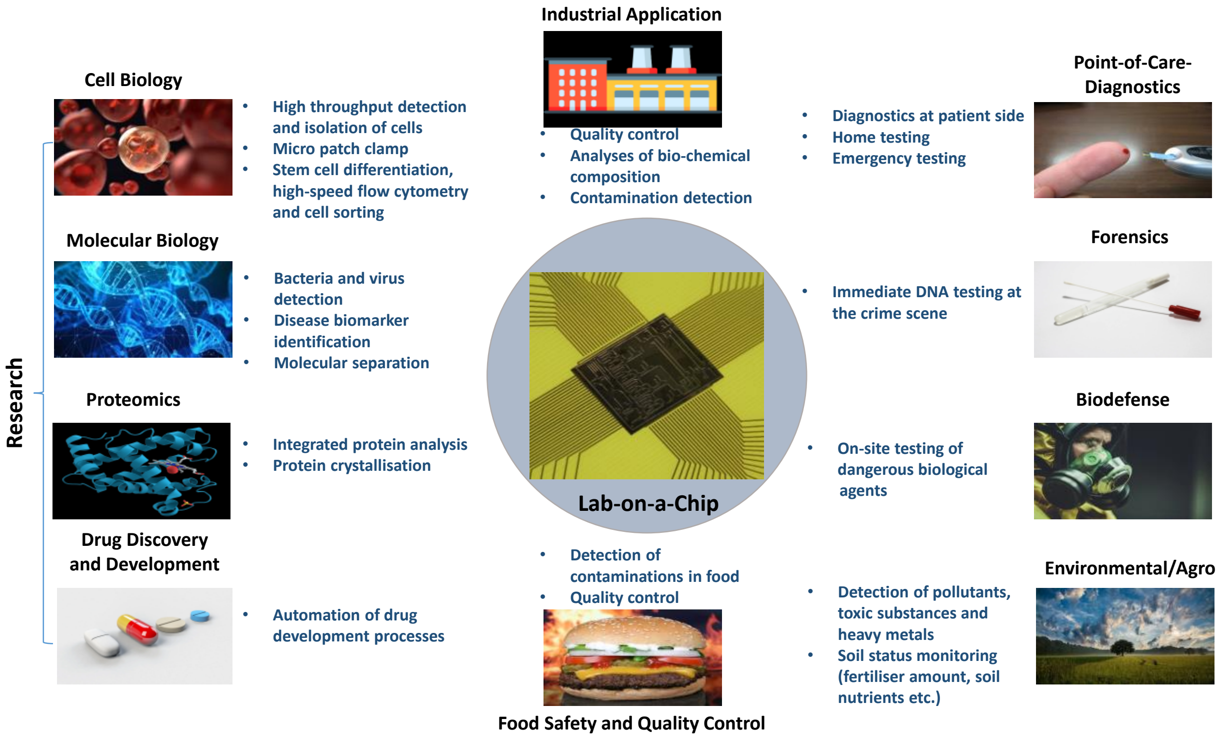
[1] Dhar and Lee. (2018).
[2] Yew et al. (2019).
[3] Nanotechnology is a key technology for the miniaturisation of bioanalytical systems by integrating sensors, fluidics and signal-processing circuits, which ensure integration of different biochemical reactions on a smaller footprint. The purpose of such miniaturised total analysis system (μTAS) is to enhance the analytical performance of laboratories and tests.
[4] Claussen and Jonathan. (2012).
[5] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/

- **Real time control and monitoring, improved sensitivity**: LOC technology enables to control in real time the environment of a chemical reaction that leads to more controlled results;
- **Improvement of diagnostics in developing countries**: LOC can contribute to the significant improvement of diagnostics and health care in developing countries by enabling rapid and cost-effective diagnosis of large groups of people in resource poor and remote locations.

Figure 1: Potential application fields of LOC-based technologies



Source: Fraunhofer ISI[6]

Numerous current and future application areas can benefit from the LOC technology. It stands to significantly advance the point-of-care medical diagnostics, holds a strong potential to improve the quality control techniques and to increase performance in different industrial applications at the points of need, such as chemicals, oil and gas, pharmaceutical and food industry. Compared with conventional systems, LOC-based technology offers huge advantages to many bio-medical research areas. It is considered an important enabling technology for advancing molecular biology, cell biology and proteomics and for making drug development processes more efficient, accurate and cost-effective. In addition, LOC is turning a high potential technology to be used in many emerging application fields, like environmental and agricultural monitoring, forensics and biodefense.

Moreover, there are highly promising application areas of the LOC technology beyond bio-chemical analyses. The convergence of LOCs and cell biology presents the most powerful potential. It allows for the in vitro study of human physiology in an organ-specific context (organ-on-a-chip), which is expected to have major applications in bio-medical science, precision medicine, therapy development, drug discovery and regenerative medicine. But also the LOC-based point-of-need and point-of-care diagnostics hold a potential to revolutionise health and diagnostic fields.[7]

Despite their high potential, LOC systems have been rarely used in everyday practical applications so far. LOC is still in the early stages of adoption across most application areas. Amongst all application areas, Point-of-Care (POC) and clinical research have the highest adoption rates.[8] In particular, the technology is increasingly used for the on-site diagnosis of some diseases, such as glucose monitoring or specific pathology detection as well as in genomic and proteomic research. In future, a considerable expansion of LOCs use for different applications is expected.[9] However, there is a number of barriers that hamper the successful diffusion of LOCs and need to be dealt with to ensure a timely introduction of advanced LOC technologies into the market and everyday use. They will be subsequently discussed in more detail.

[6] The illustration contains free images from https://pixabay.com/de/.
[7] https://www.europeanpharmaceuticalreview.com/article/79114/lab-chip-product-development/
[8] https://drug-dev.com/loc-based-devices-lab-on-chip-how-far-are-we-along-the-road/
[9] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/

Market Development According to the market research organisation Yole Développement, the size of the total global microfluidic-based point-of-need testing[10] market is going to grow at a compound annual growth rate (CAGR) of 14% by 2025, amounting to a total market size of approximately €8 833 million.[11] The market will be dominated by the human point-of-care testing. Part of the large growth in value is attributable to the growth of complex and high value molecular tests.[12] The largest markets by application are hospital tests and emergency testing, largely driven by infectious disease testing. In the human testing segment, significant growth is predicted for tests performed in decentralised healthcare settings (doctor's office, clinics and pharmacies). Home tests and forensics are currently small markets that are expected to increase rapidly in the next years. Monitoring chronic diseases (e.g. diabetes, heart failure) will be the main growth drivers in the home testing segment. Point-of-need testing in research fields and industrial and environmental settings markets are going to expand particularly strongly. In industrial fields, applications in the pharmaceutical and biotechnology industries are expected to be the growth areas with the highest potential. The most promising applications in the research field are DNA sequencing, digital immunoassays and polymerase chain reaction (PCR)[13]. Additionally, factors, such as public funding and support initiatives for research, increasing number of genomic and proteomics research efforts and development of advanced medical treatment options are likely to enhance the growth of LOC device market.[14] However, in some non-human point-of-care testing segments, like industrial, agro-food and environmental, a broad implementation of technology is still hindered by the lack of user awareness, insufficient collaborations between technology developers and potential users and regulation gaps.[15]

The costs at the hardware level, particularly of chips, and correspondingly their price, are going to decrease in future. This is the main reason for the slower average growth of the microfluidic device market value in the next years. The total microfluidic device market is projected to grow at a CAGR of 8.5 % annually between 2019 and 2025, of which the molecular diagnostics represents the largest share and fastest growing category (Figure 2). Oncology is one of the major application areas of molecular diagnostics.[16]

Regionally, North America holds the largest share of the market and is expected to keep its position in the near future owing to the quick adoption of innovative technologies and a favourable investment environment. The European Union represents the second largest market. The highest growth in the next years is predicted to be reached in the Asia Pacific region due to the vast investments and fast adaptation of healthcare technology, large patient pool, increasing number of government initiatives and growing number of research projects in related fields. The Middle East and Africa are projected to have significant growth in the future particularly because of urgent demand for cost effective ready-to-use diagnostic technologies.[17]

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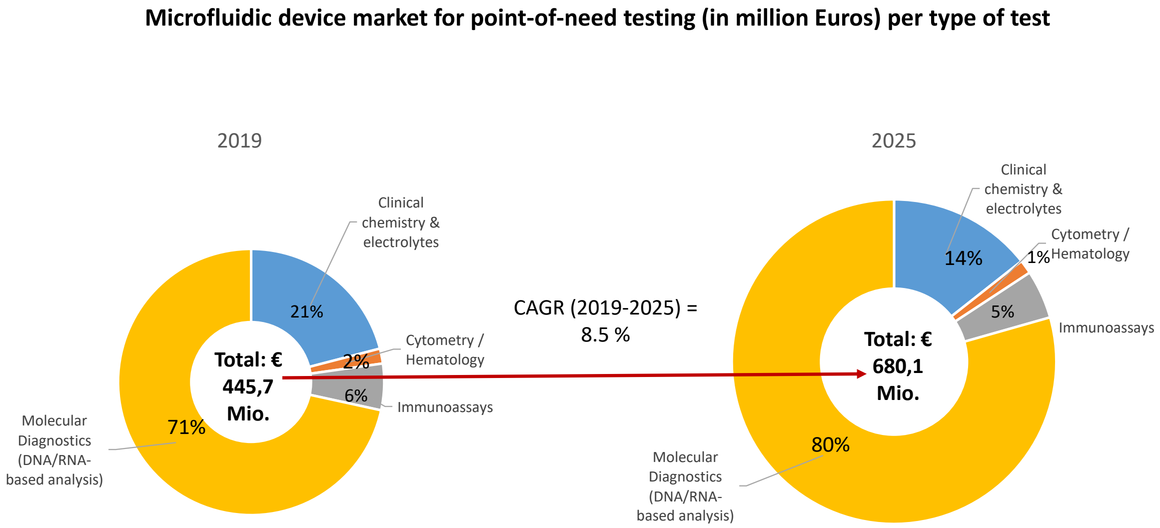
[10] Microfluidics is the core technology of Lab-on-a-Chip.
[11] Estimated values in US-$ and growth rates provided by Yole Développement 2020 were recalculated using the annual average US-Dollar/Euro exchange rate from Eurostat: https://ec.europa.eu/eurostat/web/exchange-and-interest-rates/data/database
[12] Yole Développement. (2020).
[13] Yole Développement. (2020).
[14] https://www.marketresearchfuture.com/reports/lab-on-a-chip-device-market-6215
[15] Yole Développement (2020).
[16] van Heeren, Henne (2021).
[17] https://www.marketresearchfuture.com/reports/lab-on-a-chip-device-market-6215

Figure 2: Microfluidic device market value per type of testing



Source: Calculations and the graph are based on estimations provided by Yole Développement 2020.[18] US-$ values were converted in € using official annual average US-Dollar/Euro exchange rate from Eurostat[19]. For years 2021-2025 the average exchange rate of 2020 was used.

1.2 Objectives of this report

Lab-on-a-Chip-based technology for bio-chemical analysis represents a complex high potential technology for a wide application field. It holds the potential to revolutionise the diagnostics and bio-medical research practice contributing not only to cost efficiency and performance improvement but creating advanced opportunities that lead to better healthcare. Beyond the bio-medical area, a number of further different application areas can benefit from the deployment of this technology. Despite its huge potential and a number of successful proof-of-concepts of LOC-based devices, only a small portion of them can be successfully commercialised and eventually enter the market. There are still a lot of barriers that need to be overcome for a successful uptake and diffusion of the technology.

The report aims to provide an overview of relevant stakeholders, map the value chain structure and to briefly describe the stakeholders' interactions in the value chain. The further objective is to identify strengths, opportunities, challenges and weaknesses that characterise the European microfluidics and particularly the LOC related ecosystem and to show how the EU is positioned in terms of the global competition. Analyses were based on desk-research and on the internal expertise of Fraunhofer ISI in the subject as well as on insights gained from the expert interviews.

[18] Yole Développement. (2020).
[19] https://ec.europa.eu/eurostat/web/exchange-and-interest-rates/data/database

Section 2

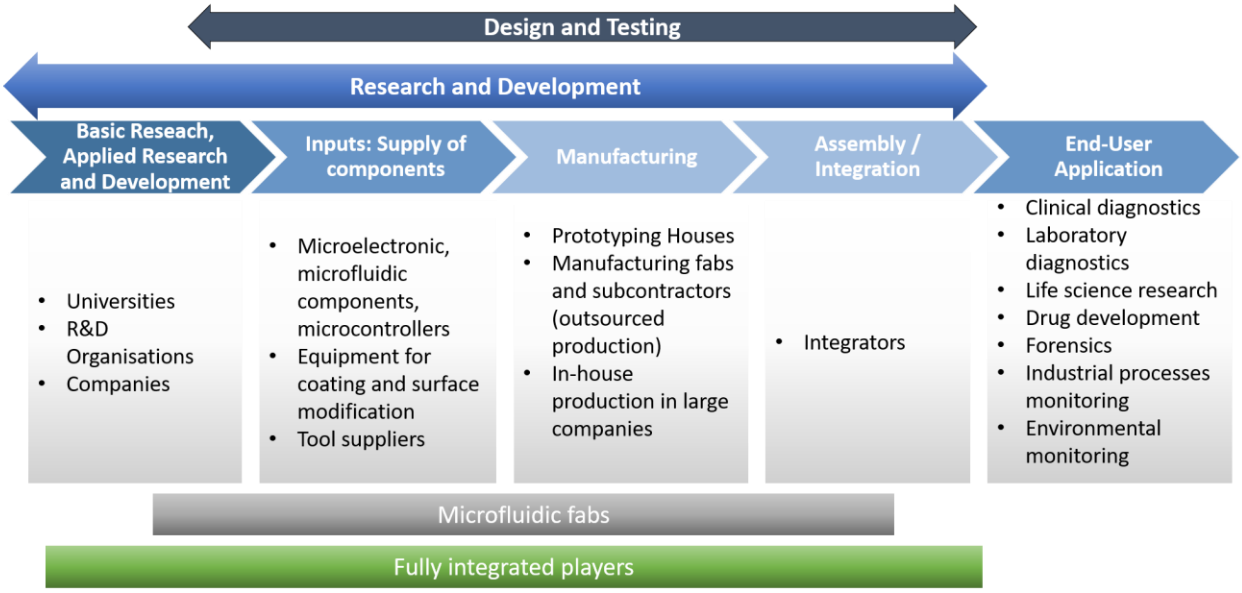
2. Value chain analysis

The following chapter explores the specific value chain of lab-on-a-chip technology including the key actors and the current state of play of the linkages across the value chain.

2.1 Value chain structure

The microfluidics industry is a very complex one with different kinds of stakeholders. The complexity of this industry is linked to its interdisciplinary and cross-functional character on the interface between microelectronics, microfluidics and the life sciences field. Breaking down and analysing the value chain is essential to understand the industry and EU's positioning on the individual value chain levels.

Figure 3: Lab-on-a-Chip technologies value chain



Source: Fraunhofer ISI

The main relevant activities and processes along the LOC technology value chain are illustrated by the Figure 3. This includes the following value chain steps:

- **Research and Development involves initial basic research** in different relevant disciplines **and development of microfluidics technology**. The R&D activities explicitly include the integration of the interdisciplinary science and technology for the development of application specific microfluidics and LOC technologies. Generally, one has to distinguish between two core R&D foci along the LOC value chain: 1) R&D on components and individual technologies and 2) R&D on interfacing, integration and assembly.
- **Inputs, supply of components and manufacturing**: The next important element of the value chain constitutes the supply of different components, tools and process technologies that will be used in the manufacturing process. The manufacturing task is performed either in-house by large companies or is outsourced to subcontractors.
- **Assembly and integration** of components and LOC into the end devices or instruments is a further essential step of the value chain. It also involves the integration of non-microfluidic technologies with microfluidics, e.g. by creating a cartridge or a module. This particular area

requires different skill sets, such as nano- and micro-systems engineering and offers potential for growth and development of new businesses in the EU, especially SMEs and start-ups.

- **End-user application:** fully integrated end products and devices can be used by the wide variety of end users in different application areas: clinical diagnostics, laboratory diagnostics, decentralised point-of-care diagnostics, life science research, industrial and environmental monitoring etc**.**

As mentioned above, **all these stages of the value chain are particularly R&D-intensive and require continuous testing and simulation activities** of the application specific designs to make necessary modifications and optimisation of technology. The design activities relate to different stages of the value chain: the component design, cross technology design and integration design.

Among the microfluidics and LOC technology players are a lot of SMEs and start-ups. Most players cover more than one value chain activity. Large companies - the so called fully integrated players - often seek to control the entire value chain or its most critical stages.

2.2 Key actors in the value chain

The microfluidic-based point-of-need testing market is dominated by large players from the human diagnostics: Abbott (20.8 %), Cepheid (18.3 %), Biomérieux (15.2 %), Roche (10.9 %), Siemens Healthineers (6.1 %) and Abaxis (4.1 %). The frequent market strategy of large players is the capitalisation of successful technologies through acquisition of start-ups and small companies to spare technology development risks. Most of the companies are located in North America and Europe.[20] In Europe, the most microfluidic companies are located in Germany, United Kingdom, the Netherlands, France and Switzerland.[21]

Research and Development: In the EU-27 there is a number of public research and technology organisations and private companies involved in the research and development of microfluidics technology in general and lab-on-a-chip based technology in particular. This includes R&D organisations that often have core competencies in microfluidics combined with biological know-how, such as for DNA separation, protein electrophoresis, cell-sorting or closely collaborate with organisations from the life science field to develop LOC devices. Many companies placed in the healthcare branch are actively involved in the development of LOC systems for different diagnostic applications. Table 1 presents a non-exhaustive list of European organisations involved in R&D activities.[22]

Table 1: Selection of organisations involved in R&D in Europe

Organisation	Country	Description	Website
Fraunhofer Institute for Microengineering and Microsystems IMM	Germany	Development and incubation of microfluidics technology for various applications by partnering with industry and academia. Key focus is the development of microfluidic technologies for drug discovery and diagnostics.	https://www.imm.fraunhofer.de/
CEA LETI	France	Microfluidics for diagnostic applications.	https://www.leti-cea.com/cea-tech/leti/english/Pages/Welcome.aspx
Natural and Medical Sciences Institute at the University of Tübingen	Germany	Custom surfacing of surfaces, simulation modelling of microfluidics and development of new in vivo and in vitro diagnostics.	https://www.nmi.de/de/
BIOS Lab-on-a-chip group University of Twente	The Netherlands	Modelling, simulation and design of new lab-on-a-chip and organ-on-a-chip (LOC) applications.	https://www.utwente.nl/en/eemcs/bios /

[20] Yole Développement. (2020).
[21] van Heeren. (2021).
[22] One of the main characteristics of the EU-27 is a large number of R&D organisations and SMEs involved in R&D activities related to microfluidics. The goal of this section was therefore to present a selection of European organisations that contribute to the advancement of microfluidics and lab-on-a-chip technology.

Organisation	Country	Description	Website
BioMediTech	Finland	Joint institute of the University of Tampere (UTA) and the Tampere University of Technology (TUT). The institute has brought together technological and bioscientific research of both universities.	https://biomeditech.fi/introduction/
STMicroelectronics	Italy /Switzerland	Development of devices capable of collecting and manipulating specific biological molecules, development of low-cost disposable chips that automate the quick preparation, analysis and evaluation of medical and forensic biological samples. Product example: Influenza virus detection chip.	https://www.st.com/content/st_com/en.html
IMEC	Belgium	Key actor for microfluidics research and development in the region. Key focus is microfluidics for molecular diagnostics. Performs active research on the interface between biological and electronic systems, development of high performance chips.	https://www.imec-int.com/en
MESA Plus Institute	The Netherlands	Modelling, simulation and testing of nanofluidics applications and devices integration of LOC applications.	https://www.utwente.nl/en/mesaplus/research/research-areas/fluidics/
Gyros Protein Technologies	Sweden	Development and production of microfluidics for drug discovery related application. Gyrolab microfluidic platform (measurement of picomolar affinity ligand binding).	https://www.gyrosproteintechnologies.com/
Cellectricon	Sweden	Research in the areas chronic pain and central nervous system diseases. Development of assay platform for in vitro neuro-generative disease research based on microfluidics technology.	https://cellectricon.com/
Technical University of Denmark's Department of Micro and Nano Technology	Denmark	Self-assembling materials and polymers for the fabrication of lab-on-a-chips, mainly for the application in cell-based research.	https://www.nano.dtu.dk/english/activities/ntch
Hahn-Schickard-Gesellschaft	Germany	Development of micropumps/dispenser for different fluids, different LOC systems, e.g. labcard used in centrifugal platforms or labdisk as a platform for automatic analytics and diagnostics.	https://www.hahn-schickard.de/
Institute for Microsystems Technology - IMTEK	Germany	Development of fluidic processes on lab-on-a-chip platforms, research on fluidic processes, immune diagnostics, cooperation with Hahn-Schickard.	https://www.imtek.de/
Biomérieux	France	Development of a multiplex PCR analyser based on microfluidic technology.	https://www.biomerieux.de/
Mobidiag Ltd	Finland	Development of the products Novodiag and amplidiag, molecular diagnostic platforms for the detection of infectious diseases and antibiotic resistances.	https://mobidiag.com/

Organisation	Country	Description	Website
Biocartis	Belgium	Provides innovative molecular diagnostics solutions with focus in oncology.	https://www.biocartis.com/
microfluidic ChipShop	Germany	Spin-off of the Fraunhofer Institute for Applied Optics and Precision Engineering and the Application Center for Microtechnology. Focus on development and manufacturing of lab-on-a-chip systems primarily in polymers.	https://www.microfluidic-chipshop.com/

Source: Fraunhofer ISI; Eberle et al., 2019[23]

Design and Testing: Application specific chips are designed according to concepts provided by technology developers. The design is typically customised to the needs and requirements of potential users in a specific application field or in order to achieve the desired scientific effect.[24] The designing capability often requires expertise in life science disciplines or medical diagnostics to be able to design microfluidic products for different application purposes. In the EU-27, many R&D organisations are involved in design activities. According to the information provided by the Microfluidics Association, European Union is particularly strong in the design of components, but not quite so in the end-use application design. Testing is further key expertise that is highly relevant for the pre-integration testing of chips and components, inline testing during the integration and assembly and post-integration testing of complete packages and modules.[25] Table 2 features a non-exhaustive list of players involved in design and testing activities.

Table 2: Selection of microfluidics design and testing players

Organisation	Country	Description	Website
Micronit	The Netherlands	Design of specific chips for the requirements.	https://www.micronit.com/
STMicroelectronics	Switzerland	Design tool with different possibilities for consumers.	https://www.st.com/content/st_com/en.html
Epigem Limited	United Kingdom	Design and manufacturing service for polymer microfluidic systems and modules.	https://www.epigem.com/microfluidic-chips/
Zimmer & Peacock	Norway	Contract design company, design of fluidics and microfluidics for biosensors	https://www.zimmerpeacocktech.com/services/fluidics-for-biosensors/
Axxicon	The Netherlands	Design and prototyping of the developed chips.	https://axxicon.com/
SallandEngineering BV	The Netherlands	Testing of microchips and design and production of testing and optimisation equipment.	https://www.salland.com/
Interdepartmental Research Centre for Industrial Research on Health Sciences and Technologies	Italy	Microscopy-based characterisation of surface and bio-functionalisation, electrochemical characterisation of bio-functionalisation layers and chemical recognition. Expertise in fluorescence microscopy.	https://www.unibo.it/en/university/campuses-and-structures/interdepartmental-centres-industrial-research
Synopsys-PhoeniXBV	The Netherlands	Specialises among others on design and testing of LOC applications.	https://synopsys.com/photonic-solutions.html
Mesa Plus Institute	The Netherlands	Modelling, simulation and testing of nanofluidics applications and devices integration of LOC applications.	https://www.utwente.nl/en/mesaplus/research/research-areas/fluidics/

[23] Eberle et al. (2019).
[24] Frost & Sullivan. (2009).
[25] Eberle et al. (2019).

Organisation	Country	Description	Website
Achira labs	India	Microfluidics design and fabrication services, prototyping, instrumentation and manufacturing	https://achiralabs.com/

Source: Fraunhofer ISI; Eberle et al., 2019.[26]

Component and equipment supply: Providers of components involve the manufacturers of microcontrollers, such as the pumps, valves, micro pressure and chemical sensors, micro-connectors and the likes. Surface modification and coating belong to the further expertise that plays a role in the value chain. These are important steps in the fabrication of many microfluidic devices. Some fabs have such surface modification capabilities along with a number of specialised companies that supply equipment for coating and surface modification, such as Integrated Surface Technologies (IST) and Yield Engineering Systems (YES).[27] European companies are among the most competitive equipment providers worldwide (e. g. measurement equipment).

Table 3: Selection of suppliers of components and equipment

Company	Country	Description	Website
Dolomite	United Kingdom	Microfluidic components, like pumps, sensors, valves, connectors.	https://www.dolomite-microfluidics.com/product-category/microfluidic-components/
Micronit	The Netherlands	Functionalities: flow-control, surface modifications, sample preparations, reagent – and transducer integration.	https://www.micronit.com/
Surfix – surface technology	The Netherlands	Nanocoatings that optimise the surface properties of glass and polymer microfluidics.	https://www.surfix.nl/technologies
Cellix Ltd	Ireland	Development and production of different biochips (for cell culture, protein interactions etc.).	https://www.wearecellix.com/
SCHOTT	Germany	Functional coatings for different applications. Manufacturing of glass components for the lab-on-a-chip usage.	https://www.schott.com/english/index.html
Elveflow	France	Development of microfluidic instruments, flow control systems, sensors, detectors, reservoirs.	https://www.elveflow.com/microfluidic-products/
Helvoet	The Netherlands	Manufacturing of polymer microfluidic components	https://www.helvoet.com/
Axxicon	The Netherlands	Offers solution for the bonding of polymers (UV, thermal, pressure-sensitive adhesive film bonding, laser welding).	https://axxicon.com/
NexperiaBV	The Netherlands	Semiconductor components for various control units, power supplies and electrostatic discharge protection, such as discrete, logic and metal–oxide–semiconductor field-effect transistor devices.	https://www.nexperia.com/support/
Nadetech Innovations S.L	Spain	Development of laboratory equipment. Provides the required instruments or technical support to scientists and engineers for the deposition of coatings,	www.nadetech.com

[26] Eberle et al. (2019).
[27] Yole Développement. (2020).

Company	Country	Description	Website
		films, colloids and other micro-nano structured materials.	
Boschmann Advanced Packaging Technologies	The Netherlands	Engineering, development and production of advanced semiconductor, microelectromechanical systems, sensors and photonic integrated circuits packaging equipment.	http://www.boschman.nl/
Epigem Limited	United Kingdom	Manufacturing of complex microfluidic chips, part of the design and component building value chain. Partner of diagnostics and instrumentation companies.	https://www.epigem.com/microfluidic-chips/
Genalyte	USA	R&D and manufacturing of silicon photonics technology for immunoassays.	https://www.genalyte.com/

Source: Fraunhofer ISI; Eberle et al., 2019.[28]

Instrumentation and manufacturing: Group of companies involved in the instrumentation and manufacturing are those that assemble the instrument after its different components have been supplied to them by specialised suppliers. Some players specialise rather in prototyping and small volume manufacturing while others focus on mass manufacturing of microfluidic devices. Large companies have many product lines and are capable of covering several steps in the value chain. Many of these companies have chosen to establish or keep the in-house production to control the production process and to limit the risks.[29]

There is a number of microfluidic fabs involved in the manufacturing of microfluidic devices. However, focusing on manufacturing alone is a rather risky business as in this area fabs are exposed to a high cost pressure. Therefore, many companies are trying to diversify their activities by expanding their value chain, such as development and design.[30]

Table 4: Selection of companies involved in instrumentation and manufacturing

Company	Country	Description	Website
Biocartis	Belgium	Production and development of the molecular testing platform performing reverse transcription polymerase chain reaction.	https://www.biocartis.com/en
Dolomite	United Kingdom	Prototyping and manufacturing of small series of microfluidic devices.	https://www.dolomite-microfluidics.com/products/custom-microfluidic-devices/
Klearia	France	Solutions for analysing metal traces in water and LOC solutions for industrial monitoring (PANDa, LabInGlass).	https://en.klearia.com/
Elveflow	France	Microfluidic product line, flow controller to control the chip.	https://www.elveflow.com/microfluidic-products/
Micronit	The Netherlands	Manufacturing of designed microfluidic products.	https://www.micronit.com/
EnzyreBV	The Netherlands	Design and small series manufacturing of LOC application for coagulation with respect to blood clotting through enzymatic reactions analysis.	http://enzyre.com/
Axxicon	The Netherlands	Full scale production of microfluidic products.	https://axxicon.com/

[28] Eberle et al. (2019).
[29] Yole Développement. (2020).
[30] Yole Développement. (2020).

Company	Country	Description	Website
Cepheid	Germany	Production/manufacturing of the different GeneXpert products and systems.	https://www.cepheid.com/
Bosch-Vivalytic	Germany	Platform for molecular diagnostics 'Vivalytic Analyser'.	https://www.bosch-vivalytic.com/
Roche	Switzerland	Manufacturing of different products and instruments.	https://diagnostics.roche.com /
SpinChip Diagnostics	Norway	SpinChip technology focused on in-vitro diagnostics.	https://www.spinchip.no/
STMicroelectronics	Switzerland	Product: VereFLu, lab on a chip device to detect and prevent viruses.	https://www.st.com/content/st_com/en.html
SCRIBA NANOTECNOLOGIE	Italy	Manufactures high-tech miniaturised chemical analysers for different market applications: environmental, energy /process and health/safety; design and manufacturing of analytical instruments, with a relevant expertise in microfluidics.	https://www.scriba-nanotec.com/
RIGENERAND	Italy	Development and manufacturing products for clinical applications of cell-based technologies for regenerative medicine and oncology.	https://rigenerand-biotech.com/

Source: Fraunhofer ISI; Eberle et al., 2019.[31]

Integration and final assembly: large companies specialising on several activities within the value chain often accomplish the task of final assembly and integration of LOC in end products, devices or consumables (e.g. cartridges or modules). Table 5 provides a non-exhaustive list of companies that perform integration and final assembly.

Table 5: Selection of integration and final assembly companies

Company	Country	Description	Website
ABAXIS	USA	Products: Piccolo Xpress with panels to analyse patient samples.	https://www.abaxis.com/
ABBOTT	USA	Product: i-STAT, point of care testing with fast results. Different product families.	https://www.pointofcare.abbott/int/en/
Cepheid	USA	Cooperation and further development of the different systems and tests (GeneXpert, lab in a cartridge).	https://www.cepheid.com/
Siemens Healthineers	Germany	LOC-devices for clinical diagnostics, point-of-care.	https://www.siemens-healthineers.com/de/
Bosch Healthcare Solutions	Germany	Product: Vivalytic is a platform for molecular laboratory diagnostics with which various samples can be tested and different analytical methods can be carried out fully-automated.	https://www.bosch-vivalytic.com/
Roche	Switzerland	Different point-of-care products.	https://diagnostics.roche.com/
Biosurfit	Portugal	Product: Spinit as an automated point-of-care diagnostics solution with different detection methods (e.g. immunoassays).	https://www.biosurfit.com/en/
Helvoet	The Netherlands	Various assembly methods to combine the different components to a final product.	https://www.helvoet.com/

[31] Eberle et al. (2019)

Company	Country	Description	Website
NanoEntek	Korea	C-Chip (disposable Hemocytometer), manufacturing, reagent integration, final assembly and quality control.	http://www.nanoentek.com/?lang=en
MicronitBV	The Netherlands	Design, manufacturing and integration of silicone and glass based integrated microfluidic chips with on chip sensors and microelectromechanical systems, for instance simulation of organs and monitoring of medication levels in blood.	www.micronit.com
Mesabiotech	USA	Molecular diagnostics, product Accula (OSCAR= new Polymerase Chain Reaction method, oscillating amplification reaction), manufacturing, reagent integration, final assembly and quality control.	https://www.mesabiotech.com/
Luminex	USA	Emergency testing, infectious disease diagnostics, detection of pathogens, the technology is based on gold nanoparticles, supply chain: manufacturing, reagent integration, final assembly and quality control.	https://www.luminexcorp.com/the-verigene-system/#overview

Source: Fraunhofer ISI; Eberle et al., 2019.[32]

2.3 Linkages along the value chain

As mentioned before, there is a high degree of vertical integration in the lab-on-a-chip technology value chain. For large microfluidics companies it is important to control the entire value chain from R&D, design activities to the integration in final products in order to control the quality of the output. They often acquire successful microfluidic start-ups.

Collaboration and interaction along the microfluidics and lab-on-a-chip-based technology value chain is essential. It is particularly driven by the pressing need of defining and testing standards in the technology. In the European Union, there is a lot of initiatives that aim to enhance the cooperation and integrate relevant players along the value chain. EU funded projects contribute significantly to the collaboration activities between different players in the relevant fields of technology that keep collaborating beyond the scope of the funded project. However, more efforts are still necessary to help intensify the collaboration between technology developers, different suppliers and integrators for the development of standards in microfluidics and to optimise the quality and efficiency of production. A special focus should be laid on the integration of SMEs in the collaboration networks that are particularly exposed to these challenges. Moreover, the standardisation process requires a better involvement of end users.

The European R&D landscape is versatile and has many strengths. Many European countries have developed and are further strengthening their individual R&D capacities that cover different relevant technology areas and are capable of sustaining in global competition in terms of technological performance. This fragmentation of the European R&D landscape is quite essential for a sound competition and for building of critical mass in the region providing a broad range of technologies. A number of cooperation activities between R&D players in different European regions is already in place. However, according to the experts' opinion more efforts are needed for a better networking and cooperation between European R&D organisations to make a better use of available technological infrastructure and to share the know-how.

[32] Eberle et al. (2019).

Section 3

3. Analysis of EU competitive positioning

Figure 4 provides an overview of the key strengths, opportunities, challenges and risks for the Lab-on-a-Chip-based technologies in the EU.

Figure 4: Strengths, opportunities, challenges and risks for the Lab-on-a-Chip-based technology value chain

Strengths

- Strong scientific and technological basis
- Large market size and favourable framework conditions
- Increasing demand and wide range of applications in different sectors

Challenges

- Lack of standardisation and of compatible integration
- Lack of testing and certification for integrated technologies
- Strict regulation of medical products
- Slow adaptation of norms and standards
- Availability of funds for start-ups

Opportunities

- Favourable prospects for the future development of microfluidics
- Benefits for a wide range of applications
- Opportunities from combination of LOCs with AI
- Stringent regulatory provisions for toxicity testing

Risks

- Rising complexity, accelerated pace of innovation
- High development costs and reimbursement concerns
- Management of genetic and other medical data
- Ethics and human behaviour
- Lack of visibility and user awareness in new application fields

Source: Fraunhofer ISI

3.1 Strengths

Overall, Europe has a **strong and sound technological and scientific basis in microfluidics and LOC technology**. It excels in an advanced R&D ecosystem consisting of a large number of high profile R&D organisations and businesses capable of developing and manufacturing a broad range of competitive complex microfluidics technologies. This gives the EU a significant competitive advantage in this field of technology.

The European Union is the **second largest market in LOC technology and microfluidics**. A lot of competitive companies are located here, that focus on technology development and design, supply of different components or tools, manufacturing and integration activities. Particularly well positioned are Germany, the Netherlands, France and Belgium. They accommodate a large share of the competitive players in this area of technology.

The technology benefits significantly from a number of **favourable framework conditions** in the EU that boost the technology development and the market uptake, such as advanced medical device market, numerous public endeavours to promote clinical and life science R&D and the rising income of the population in the Eastern and Central European countries.

Breadth of application offerings is a further beneficial aspect of Europe. Advantages of the LOC technology drive its adoption for a **wide range of applications**. Point-of-care testing is gaining significance in Europe, currently mostly used in the hospitals and clinical centres and is expected to dynamically grow in the future. In addition, the diagnostics in decentralised testing settings and testing at patient side will become more important in the near future providing tremendous potential for the LOC and microfluidics technology market. LOC as an enabling technology for cell-based assays, which are particularly important in the early drug screening and development, is likely to have a huge impact on the European pharmaceutical and biotechnology sectors. Also the growing importance of genomics and proteomics in Europe will positively influence the demand for LOC and microfluidics allowing them to progress more quickly. A number of key players in Europe currently invest in the development of advanced microfluidics technologies.[33]

3.2 Opportunities

Overall, the EU's strong research, development, design and manufacturing ecosystem capable of developing and producing advanced and complex microfluidics and LOC-based technologies offers **favourable prospects for the future development of the microfluidics technology** in the EU. Major opportunities provided by the microfluidics and point-of-care technologies in Europe are associated with their manifold application. The adoption of microfluidic technology and of the LOC in particular provides **multiple benefits to a wide range of application areas**, such as point-of-care diagnostics, high-throughput screening, DNA analysis, protein analysis, cell-based assays, forensics, food safety, industrial and environmental monitoring. For example, the European pharmaceutical and biotechnology companies can gain significant efficiency improvements, such as quality improvement, cost and resource reduction and speeding up of processes. For drug companies, the deployment of the LOC technology would help cut down the expenses for drug development and speed up the time-to-market. Moreover, the LOC technology provides a very promising concept for the development of precision pharmaceutics. It is still at a low technology readiness level but is expected to be a game changer in the future.

The **combination of LOCs with artificial intelligence** offers huge opportunities. LOC technology is a powerful data provider. It can generate high-content data (e.g. on size, shape, structure, composition, interaction) required for the training of deep learning networks. When paired with sorting and DNA/RNA sequencing data, AI can help to receive insights into phenotype–genotype relations. In addition, combined with AI, LOC-based technology can also be used for accurate identification, characterisation, classification and prediction of objects in mixed, heterogeneous or unknown samples.[34] Integration of AI and LOC technologies provides new advanced opportunities for studying diseases, such as cancer, and developing more effective therapies against them.

Stringent European regulatory demands pose on the one hand some challenges for the market uptake of the microfluidic technology. On the other hand, **the stringent regulatory provisions for early toxicity testing** is an indirect driver for the microfluidics and LOC-based technology, as conventional testing procedures, such as animal testing and enzyme-linked immunosorbent assay (ELISA) are very tedious, and microfluidic technology enables much easier and quicker tests and assays.[35]

3.3 Risks

There are some risks that need to be taken into consideration when analysing the technology and its framework conditions. As most cross-cutting, rapidly evolving advanced technologies, the microfluidics and LOC-based technologies are increasingly characterised by the **rising complexity**, **accelerated pace of innovation** (time between the initial discovery and its commercialisation), **fast changing markets and high costs**. The ability to cope with risks associated with these aspects are essential for the market players to sustain in the global competition. EU players are increasingly confronted with **fierce competition** from large multinational companies, such as Bio-Rad Laboratories, Calipers Life Science, Danaher, Thermo Fisher Scientific, Agilent and Roche.

Further risks are associated with **high costs** needed f**or the development of the tests and reimbursement concerns** of these tests. For a microfluidic company, getting a foothold in the medical diagnostic market (from founding to approval of the product) needs between €50 and €150 million and at least 10-15 years.[36] Small companies and start-ups are particularly exposed to **risks of not getting sufficient investments** in order to be able to enter the next business stage. However, only one in three investments ends positively.[37]

In the emerging non-human need-of-care testing segments, like industrial, agro-food and environmental, there is a risk of broad implementation of technology being hindered by the **lack of user awareness** and insufficient collaborations between technology developers and potential users.

[33] https://www.databridgemarketresearch.com/reports/europe-point-of-care-diagnostics-market
[34] Isozaki et al. (2020).
[35] Frost & Sullivan. (2009).
[36] van Heeren. (2021).
[37] van Heeren. (2021

Further risks arise from uncertainties related to the **management** of huge amount **of genetic or other clinical data** that microfluidics or microarrays may produce. There are also potential risks related to the **ethics and human behaviour**. It is feared that real-time processing and the widespread accessibility of the lab-on-a-chip-based technologies and their operation by untrained persons may generate some potential for infections at home. Moreover, the DNA sequencing potential of lab-on-a-chip enabling anyone to sequence the DNA of others using a drop of saliva bears risks of irresponsible or unethical actions.[38]

3.4 Challenges

The technology is currently facing a number of challenges. The future success of technology depends to a large extent on the ability to effectively address them.

One of the major challenges microfluidics and LOC technologies need to overcome for the successful uptake and diffusion of technology is the **lack of standardisation and of compatible integration techniques**. Standardisation is needed to be able to better integrate different components coming from different players of the supply chain as well as when combining microfluidics with other technologies. The challenge of heterogeneous integration and interfacing is considered as the most pressing one.[39] Missing standardisation is especially a big problem for SMEs, as they need large investments for the integration of not standardised technologies. For this reason the technology cannot be easily taken up by SMEs. The solution could be the development of integration platform technologies and plug-and-play systems. Moreover, microfluidics need standard testing strategies, methods and reliability models.[40] There is also a **lack of testing and certification for integrated technologies**.

Lack of interoperability of microfluidic devices with existing laboratory equipment represents a stumbling block for incorporating microfluidic devices into existing workflows and adopting them into regularised drug screening and discovery processes.[41]

Despite successful demonstration of several theoretical models and proof-of-concept studies, only a few LOC-based systems have been successfully produced and introduced into the market.[42] Most lab-on-a-chip technologies are not yet ready for commercialisation. **Lack of appropriate fabrication technology and processes and a good manufacturing practice** for the production of optimised LOC devices[43] constitute a serious challenge for the successful product implementation. As heterogeneous systems, microfluidics need more **in-depth understanding of microfluidic fault modes** that occur frequently at the functional level, in the manufacturing and at the application level in order to be able to better prevent and detect them.[44]

Apart from the standardisation challenge, some **technical problems** might occur when integrating LOC technologies in external systems. External devices increase the final size and cost of the overall system and some, particularly flow control equipment, can often impose performance limitations for LOCs. For some applications, miniaturisation increases the signal/noise ratio with a consequence that lab-on-a-chip might provide more inaccurate results than conventional techniques.[45]

Furthermore, the diffusion of LOC systems is often inhibited by the **strict regulation of medical products**. **Established standards and norms in the EU are slow to be adapted**. This is considered a further barrier for getting innovative LOC-based technologies for bio-chemical analyses into the market.

Investments and access to funding are crucial to develop and implement innovative technologies. It is a well-known fact that Europe lags behind the United States in terms of **access to the venture capital and availability of funds for start-ups**. This problem also affects microfluidics start-ups in Europe. According to the information provided by the Microfluidics Association,[46] the venture capital investments in microfluidics in the US are 4 times larger than in Europe.

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[38] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/
[39] Eberle et al. (2019).
[40] van Heeren. (2021). Trends and Challenges in the Microfluidic Industry. Microfluidics Symposium: Addressing Challenges in Life Science Fluidics.
[41] https://drug-dev.com/loc-based-devices-lab-on-chip-how-far-are-we-along-the-road/
[42] https://www.azolifesciences.com/article/What-is-Lab-on-a-Chip.aspx
[43] https://www.europeanpharmaceuticalreview.com/article/79114/lab-chip-product-development/
[44] van Heeren. (2021).
[45] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/
[46] https://microfluidics-association.org/

Section 4

4. Conclusions & outlook

4.1 Conclusions

In the past decades, there have been rapid developments of microfluidic technologies in various areas for different applications. These developments contributed to significant improvements in the integration of laboratory systems onto one single chip. LOC-based technology holds the potential to dramatically improve the speed, efficiency and cost of many bio-chemical diagnostics procedures providing a paradigm shift for bio-analyses. A wide range of current and future application areas can benefit from the deployment of this technology. Apart from its large potential to enable improved point-of-care applications, LOC-based technology offers advanced opportunities and considerable efficiency gains for many bio-medical research areas, drug discovery and development, different industrial and emerging applications, such as environmental and agricultural monitoring, forensics and biodefense.

Despite its high potential, LOC systems have been so far rarely used in practical applications. LOC is still in the early stages of adoption across most application areas. Amongst all application areas, Point-of-Care (POC) and clinical research have the highest adoption rates. In the future, a considerable expansion of LOC use for different applications is expected.

Overall, EU-27 has a strong and sound technological and scientific basis in microfluidics and LOC technology. It excels in an advanced R&D ecosystem consisting of a large number of high profile R&D organisations and businesses capable of developing and manufacturing a broad range of competitive complex microfluidics technologies. However, there is a number of barriers that hamper the successful diffusion of the LOC technology and need to be dealt with to ensure a timely introduction of advanced LOC technologies into the market and everyday use. One of the major challenges microfluidics and LOC technologies need to overcome for the successful uptake and diffusion of technology is the lack of standardisation and of compatible integration techniques.

4.2 Outlook

The potential and advantages that the LOC-based technology promises for many application areas attracts a lot of interest in this technology. There are a lot of R&D efforts on advancing the technology in the European Union and other regions. A lot of activities aim at improving the capability to incorporate a large number of individual operations on the same chip in order to decrease costs and increase ergonomics/ease of use as well as the speed of diagnosis.[47] Much research is devoted to improving current technologies for cell separation, DNA sequencing through nanopores, micro quantitative polymerase chain reaction and micro reactors and on increasing efficiency and sensitivity of analyses. Further developments in the field of biomarkers and nanotechnology will expand the application range of LOC systems.[48]

In future, LOC technology may play a major role in the early detection of life threatening and highly contagious viruses, such as COVID-19, Zika, Ebola, Dengue and the African swine virus. That's because the early and rapid detection in local settings is essential for reducing the scale of outbreaks and improving response to infection viruses. During the last decades, there has been a lot of progress in virus testing microfluidics. However, there are still challenges concerning some unsolved technological issues and practical implementation that need to be overcome, which requires collaboration between scientists with different expertise. However, to be able to come up with the most effective solutions, research should not be limited to the microfluidic technology.[49]

In addition, LOC-based technology is expected to have highly positive impact on healthcare systems in the developing countries that lack cost-effective, high-performance diagnostic methods. A broad application of this technology enabling accurate diagnostics in local settings would lead to the drastic improvement of the overall healthcare outcome in these countries.[50] For this, microfluidic products need to meet the WHO criteria for POC diagnostics including being affordable, containing high sensitivity,

[47] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/
[48] https://www.elveflow.com/microfluidic-reviews/general-microfluidics/introduction-to-lab-on-a-chip-review-history-and-future/
[49] Zhuang et al. (2020).
[50] Mao and Huang. (2012).

high specificity, being user-friendly, rapid and robust, equipment free and delivered to those who need it.[51]

As it was demonstrated in this report, EU-27 has a lot of strengths and capabilities contributing significantly to the advancement of the microfluidics technology. However, there are still some technology and industry specific challenges that need to be tackled. To facilitate efficient fabrication and commercialisation of technology, further efforts are necessary to define and implement common standards, develop integration technologies and adapt fabrication processes. Significant and continuous R&D efforts in the EU resulted in the development of many useful and advanced components and technologies in the field of nano-enabled microsystems for bio-analysis. However, the sector needs most urgently to strengthen its R&D efforts on interfacing, integration and assembly. There are already some microfluidics standardisation activities in the EU that have been initiated by European projects. However, more endeavours are required to promote standardisation, but also to support demonstration, testing and certification of integrated technologies. Pilot lines and demonstration cases on the integration are considered important to effectively support the maturation of the interfacing, integration and assembly technologies (including standardisation) to higher TRLs. European programmes may help bring relevant players together and support investments in better integration technologies with a special focus on SMEs that play an important role in advancing the LOC technology and are particularly affected by the challenges linked to the lack of standardisation and cost-efficient integration technologies. Apart from this, implementation of automation technologies in manufacturing, integration, assembling and testing is necessary to improve the processes and quality of products while lowering operational and production costs and help European companies compete globally. Moreover, additional efforts are needed to bring the technologies towards higher TRLs and to introduce them successfully onto the market overcoming the valley of death, which refers to the gap between academic-based innovations and their commercial application in the marketplace.

As to the type of LOC-based technologies, opportunities for the EU exist particularly in the development and production of complex and application specific high-value LOC tests. These opportunities are associated with the high growth potential of these technologies and exploitation as well as further strengthening the EU's present competitive advantage in related areas. Examples for such high-value tests are complete blood count (CBC), multi-omics tests with a set of biomarkers, complex PCR tests, sequencing, complex assays for cell and gene therapy on chip, as well as organ-on-chip. They are based on a complex technology integration, which once again emphasises the need to support the further development of integration technologies in the EU. Such products can be produced in Europe by a combination of existing and new capabilities offering new opportunities especially for SMEs, both incumbent and new.

Last but not least, Europe can position itself and excel in developing and providing solutions to increase resource efficiency and circularity across the value chain and product life cycle of microfluidic products.

4.3 COVID-19 impact on Lab-on-a-Chip technology

There is an enormous impact of COVID-19 on the LOC technology. The COVID-19 crisis has led to disruptions of supply chain of the lab-on-a-chip based point-of-need technology in many countries. Particularly those companies that depend on suppliers from China were heavily affected. But most significantly, the situation highlighted the urgent need for accurate and rapid diagnostic tools at the point of need to help effectively manage the infectious disease. Apart from this, the LOC technology plays an important role in the development of vaccines. Consequently, the demand for COVID-19 and other pathogen tests increased enormously and so the amounts of investments for COVID-19 diagnostics and point-of-care during the pandemic. This accelerated the R&D efforts and has led to the development of new nano-based lab-of-a-chip technologies for rapid and personalised disease diagnostics.[52] However, the current production capabilities in most countries are not sufficient to respond to that high demand. Moreover, the current standard POC testing technology does not provide high throughput to enable the mass population testing.[53]

[51] Zhuang et al. (2020).
[52] See for example: Mujawar et al. (2020).
[53] Yole Développement. (2020).

Section 5

5. Annexes

5.1 List of interviewees

Interviewee	Organisation	Country
Dr. Wolfgang Eberle	IMEC	Belgium
Henri Janssens	Oost nl	The Netherlands
Dr. Ivan Stojanovic	Oost nl	The Netherlands
Andreas Morschhauser	Fraunhofer ENAS	Germany
Henne van Heeren	Microfluidic Association	The Netherlands
Stefano Zampolli	Institute for Microelectronics and Microsystems	Italy
Dr. Fabrizio Ciarmatori	ART-ER	Italy
Lorenzo Calabri	ART-ER	Italy

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About the 'Advanced Technologies for Industry' project

The EU's industrial policy strategy promotes the creation of a competitive European industry. In order to properly support the implementation of policies and initiatives, a systematic monitoring of technological trends and reliable, up-to-date data on advanced technologies is needed. To this end, the *Advanced Technologies for Industry* (ATI) project has been set up. It provides policymakers, industry representatives and academia with:

- Statistical data on the production and use of advanced technologies including enabling conditions such as skills, investment or entrepreneurship;
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