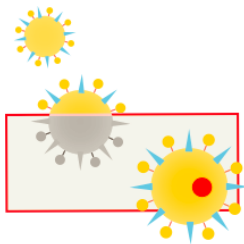


PROJECT FINAL REPORT



PORTFASTFLU

Portable and Automated Test for Fast detection and surveillance of influenza

Grant Agreement number: 201914

Project acronym: **PORTFASTFLU**

Project title: Portable automated test for fast detection and surveillance of influenza

Funding Scheme: Collaborative Project Small or Medium scale focus research project

Date of latest version of Annex I against which the assessment will be made: 22/12/2009

Period covered: **From the 1st of January 2008 to the 31st of December 2010**

Name, title and organisation of the scientific representative of the project's coordinator:

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Project website address: <http://www.portfastflu.com>

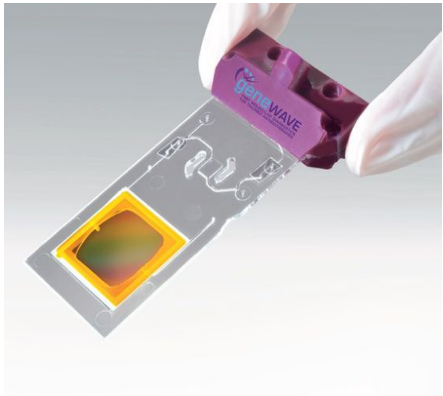
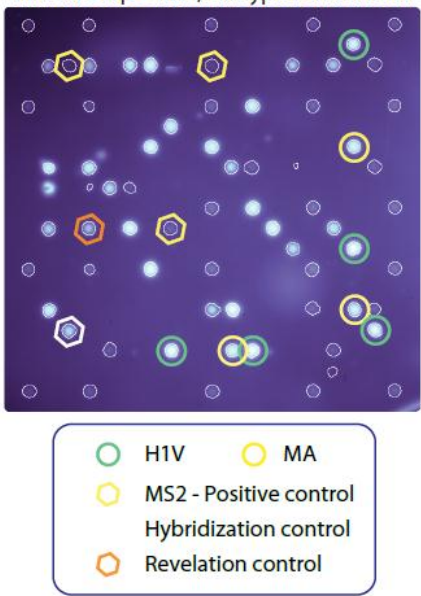
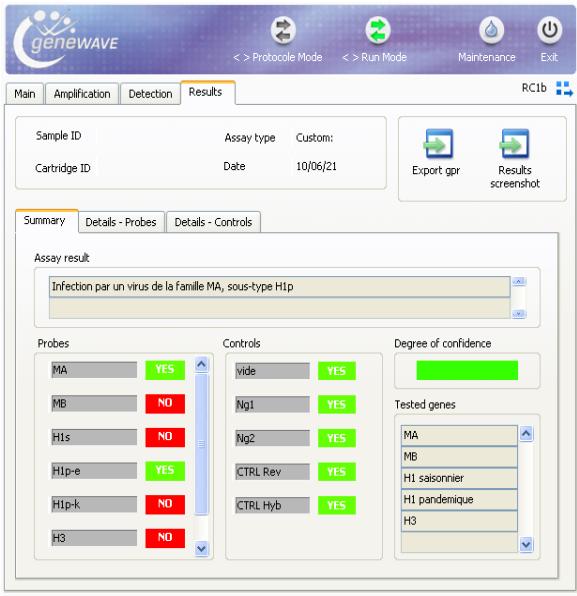


4.1 Final publishable summary

Executive summary

The project's objective was to develop and validate a rapid diagnostic test for human influenza that would be used for surveillance and early detection of influenza and as a point-of-care tool in developed and developing countries. The diagnostic test had to enable the rapid detection of influenza infection in a fast and specific way (typing and sybtyping) using a monolithic disposable cartridge placed in a compact, portable analytical instrument.

The PORTFASTLU project achievements can be summarized in four snapshots:

	
<i>The PORTFASTLU automated molecular diagnostics system GeneSpress®</i>	<i>The PORTFASTLU Lab-on-a-Chip cartridge</i>
Influenza A positive, subtype Pandemic H1 	
<i>Image of a microarray detecting H1N1v</i>	<i>Display of the diagnostics result obtained in an automatic unsupervised process.</i>

Project context and objectives

The threat of infectious diseases

Infectious disease represents the greatest risk to global human health. This can range from classical infectious diseases such as tuberculosis, cholera, dysentery, and typhoid; annual epidemics such as Norovirus, Influenza, and seasonal colds; emerging infectious diseases such as avian influenza and haemorrhagic fevers; through to global pandemics such as HIV and the current newly emerged H1N1v outbreak (commonly referred to as swine flu). Infectious diseases account for 10% of all deaths recorded annually, and are responsible for 1/3rd of all General Practitioner consultations. The projected total cost for treatment of infectious diseases in the US alone is around US\$ 120 billions per annum.

With diagnosis of infectious disease firmly entrenched in classical culture techniques developed in the 19th and 20th century, there is a clear need for the development of fully automated, accurate and robust rapid diagnostic devices to alleviate the economic and health burden presented by pathogenic viruses and bacteria. In particular molecular assays which can distinguish pathogenic subtypes within species would allow fine detailed diagnosis of infections, as well as allow more rapid assessment of effective treatment measures and more rapid initiation of relevant control measures and epidemiological analysis.

The EU FP7 PORTFASTFLU (PFF) project produced a novel diagnostic system that allows rapid automated detection and subtyping of influenza viruses in clinical and field samples. The approach is based on the integration of a Lab-on-a-Chip (LOC) consumable cartridge for automated extraction and amplification of the RNA of the virus (carrying its genetic information), followed by hybridization and real-time detection on a microarray, in a single portable and easy to use machine (concept shown in figure 1) called the GeneSpress® platform.

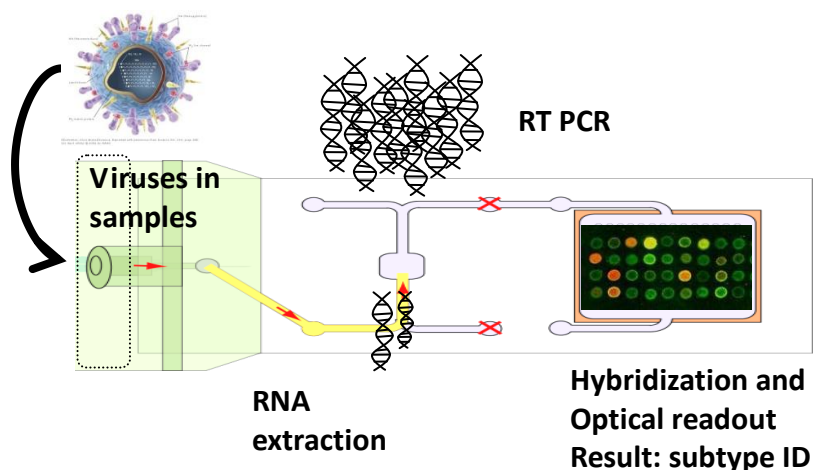


Figure 1: Principle of the PORTFASTFLU diagnostics test for influenza: viral RNA is extracted from the human sample. RNA is reverse-transcribed into cDNA, followed by PCR amplification of sequences to be recognized. The amplicons are identified by microarray hybridization.

The original objective of the PORTFASTFLU was to identify the influenza virus for the most usual types, A or B, and among the A types various subtypes H1, H2, H3, H5, H7, N1 and N2. However while the project was well into its second year, the H1N1v new virus appeared worldwide (april 2009) up to a situation where a pandemic was declared, and now the H1N1v has become the “standard” seasonal species of H1N1. The PORTFASTFLU team demonstrated quickly that the PORTFASTFLU system was capable of detecting the new influenza subtype and the final detection kit is able to detect the original target influenza subtypes as well as the new one. To ensure a reliable and verifiable operation of the PORTFASTFLU system, a positive control RNA molecule is added to the patient virus in order to verify that the diagnostic system has been operating well on the patient’s sample. The PortFastFlu diagnostics system concept is demonstrated through the use of a disposable lab on a chip cartridge, inserted in a machine which performs the various steps of the diagnostic protocol, detects the hybridized species and processes the signals and data (figure 2 below).



The PORTFASTFLU consortium

In order to reach its objectives, the PORTFASTFLU project led to the assembling of a team with wide-reaching competences: the coordinator, Genewave (Paris, France) is a molecular diagnostic company with all competences from molecular diagnostics kit design to large scale fabrication of consumables and automated diagnostics systems; Biosensia (Dublin Ireland) is a company devoted to Point-of-Care in vitro diagnostics; Ikerlan (Mondragon, Basque region, Spain) is a technology centre devoted to microtechnologies for in vitro diagnostics, Gaiker (Bilbao, Basque region, Spain) is a Technological Centre with competences in molecular biology, microbiology, immunochemistry and enzymology to develop innovative biodetection systems; The Molecular Virology group at VIB (University of Gent, Belgium) is a scientific research institute for Molecular Biomedical Research; Nottingham Trent University, School of Biomedical and Natural Sciences (Nottingham, UK), is a group devoted to research into emerging food-borne pathogens, molecular mechanisms of pathogenicity in bacteria and viruses; CIRAD (Montpellier, France) is a French public Institute that makes research in agronomy for developing countries, strongly involved in research and development for the control of infectious diseases of cattle, small ruminants, swine and poultry. Whatman (part of GE healthcare) is a global leader in separations technology for the research and diagnostic community which has developed total sample preparation solutions; Foundation BIOEF and Hospital Donostia (San Sebastian, Basque region, Spain) which form a joint research unit, in which Hospital Donostia is the Basque Country Reference Laboratory for Influenza virus.

The roles of the partners

The PORTFASTFLU consortium partners had well defined roles:

- Genewave acted as the architect of the diagnostics system and as the integrator of the various technologies.
- Biosensia worked on microfluidic designs
- Ikerlan developed the lab on a chip cartridge and associated hardware and electronics transfer and adapted the sample preparation and PCR reactions from the tube to the chip. Ikerlan developed fabrication techniques for large-scale production of diagnostics kits
- Gaiker developed and validated biochemical protocols for influenza diagnostics for lab on chip operation
- VIB-University of Gent developed, produced and purified large preparations of influenza A and B viruses, and an internal reference RNA used as an internal control for RT-PCR. VIB provided biological material containing known and unknown amounts of IVA, IVB and RSV virus for validation testing of the new device, and tested the PORTFASTFLU system.
- Nottingham University provided recent influenza isolates. They acted as experts for the definition of the PORTFASTFLU products.
- CIRAD designed and validated primers and probes, worked on amplification techniques, tested the sensitivity, specificity and reproducibility of the PORTFASTFLU test.

- Whatman provided FTA filter paper technology for the processing of samples to yield RNA for amplification
- Hospital Donostia provided human samples infected with other respiratory viruses (VRS, parainfluenza, adenovirus, metapneumovirus, coronavirus, bocavirus, and rhinovirus) as well as samples infected with influenza A H1N1, H3N2, influenza B, and influenza C. They compared extraction methods of RNA/DNA. They evaluated sensitivity of the PORTFASTFLU system with clinical samples.

Description of the PORTFASFLU system for influenza diagnostics

The PORTFASFLU system comprises three items:

- The consumable lab on a chip cartridge, which performs sample preparation, RNA transcription into DNA, DNA amplification, microarray hybridization.
- The portable automated system houses the fluidics, the pneumatic actuation system, the electronics and the interface with the control computer.
- The measurement and analysis system performs the readout of the hybridization result, the signal and data automated analysis.

The PORTEASTLU microfluidic card for automated viral RNA extraction, amplification and microarray detection

The PORTEASTLU consortium developed a portable microfluidic cartridge for viral RNA isolation, amplification and hybridization taking into account the lab on a chip concept. The cartridge detects in a specific and rapid way human influenza viruses from clinical samples (nasopharyngeal and throat swabs). The samples used for this work consisted of viral cultures and nasopharyngeal samples from human patients prepared and supplied by Hospital Donostia and VIB.

The packaged microfluidic chip performs (i) viral RNA extraction (ii) amplification by RT-PCR reaction and (iii) hybridization.

The microdevice can extract viral RNA from real samples, generate cDNA and amplify influenza molecular markers by PCR inside one-single-chamber chip (figure 3). The reduction of the biochemical steps has allowed us to simplify the lab on a chip concept avoiding reaction yield losses. Two materials (SU-8 and Cyclic Olefin Copolymer, COC) have been successfully assayed for the microdevice manufacturing, but the COC cartridges prove to be amenable to large scale, low cost production through injection molding.

A COC cartridge integrating the single chamber chip of above plus a hybridization chamber has been developed. The fabrication process is based on the bonding between an injected COC piece with the desired channels and chambers already patterned and a thin (100 μm) COC film (figure 3).

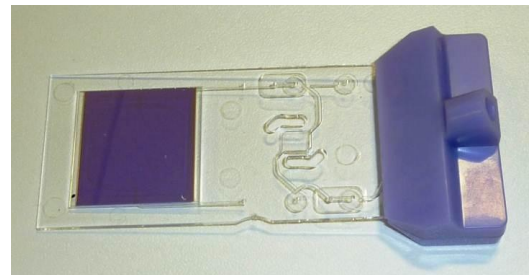
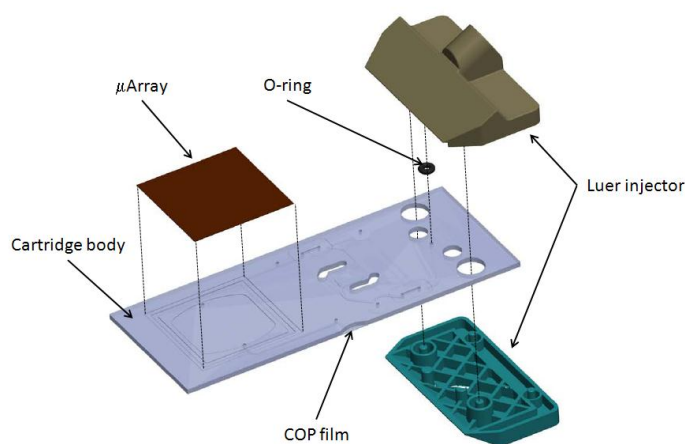


Figure 3: COC cartridge design and fabrication: one sees the microarray slide on the left side of the COC chip, in its center the PCR chamber, and on the right the injection port of the sample.

The complexity of a multi chamber cartridge is quite high as it involves elements/structures that allow the proper handling of the various liquids required to perform the various steps of the process leading from the viral sample to the readout of a hybridized microarray. Thus “out-line” and “in-line” microvalves have been developed and fabricated able to open or close the liquid flow at different places than the inlet and outlet ports.

The PORTFASTLU portable automated machine: GeneSpress®

Many laboratories worldwide have developed LOC systems for genetic or cell analysis. These however remain laboratory objects as they require a large range of devices and equipment surrounding them to operate. To reach its goals of portability and automation, the PORTFASTLU consortium developed a diagnostics system which acts as a docking station for the LOC consumable cartridge. It is highly integrated as it incorporates all the control electronics, the optical detection system of the microarray fluorescence, the pneumatic elements to control the fluids in the cartridge, the various fluids needed to perform the various biochemical steps of the molecular recognition protocol. The signal and data analysis is automatically done without supervision by a computer linked to the PORTFASTLU machine through a USB link. To keep the cartridge and system as simple as possible, only validated concepts of LOCs have been implemented, and versatility is obtained by having all reagents injected as required from an ensemble of 14 reagent bottles placed in the machine, two of them refrigerated for temperature-sensitive reagents (figure 4).

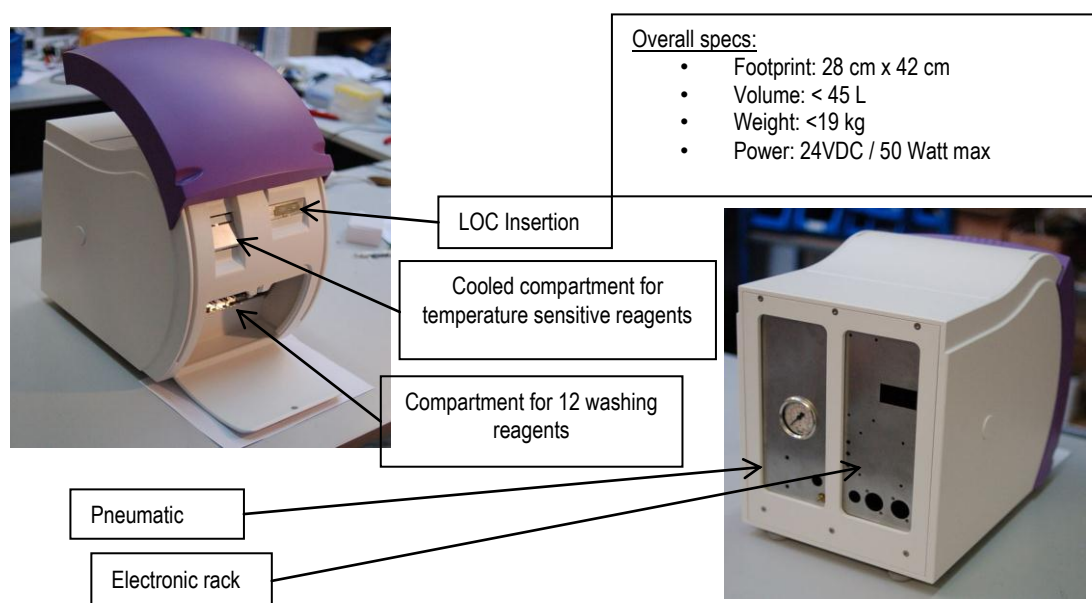


Figure 4: picture of the PORTFASTLU machine GeneSpress® showing the compartments for 14 reagent bottles, the insertion slot for the cartridge. The rear view displays the modularity of the machines with two specialized racks, one for electronics, one for pneumatic functions, which simplifies the systems maintenance.

Measurements and data analysis

The integration of the full protocol for the analyses of nasopharyngeal samples in the multichamber cartridges is carried out without supervision using the PORTFASTLU machine GeneSpress®. For that, the three different steps (extraction/purification, amplification, hybridization) have been optimized separately on breadboard systems, and then adjustments has been made to link these steps together along with specific adaptation of the protocol to the GeneSpress® system and cartridges, specifically in regard to the fluid handling. We have demonstrated a full protocol implementation (figure 5). The fluorescence image resulting from the analysis of an H1N1v sample is shown, next to the display of the automated signal and data analysis.

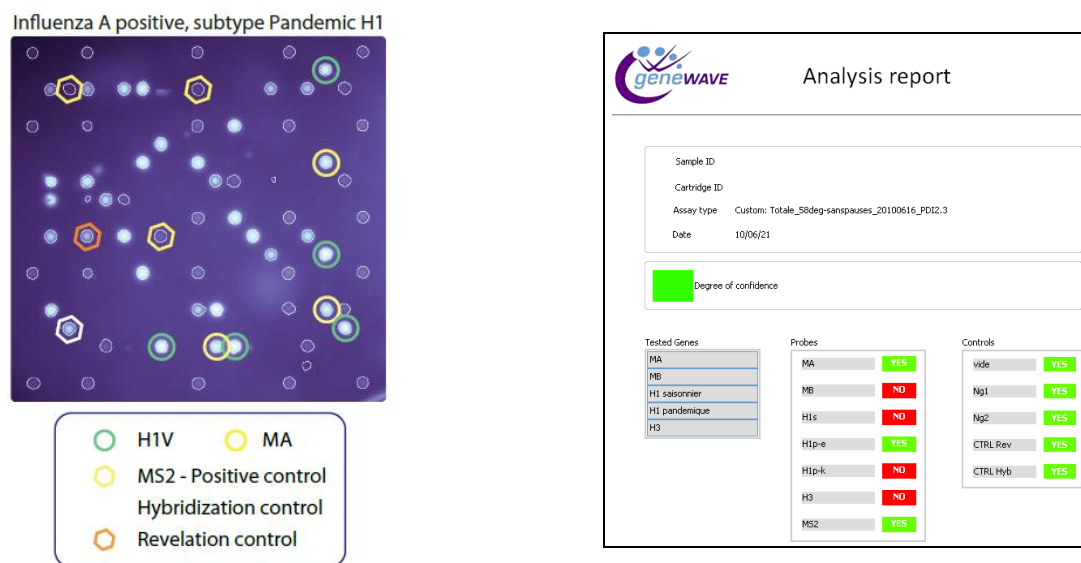


Figure 5: Full protocol result. Positive detection of H1N1v.

4.2 Use and dissemination of foreground

PORTFASTFLU was committed to maximizing the potential impact of the knowledge and foreground to be created both in terms of their dissemination and use.

Dissemination

All along the project, we have communicated a lot to relevant end-users, including industry, authorities, regulatory bodies, citizens groups, etc. These contacts highlighted the scientific achievements of the project and its future commercial use.

Many public media were used, such as newspapers, radio or TV broadcasts. This has been helped by the outbreak of the new pandemic species H1N1v which raised broad public interest about the means to control new infectious diseases by rapid diagnostics methods.

We have also been in contact with authorities, mainly through discussions with the national reference laboratories. Among the many activities, we can single out the exhibit by Genewave of the PortFastFlu prototype at a meeting of the Haut Comité Français pour la Défense Civile.

The publication output has been below our early expectations. As the technologies developed within the project evolved strongly (in particular the switch from SU8 to COC cartridges), biological results of interest came out only slowly. The final clinical validations are still in the making.

The results on the use of bio microtechnology for different processes require also more experiments. It should be however kept in mind the confidentiality of technology itself, and of some of the results.

On novel technologies developed within PORTFASTFLU, patents will be applied for whenever possible.

Plan for the use of Foreground

The summary of the planned commercialization is the following:

	<i>Products</i>	<i>Commercial Targets</i>	<i>Applications</i>
<i>GENEWAVE</i>	<i>POC reader</i>	<i>Diagnostic companies end users</i>	<i>Infection diseases NAT based diagnostics</i>
	<i>infectious diseases kits</i>	<i>End users</i>	<i>VAP Hospital acquired diseases Respiratory infections panel</i>
<i>BIOSENSIA</i>	<i>design and manufacture of disposable cartridges for DNA hybridisation and integration of the same with Portable read out instrumentation</i>	<i>All companies and clinical diagnostic applications</i>	<i>All clinical diagnostic applications</i>
<i>IKERLAN</i>	<i>Diagnostics preparation LOCs</i>	<i>All companies and clinical diagnostic applications</i>	<i>All clinical diagnostic applications</i>

Summary of the outcome of the IP studies

Genewave appointed a specialized law firm to assess intellectual property issues regarding the use of technology within the PFF project.

These studies are strictly confidential but can be made available to the European Commission, on request and upon signature of a specific confidentiality agreement. These studies cover:

- IP issues related to the PFF panel of molecular targets for the identification of respiratory viruses
- Freedom of exploitation for the on-chip PCR technology
- Freedom of exploitation for on-chip valves
- Patentability of the cartridge architecture

A patent has been filed regarding the specific architecture of the cartridge developed by Genewave, while Ikerlan has filed a patent regarding the bonding process of the cartridge.

Regarding the on-chip valves and on-chip PCR, the technology employed is significantly different from what is described in US patent applications identified. The technology used for PCR amplification and fluidic control within the lab-on-a-chip cartridge is not patented in Europe.

Regarding the molecular biology techniques for the detection of respiratory virus markers, a few patents have been filed in the 90s. All rights will fall into the public domain in 2013.

Thus, the technology employed is either free of exploitation rights or patented by the PFF partners.

Comment on the foreground developed by Genewave and its future exploitation.

• Purpose

The foreground developed by Genewave during the PORTFASTFLU project is very broad and encompasses all aspects of molecular diagnostics system, as the end product is a full diagnostics system, including the kit development and consumables, in addition to the diagnostic system itself.

Therefore, Genewave developed foreground or further developed background in the following areas:

- ✓ Molecular diagnostic kit for influenza virus identification: primer and probe design
- ✓ Testing tools for molecular diagnostic kits based on its HybLive tool
- ✓ Protocol for the diagnostic chain of steps: RNA extraction, purification, reverse transcription, PCR amplification, hybridisation, revelation, etc...
- ✓ Design and fabrication techniques for the lab on a chip and microarray cartridge (in strong cooperation with Ikerlan).
- ✓ Docking system making the interface between the cartridge and the measuring system: it provides the following functionalities: mechanical placement, pneumatic (for cartridge valve operation), fluidic connections, heating (for PCR), optical coupling of the microarray to the image sensor.
- ✓ Control software of the GeneSpress diagnostic system
- ✓ Image analysis and automated spot recognition and quantification
- ✓ Data analysis for automated display of the diagnostic results.

Thus , PORTFASTFLU provided at the end a full automated system for influenza diagnostic.

• Foreseen foreground exploitation plan

In the course of PORTFASTFLU, Genewave explored the possibility of commercializing an influenza diagnostics kit. There are several reasons which make such a market unreliable:

- ✓ There is no clear cut demand for a systematic diagnosis of influenza. While such a system would be very useful in epidemiology for an early warning of an epidemic scenario or to detect and monitor a new mutation, in the case of a pandemic the dominant species is so prevalent that subspecies identification is not demanded.
- ✓ While there seems to be a demand for civil authorities such as airports or ports of entry, the access to the market for these entities is not yet identifiable.
- ✓ In emergency rooms of hospitals where patients with severe symptoms will be treated, advanced single-plex molecular diagnostics tools exist to determine if the patient is subject to the prevalent influenza subtype at the time.
- ✓ The PORTFASTFLU consortium does not possess any key marker IP, nor is it clear that such protecting IP would exist.
- ✓ The need clearly expressed by hospital practitioners is for a multiplex diagnostics of a panel of respiratory infectious diseases, of which influenza is just one among several other critical ones. Such applications of the GeneSpress® platform are planned for 2014.

• Present plans for exploitation by Genewave

For the time being, Genewave plans to market molecular diagnostics kits and systems aimed at hospital acquired infections (HAIs). The first product should be targeting Ventilatory Acquired

Pneumonia (VAP) in 2012 and screening patients carrying multi drug resistance (MDR) bacteria in 2013.

This exploitation will involve beneficiary Ikerlan for the manufacture of the LOC cartridge.

- IPR exploitable measures taken or intended

Genewave has applied for one patent on the cartridge architecture and is writing another one on the docking station.

- Potential/expected impact

Under the PortFastFlu project, Genewave has successfully developed critical building blocks that are essential for the development of a point-of-care device for the rapid diagnostic of VAP and rapid detection of MDR bacteria.

Clinical impact

The clinical impact of rapid identification of pathogens and resistance may be summarized as follows:

- A novel diagnostic tool permitting rapid identification of pathogens and resistance genes in respiratory samples could positively affect the patient's outcome. Many previous studies have demonstrated a clear relationship between appropriate antibiotic use and survival in intensive care units (ICU). Putative etiologic agents and their antibiotic susceptibility patterns are suggested by local epidemiologic studies, prior duration of hospitalization/mechanical ventilation before the onset of VAP and prior exposure to antibiotics. This strategy is inaccurate and can lead to inappropriate antibiotic therapy, increasing mortality and morbidity. A targeted antibiotic would improve the outcome for the patient, constituting a strong benefit for the individual, as well as decreasing the length-of-stay in ICU, which is an economic benefit for the hospital.

- Several previous studies suggest that even a short duration of broad-spectrum antibiotics such as imipenem may modify digestive flora. This short duration corresponds to duration of empirical antibiotic therapy. By identifying resistance genes (or their absence), a new strategy, avoiding as much as possible the use of broad-spectrum molecules, would reduce the so called "selective pressure", which is a long-term ecological benefit for the community.

Socio-economic impact

It has been estimated that VAP increases the risk of hospital death, the duration of ICU stay (approximately 6 days) and the cost (25-35,000€ per episode). The socioeconomic impact of a novel diagnostic tool permitting very rapid identification of pathogens and resistance genes may be as follows:

- Improvement in outcome due to a more appropriate choice in antibiotic therapy could translate in in the number of lives saved. Because physicians now use very-broad spectrum antibiotics, the percentage of VAP patients with non-appropriate antibiotics is generally between 20 and 30%. This figure is still high. Rapid detection of resistance could decrease this percentage to near zero. Moreover, an initial non appropriate antibiotic treatment is associated with rapid growing of lung bacterial inoculum. As a consequence, VAP may be more difficult to treat and this could result in a longer ICU stay.

- Less acquisition costs and side effects: several broad spectrum antibiotics such as new carbapenems and oxazolidinones are expensive. A strategy permitting to use these molecules

parsimoniously will probably be cost-effective. In addition, some of these molecules may have severe side effects, which increases morbidity

- Breaking the vicious circle of the administration of carbapenems to many patients because of the fear of extended-spectrum betalactamases enterobacteriaecae, resulting in an increase in carbapenem-resistant strains

- Developing point of care tools enabling a fast diagnosis of bacteria and resistance assay may prove to be cost-effective in an era of resource-limited settings (decentralised biology lab) or out of hours.

Section A (public)

LIST OF SCIENTIFIC (PEER REVIEWED) PUBLICATIONS, STARTING WITH THE MOST IMPORTANT ONES										
NO.	Title	Main author	Title of the periodical or the series	Number, date or frequency	Publisher	Place of publication	Year of publication	Relevant pages	Permanent identifiers (if available)	Is/Will open access provided to this publication?
1	<i>SU-8 and COC LOC devices for fast RNA extraction and identification by one step RT-qPCR of influenza viruses in human samples</i>	<i>Dolores Verdoy</i>	<i>Lab on a Chip (pending of delivery)</i>				2011			No
2	<i>Development of rapid, automated diagnostics for infectious disease: Advances and challenges</i>	<i>Alan McNally</i>	<i>Expert reviews in medical devices</i>	Vol 6	<i>Expert reviews Ltd</i>		2009	641-651		No

LIST OF DISSEMINATION ACTIVITIES

NO.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
1	Conference, poster (Lab on a chip for human influenza viral RNA isolation and one step RT-qPCR detection)	Dolores Verdoy	Lab on a Chip Europe	25-26 May 2010	Dublin, Ireland	Scientific Community Industry		Europe
2	Conference, oral communication (Pathogen and virus detection using a lab-on-a-chip that integrates crude biological sample preparation)	Jesus M. Ruano-López	Rapid Methods Europe	25-27 January 2010	Noordwijk, the Netherlands	Scientific Community Industry	150	Europe
3	Conference, poster (Lab on a chip for fast RNA extraction and identification by one step RT-qPCR of influenza viruses in human samples)	Dolores Verdoy	uTAS	1-5 November 2009	Jeju, Korea	Scientific Community Industry	900	International
4	Conference, poster (Rapid detection of influenza viruses in one step RT-qPCR portable microdevice)	Dolores Verdoy	qPCR, 4th international qPCR Symposium	9-13 March 2009	Freising, Germany	Scientific Community Industry	500	Europe
5	Oldartu 58 / http://www.gaiker.es/document/oldartu/Oldartu_58_castellano.pdf	Gaiker-IK4	Reunión del proyecto europeo PORTFASTFLU	July 2008		Scientific community, Medias		Spain
6	Conference / Trade Show	Diarmuid Flavin Christof Schaefauer	MEDICA 2010	17-20 November 2010	Dusseldorf Germany	Scientific community, Industry		Europe
7	Point-of-care workshop	Diarmuid Flavin	AACC 2010	28 July 2010	California	Scientific community, Industry		Global
8	Boletín Perspectivas de Asebio /Nº 40 / Enero 2011 http://www.asebio.com/es/boletin.cfm?bid=15	Gaiker-IK4	GAIKER-IK4 desarrolla una prueba portátil para la detección rápida de la gripe	01/2011		Industry, Scientific community, Medias		Spain

9	<i>Oldartu 68 (February 2011)</i>	<i>Gaiker-IK4</i>		<i>02/2011</i>		<i>Scientific community</i>		<i>Spain</i>
10	<i>Exhibition</i>	<i>Alan McNally</i>	<i>Da Vinci health technology awards</i>	<i>February 2008</i>	<i>Leicester UK</i>	<i>Industry/policy makers</i>	<i>250</i>	
11	<i>Articles published in popular press</i>	<i>Alan McNally</i>	<i>The Times, The Daily telegraph</i>	<i>August 2008</i>		<i>Civil society</i>	<i>Several million</i>	<i>Global</i>
12	<i>Media briefings</i>	<i>Alan McNally</i>	<i>BBC Radio 4</i>	<i>April 2009</i>		<i>Civil society</i>	<i>Several million</i>	<i>Global</i>
13	<i>Articles in special interest press</i>	<i>Alan McNally</i>	<i>Nature.com/news (http://blogs.nature.com/news/thegreatbeyond/2008/08/british_scientist_does_good_1.html)</i>	<i>August 2008</i>		<i>Scientific community</i>	<i>Several million</i>	<i>Global – US focus</i>
14	<i>Conferences</i>	<i>Alan McNally</i>	<i>Distinguished speaker, Advances in biodetection technologies conference</i>	<i>August 2009</i>	<i>London</i>	<i>Scientific community</i>	<i>200</i>	<i>Global – US focus</i>
15	<i>Conferences</i>	<i>Alan McNally</i>	<i>Distinguished lecture, Nottingham Biocity lecture series</i>	<i>November 2009</i>	<i>Nottingham</i>	<i>Policy makers</i>	<i>200</i>	<i>Global</i>
16	<i>Conferences</i>	<i>Alan McNally</i>	<i>Presentation, Infectious diseases research network</i>	<i>February 2010</i>	<i>Leicester</i>	<i>Scientific community Industry</i>	<i>200</i>	<i>Global</i>

Articles mentioning the EU-FP7 PortFastFlu project

News briefs

21/8 Cage and Aviary Birds

NTU developing device for rapid diagnosis of bird flu

Molecular project aims for rapid detection of AI

25/8 Veterinary Times

NTU developing device for rapid diagnosis of bird flu

New machine to detect avian flu

14/8 Express and Star

NTU developing device for rapid diagnosis of bird flu

Machine to speed up bird flu tests

14/8 Shropshire Star

NTU developing device for rapid diagnosis of bird flu

New machine will detect avian flu

14/8 Reading Evening Post

NTU developing device for rapid diagnosis of bird flu

Europe develops rapid flu tests

15/8 Animal Pharm

NTU developing device for rapid diagnosis of bird flu

Faster avian flu test boosts vaccine efficacy

18/8 Pharma Marketletter

NTU developing device for rapid diagnosis of bird flu

Machine set to speed up bird flu detection

14/8 Yorkshire Post

NTU developing device for rapid diagnosis of bird flu

Machine 'could spot bird flu in just two hours'

14/8 Manchester Evening News

NTU developing device for rapid diagnosis of bird flu

Bird flu test boost

14/8 Guernsey Press and Star

NTU developing device for rapid diagnosis of bird flu

Machine 'speeds up bird flu detection'

14/8 Evening Leader (Chester)

NTU developing device for rapid diagnosis of bird flu
(Same article appeared in Shields Gazette)

Hope of bird flu breakthrough

14/8 Edinburgh Evening News

NTU developing device for rapid diagnosis of bird flu

Bird flu detection boost

14/8 Evening Courier (Halifax)

NTU developing device for rapid diagnosis of bird flu

Bird flu project

15/8 The Journal (Newcastle)

NTU developing device for rapid diagnosis of bird flu

Bird flu detection

17/8 Scotland on Sunday

NTU developing device for rapid diagnosis of bird flu

A bird flu revolution

14/8 Western Daily Press

NTU developing device for rapid diagnosis of bird flu

Breakthrough on bird flu detection

14/8 Eastern Daily Press

NTU developing device for rapid diagnosis of bird flu

Machine set to speed up bird flu detection

14/8 Yorkshire Post

NTU developing device for rapid diagnosis of bird flu

Machine speeds up bird flu detection

14/8 Press & Journal (Aberdeen)

NTU developing device for rapid diagnosis of bird flu

Machine may be able to detect bird flu in two hours

14/8 The Herald (Glasgow)

NTU developing device for rapid diagnosis of bird flu

Quick test for bird flu

14/8 Star (Sheffield)

NTU developing device for rapid diagnosis of bird flu

Health Highlights: Aug 14, 2008

14/8 womenshealth.gov

NTU developing device for rapid diagnosis of bird flu

<http://www.womenshealth.gov/news/english/618482.htm>

Portable machine to detect bird flu outbreak in 'two hours'

14/8 economictimes.indiatimes.com

NTU developing device for rapid diagnosis of bird flu

http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare_Biotech/Healthcare/Portable_machine_to_detect_bird_flu_outbreak_in_two_hours/articleshow/3365105.cms

New machine could detect bird flu outbreak in hours

14/8 foodlineweb.co.uk

NTU developing device for rapid diagnosis of bird flu

Plans for rapid bird flu testing kit

15/8 Healthcare Today (web)

NTU developing device for rapid diagnosis of bird flu

<http://www.hc2d.co.uk/content.php?contentId=7878>

Clues to bird flu epidemic

15/8 englemed.co.uk

NTU developing device for rapid diagnosis of bird flu

<http://www.englemed.co.uk/week08aug15.php>

Scientists develop a machine to detect H5N1 virus

19/8 topnews.in

NTU developing device for rapid diagnosis of bird flu

<http://www.topnews.in/scientists-develop-machine-detect-h5n1-virus-260162>

New developments in fight against bird flu

19/8 meatinfo.co.uk

NTU developing device for rapid diagnosis of bird flu

<http://www.meatinfo.co.uk/articles/65886/New-developments-in-fight-against-bird-flu.aspx?categoryid=9045>

Bird flu (news) strikes again

15/8 Nature

NTU developing device for rapid diagnosis of bird flu

http://blogs.nature.com/news/thegreatbeyond/2008/08/bird_flu_news_strikes_again.html

Avian flu breakthrough: virus detection 'in two hours'

16/8 The Med Guru

NTU developing device for rapid diagnosis of bird flu

http://www.themedguru.com/articles/avian_flu_breakthrough_virus_detection_in_two_hours-8617572.html

Uni's design help on bird flu detector

14/8 Nottingham Evening Post

NTU developing device for rapid diagnosis of bird flu

<http://www.thisisnottingham.co.uk/displayNode.jsp?nodeId=195917&command=displayContent&sourceNode=134241&contentPK=21284347&folderPk=78486&pNodeId=133951>

Scientists develop new machine which can detect bird flu in just TWO hours

14/8 Daily Mail Online

NTU developing device for rapid diagnosis of bird flu

<http://www.dailymail.co.uk/health/article-1044810/Scientists-develop-new-machine-detect-bird-flu-outbreaks-just-TWO-hours.html>

Machine to detect bird flu fast

14/8 The Sun Online

NTU developing device for rapid diagnosis of bird flu

<http://www.thesun.co.uk/sol/homepage/news/article1557838.ece>

Bird flu detection breakthrough

14/8 Farm Business

NTU developing device for rapid diagnosis of bird flu

<http://www.farmbusiness.cc/cogcms/default.aspx?page=15&article=3048>

Novo exame poderia acelerar diagnostico da gripe aviaria

14/8 BBC World Service (Brazil)

NTU developing device for rapid diagnosis of bird flu

http://www.bbc.co.uk/portuguese/reporterbbc/story/2008/08/080814_gripeaviariateste_np.shtml

Una nueva maquina podra detectar un estallido de la gripe aviar in situ

14/8 La Opinion

NTU developing device for rapid diagnosis of bird flu

http://www.laopinion.es/secciones/noticia.jsp?pRef=2008081400_18_164867_Ciencia-y-Tecnologia-nueva-maquina-podra-detectar-estallido-gripe-aviar-situ

Rapid bird flu test under development

14/8 United Press International

NTU developing device for rapid diagnosis of bird flu

http://www.upi.com/Science_News/2008/08/14/Rapid_bird_flu_test_under_development/UPI-14641218759433/

Bird flu hits UK newspapers

14/8 Nature

NTU developing device for rapid diagnosis of bird flu

http://blogs.nature.com/news/thegreatbeyond/2008/08/british_scientist_does_good_1.html

Portable machine to detect bird flu

14/8 The Hindu

NTU developing device for rapid diagnosis of bird flu

<http://www.hindu.com/2008/08/15/stories/2008081559672200.htm>

Bird flu detection 'in two hours'

14/8 Ananova

NTU developing device for rapid diagnosis of bird flu

http://www.ananova.com/news/story/sm_2966069.html

(Same article appeared in Asian Image, Halifax Evening Courier, North Wales Chronicle, Rugby Today, Yahoo News)

Machine speeds up bird flu detection

14/8 Fife Online

NTU developing device for rapid diagnosis of bird flu

<http://www.fifetoday.co.uk/latest-east-midlands-news/machine-speeds-up-bird-flu.4389554.jp>

Portable test could reduce H5N1 diagnosis to just two hours

15/8 Medical Laboratory World

NTU developing device for rapid diagnosis of bird flu

<http://www.mlwmagazine.com/story.asp?sectioncode=201&storyCode=2048347>

Faster, portable bird flu test being developed

15/8 RedOrbit

NTU developing device for rapid diagnosis of bird flu

http://www.redorbit.com/news/health/1521900/faster_portable_bird_flu_test_being_developed/#

Coming soon, a device that can detect bird flu outbreak in two hours

14/8 Thaindian News

NTU developing device for rapid diagnosis of bird flu

http://www.thaindian.com/newsportal/entertainment/coming-soon-a-device-that-can-detect-bird-flu-outbreak-in-two-hours_10083883.html

Portable test for bird flu promises to save many lives

14/8 News-Medical

NTU developing device for rapid diagnosis of bird flu

<http://www.news-medical.net/?id=40725>

Machine speeds up bird flu detection

14/8 Fenland Citizen

NTU developing device for rapid diagnosis of bird flu

<http://www.fenlandcitizen.co.uk/latest-east-midlands-news/Machine-speeds-up-bird-flu.4389554.jp>

Bird flu detection 'in two hours'

14/8 Channel 4 News

NTU developing device for rapid diagnosis of bird flu

<http://www.channel4.com/news/articles/uk/bird%20flu%20detection%20in%20two%20hours/2399782>

British researchers eyeing quick test to verify bird flu outbreak

14/8 AHN

NTU developing device for rapid diagnosis of bird flu

<http://www.allheadlinenews.com/articles/7011934689>

Experts closing in on avian flu breakthrough

14/8 Medical News Today

NTU developing device for rapid diagnosis of bird flu

<http://www.medicalnewstoday.com/articles/118044.php>

Machine may be able to detect bird flu in two hours

14/8 The Herald

NTU developing device for rapid diagnosis of bird flu

http://www.theherald.co.uk/news/other/display.var.2424715.0.Machine_may_be_able_to_detect_bird_flu_in_two_hours.php

Rapid diagnosis of avian influenza

1/9 Biomedical Scientist

NTU developing device for rapid diagnosis of bird flu

These articles are available in pdf format on request from:

Matt Wallace MCIPR

Press Officer

Nottingham Trent University

Burton Street

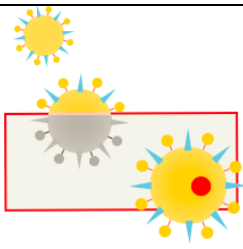
Nottingham NG1 4BU

Tel: +44 (0)115 848 8785

E-mail: matt.wallace@ntu.ac.uk

www.ntu.ac.uk/news

The PortFastFlu consortium organised a workshop in March 2011



PORTFASTFLU

Portable and Automated Test for Fast detection and surveillance of influenza

PortFastFlu Workshop

Collège des Ingénieurs, Paris

March 22, 2010

Programme



Tuesday, March 22nd

Location: Collège des Ingénieurs, 215 boulevard St Germain, 75007 Paris
Métro: Solférino or Rue du Bac

8.30-9.00	Arrival, Coffee and pastries
9.00-9.15	Welcome and Introductory remarks & round robin introduction (Claude Weisbuch)
<u>9.15-10.15</u>	<u>Outcome of the PortFastFlu project</u>
9.15-9.45	Claude Weisbuch Chief Scientific Officer, Genewave PortFastFlu results and perspectives
9.45-10.15	Discussion (Moderator: Philippe Loiseau)
<u>10.15-12.15</u>	<u>The future of rapid diagnostics instruments</u>
10.15-10.45	Key Note Speaker Neil Leblanc FP7 Project "EPIZONE", National Veterinary Institute, Sweden Detection and Subtyping of Influenza A using a Dedicated Suspension Microarray
10.45-11.15	Discussion (Moderator: Emmanuel Albina)
11.15-11.45	Key Note Speaker Helen Lee Head of the Diagnostics Development Unit, University of Cambridge, UK Rapid Diagnostics Developments in the context of Flu Detection
11.45-12.15	Discussion (Moderator: Alan McNally)
12.30-14.00	Lunch at Restaurant Les Ministères , Rue du Bac, Paris 7ème
<u>14.30-15.30</u>	<u>The future of rapid diagnostics tests</u>
14.30-15.00	Key Note Speaker Alice McHardy Max Planck Institute for Computer Science, Germany How to read Influenza Genomes
15.00-15.30	Discussion (Moderator: Xavier Saelens)
<u>15.30-16.30</u>	<u>Infection control and diagnostic policies</u>
15.30-16.00	Key Note Speaker Nick Phin Professor, Health Protection Agency, UK Flu Diagnostics policies in the UK
16.00-16.30	Discussion (Moderator: Alan McNally)

16.30-17.00	Key Note Speaker Vincent Enouf (confirmed) Deputy Head of the National Reference Centre for Influenzae, Pasteur Institute, France The various needs for Influenzae diagnostics
17.00-17.30	Discussion (Moderator: Yann Marcy)
17.30-18.00	Conclusions (Claude Weisbuch, Project Coordinator)
18.00	End of Workshop

Main take-home messages from the workshop

The choice was made not to inject the swab directly into the cartridge, but to split the sample in two parts by first putting the swab in a tube containing the lysis solution and the magnetic beads, and then injecting part of the beads contained in the tube. This appeared a good approach to the expert panel: it simplifies significantly the cartridge, and at the same time it provides a saved portion of the sample.

The market needs for a multiplex rapid POC test of influenza is not obvious, as the diagnostics need is based in hospitals where molecular diagnostics tools and qualified personnel exist.

However a market should be in high demand for such a multiplex capacity, that of hospital acquired infections. This is just the approach taken by GW to commercialize part of the platform developed in PFF.

Section B: all information contained within this section is confidential

LIST OF APPLICATIONS FOR PATENTS, TRADEMARKS, REGISTERED DESIGNS, ETC.					
Type of IP Rights	Confidential	Foreseen embargo date	Application reference(s)	Subject or title of application	Applicant (s) (as on the application)
<i>Patent</i>	Yes	<i>Fall 2011 public release depending on Genewave authorisation</i>		<i>Docking station / world to chip interface technologies</i>	<i>Genewave</i>
<i>Patent</i>	Yes	<i>Fall 2011, public release depending on Genewave and Ikerlan authorisation</i>		<i>Lab-on-a-chip production</i>	<i>Genewave and Ikerlan</i>
<i>Trademark</i>	No	NA	103721480	GeneSpress® <i>The trademark is registered in France and under examination in the European Union and in the United States</i>	<i>Genewave</i>
<i>Patent</i>	Yes	<i>Spring 2012</i>	1059425	<i>Lab-on-a-chip cartridge design for microarray</i>	<i>Genewave</i>
<i>Patent</i>	Yes	<i>Spring 2012 public release depending on Ikerlan authorisation</i>	ES2010070468	<i>Lab-on-a-chip fabrication process</i>	<i>Ikerlan</i>
<i>Patent</i>	Yes	<i>31-12-2012, public release depending on Gaiker authorisation</i>		<i>Biochemistry Method for viral RNA extraction from clinical samples on miniaturized systems polymer chamber/s</i>	<i>Gaiker</i>
<i>Patent</i>	Yes	<i>31-12-2012, public release depending on Gaiker authorisation</i>		<i>Biochemistry Method for retro amplification reaction on miniaturized systems polymer chamber/s</i>	<i>Gaiker</i>
<i>Others (tbd)</i>	Yes	<i>31-12-2012, public release depending on Gaiker authorisation</i>		<i>Method to evaluate biocompatibility of materials applied to molecular biology</i>	<i>Gaiker</i>
<i>Patent</i>	Yes	<i>To be determined</i>		<i>Method and Device for on chip RNA extraction, RT, amplification and hybridization detection</i>	<i>Partners</i>

EXPLOITABLE FOREGROUND

Type of Exploitable Foreground	Description of exploitable foreground	Confidential	Foreseen embargo date	Exploitable product(s) or measure(s)	Sector(s) of application	Timetable, commercial or any other use	Patents or other IPR exploitation (licences)	Owner & Other Beneficiary(s) involved
Know how	GeneSpress Measuring system	Yes		Production	Molecular diagnostics	2012		Genewave
Know how	Image analysis software	Yes		Production	Molecular diagnostics	2012		Genewave
Know how	Microarray data analysis and display	Yes		Production	Molecular diagnostics	2012		Genewave
Know how	Automated protocol for influenza diagnostic	Yes		Future molecular diagnostics for panel of infectious respiratory diseases		2013/2014	Requires further markers for infectious respiratory diseases	To be further developed by Genewave
Know how	design and manufacture of disposable cartridges for DNA hybridisation and integration of the same with Portable read out instrumentation	No	N/A	MRI equipment	Medical	No fixed time table	No Patents planned	Biosensia
General advancement of knowledge	Method to evaluate biocompatibility of materials applied to molecular biology	Yes	31-12-2012, public release depending on Gaiker and Ikerlan authorisation	General advancement of knowledge	Medical, Environmental Agricultural	2 Years and a half		Gaiker and Ikerlan

Commercial Exploitation of R&D results	Biochemistry Method for viral RNA extraction from clinical samples on miniaturized polymer systems comprising chamber/s	Yes	31-12-2012, public release depending on Gaiker authorisation	General advancement of knowledge Miniaturized system, ready to use applied to life sciences	Medical, Environmental Agricultural	2 Years and a half	IPR will be sought previously to technology valorisation and commercial dealing	Gaiker
Commercial Exploitation of R&D results	Biochemistry Method for retro amplification reaction on miniaturized polymer systems comprising chamber/s	Yes	31-12-2012, public release depending on Gaiker authorisation	General advancement of knowledge Miniaturized system ready to use applied to life sciences	Medical, Environmental Agricultural	2 Years and a half	IPR will be sought previously to technology valorisation and commercial dealing	Gaiker
Commercial exploitation of R&D results	Method and portable compact device fully equipped	Yes		Method and Device for on chip RNA extraction/ amplification, labelling and hybridization detection	Medical, Environmental , Agricultural	3 Years	* Gaiker could contribute actively for the industrial partening . Once defined the business plan and industrialization requirements for product market launching, Gaiker could contribute at both levels: specific clinical approach disposable components industrial processing design	All partners

4.3 Report on societal implications

A General Information <i>(completed automatically when Grant Agreement number is entered).</i>	
Grant Agreement Number:	201914
Title of Project:	PORTFASTFLU
Name and Title of Coordinator:	DR CLAUDE WEISBUCH
B Ethics	
1. Did your project undergo an Ethics Review (and/or Screening)? If Yes: have you described the progress of compliance with the relevant Ethics Review/Screening Requirements in the frame of the periodic/final project reports? Special Reminder: the progress of compliance with the Ethics Review/Screening Requirements should be described in the Period/Final Project Reports under the Section 3.2.2 'Work Progress and Achievements'	No
2. Please indicate whether your project involved any of the following issues (tick box) :	
RESEARCH ON HUMANS	
• Did the project involve children?	
• Did the project involve patients?	
• Did the project involve persons not able to give consent?	
• Did the project involve adult healthy volunteers?	
• Did the project involve Human genetic material?	
• Did the project involve Human biological samples?	x
• Did the project involve Human data collection?	
RESEARCH ON HUMAN EMBRYO/FOETUS	
• Did the project involve Human Embryos?	
• Did the project involve Human Foetal Tissue / Cells?	
• Did the project involve Human Embryonic Stem Cells (hESCs)?	
• Did the project on human Embryonic Stem Cells involve cells in culture?	
• Did the project on human Embryonic Stem Cells involve the derivation of cells from Embryos?	
PRIVACY	
• Did the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	
• Did the project involve tracking the location or observation of people?	
RESEARCH ON ANIMALS	
• Did the project involve research on animals?	
• Were those animals transgenic small laboratory animals?	
• Were those animals transgenic farm animals?	
• Were those animals cloned farm animals?	
• Were those animals non-human primates?	
RESEARCH INVOLVING DEVELOPING COUNTRIES	
• Did the project involve the use of local resources (genetic, animal, plant etc)?	
• Was the project of benefit to local community (capacity building, access to healthcare, education etc)?	
DUAL USE	
• Research having direct military use	

• Research having the potential for terrorist abuse		
C Workforce Statistics		
3. Workforce statistics for the project: Please indicate in the table below the number of people who worked on the project (on a headcount basis).		
Type of Position	Number of Women	Number of Men
Scientific Coordinator	1	1
Work package leaders	1	4
Experienced researchers (i.e. PhD holders)	5	8
PhD Students	2	1
Other	8	5
4. How many additional researchers (in companies and universities) were recruited specifically for this project?		4
Of which, indicate the number of men:		1

D Gender Aspects									
5. Did you carry out specific Gender Equality Actions under the project?								☐ X	Yes No
6. Which of the following actions did you carry out and how effective were they?									
								Not at all effective	Very effective
		☐	Design and implement an equal opportunity policy				☐	☐	☐
		☐	Set targets to achieve a gender balance in the workforce				☐	☐	☐
		☐	Organise conferences and workshops on gender				☐	☐	☐
		☐	Actions to improve work-life balance				☐	☐	☐
		☐	Other:						
7. Was there a gender dimension associated with the research content – i.e. wherever people were the focus of the research as, for example, consumers, users, patients or in trials, was the issue of gender considered and addressed?									
		☐	Yes- please specify						
		X	No						
E Synergies with Science Education									
8. Did your project involve working with students and/or school pupils (e.g. open days, participation in science festivals and events, prizes/competitions or joint projects)?									
		☐	Yes- please specify						
		X	No						
9. Did the project generate any science education material (e.g. kits, websites, explanatory booklets, DVDs)?									
		☐	Yes- please specify						
		X	No						
F Interdisciplinarity									
10. Which disciplines (see list below) are involved in your project?									
		X	Main discipline: 1.5.						
		X	Associated discipline: 3.3.				X	Associated discipline: 2.3.	
G Engaging with Civil society and policy makers									
11a Did your project engage with societal actors beyond the research community? (if 'No', go to Question 14)								☐ X	Yes No
11b If yes, did you engage with citizens (citizens' panels / juries) or organised civil society (NGOs, patients' groups etc.)?									
		☐	No						
		☐	Yes- in determining what research should be performed						
		☐	Yes - in implementing the research						
		☐	Yes, in communicating /disseminating / using the results of the project						

11c In doing so, did your project involve actors whose role is mainly to organise the dialogue with citizens and organised civil society (e.g. professional mediator; communication company, science museums)?		☐ ☒	Yes No
12. Did you engage with government / public bodies or policy makers (including international organisations)			
		☒	No
		☐	Yes- in framing the research agenda
		☐	Yes - in implementing the research agenda
		☐	Yes, in communicating /disseminating / using the results of the project
13a Will the project generate outputs (expertise or scientific advice) which could be used by policy makers?			
		☐	Yes – as a primary objective (please indicate areas below- multiple answers possible)
		☐	Yes – as a secondary objective (please indicate areas below - multiple answer possible)
		☒	No
13b If Yes, in which fields?			
Agriculture Audiovisual and Media Budget Competition Consumers Culture Customs Development Economic and Monetary Affairs Education, Training, Youth Employment and Social Affairs		Energy Enlargement Enterprise Environment External Relations External Trade Fisheries and Maritime Affairs Food Safety Foreign and Security Policy Fraud Humanitarian aid	Human rights Information Society Institutional affairs Internal Market Justice, freedom and security Public Health Regional Policy Research and Innovation Space Taxation Transport

13c If Yes, at which level?			
	☐	Local / regional levels	
	☐	National level	
	☐	European level	
	☐	International level	
H Use and dissemination			
14. How many Articles were published/accepted for publication in peer-reviewed journals?			2
To how many of these is open access provided?			0
How many of these are published in open access journals?			
How many of these are published in open repositories?			
To how many of these is open access not provided?			2
Please check all applicable reasons for not providing open access:			
☐ publisher's licensing agreement would not permit publishing in a repository ☐ no suitable repository available ☒ no suitable open access journal available ☐ no funds available to publish in an open access journal ☐ lack of time and resources ☐ lack of information on open access ☐ other:			
15. How many new patent applications ('priority filings') have been made? <i>("Technologically unique": multiple applications for the same invention in different jurisdictions should be counted as just one application of grant).</i>			2
16. Indicate how many of the following Intellectual Property Rights were applied for (give number in each box).	Trademark		1
	Registered design		0
	Other		0
17. How many spin-off companies were created / are planned as a direct result of the project?			0
<i>Indicate the approximate number of additional jobs in these companies:</i>			
18. Please indicate whether your project has a potential impact on employment, in comparison with the situation before your project:			
☒	Increase in employment, or	☐	In small & medium-sized enterprises
☐	Safeguard employment, or	☐	In large companies
☐	Decrease in employment,	☐	None of the above / not relevant to the project
☐	Difficult to estimate / not possible to quantify		
19. For your project partnership please estimate the employment effect resulting directly from your participation in Full Time Equivalent (FTE = one person working fulltime for a year) jobs:			<i>Indicate figure:</i>
			4
Difficult to estimate / not possible to quantify			☐

I Media and Communication to the general public				
20. As part of the project, were any of the beneficiaries professionals in communication or media relations?				
	☐	Yes	☒	No
21. As part of the project, have any beneficiaries received professional media / communication training / advice to improve communication with the general public?				
	☐	Yes	☒	No
22 Which of the following have been used to communicate information about your project to the general public, or have resulted from your project?				
☒	Press Release	☒	Coverage in specialist press	
☐	Media briefing	☒	Coverage in general (non-specialist) press	
☐	TV coverage / report	☒	Coverage in national press	
☒	Radio coverage / report	☒	Coverage in international press	
☐	Brochures /posters / flyers	☒	Website for the general public / internet	
☐	DVD /Film /Multimedia	☐	Event targeting general public (festival, conference, exhibition, science café)	
23 In which languages are the information products for the general public produced?				
☒	Language of the coordinator : French	☒	English	
☒	Other language(s) : Spanish			