zidechip

Point of Care for simultaneous detection of Zika, Dengue and Chikungunya viruses

ALIFAX R&D

ICGEB

LABRIUNITI

www.zidechip-project.it

ABSTRACT

About 80% of the world's population lives in areas affected by diseases transmitted by insects (Global Vector Control Response, WHO, 2017).

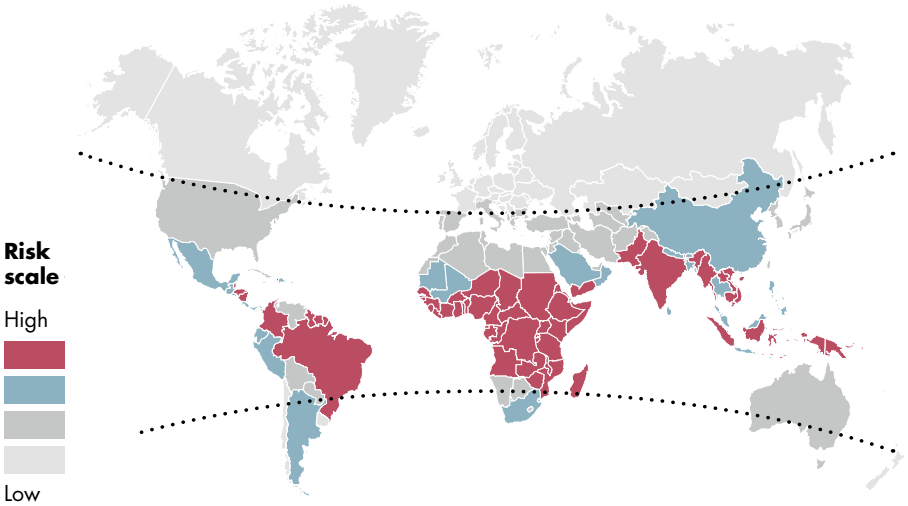
The World Health Organization (WHO) is currently conducting surveillance on virus spread, developing and distributing better diagnostic tests, and providing guidance to states and localities in the areas at risk on strengthening mosquito growth control.

Mosquito control programs, scientific expertise, and financial resources vary significantly throughout the world, ranging from absent or limited capacity in some jurisdictions to advanced integrated mosquito management programs in others. In particular, the transmission of arboviral diseases through Dengue [DENV], Chikungunya [CHIKV], and Zika [ZIKV] viruses pose new challenges for public health.

These three pathogens can produce similar clinical symptoms, mainly during the acute phase, hindering clinical diagnosis and creating problems for appropriate case management, sometimes triggering fatal events.

In this perspective, Alifax R&D will address patients' needs by applying its innovative rapid real-time qualitative polymerase chain reaction (RT-qPCR) device to create a robust diagnostic point-of-care (PoC) for genotyping of ZIKV, DENV, and CHIKV.

In the **ZIDECHIP** project (Funded by POR FESR, 1489/2017), the leading company, Alifax R&D, will combine its technology with the expertise on the field of tropical diseases of International Center for Genetic Engineering and Biotechnology (ICGEB), to develop an in vitro diagnostic device that will be validated in collaboration with Laboratori Riuniti of Trieste.



Innovative features & competitive advantage

the **ZIDECHIP** project aims to develop a point-of-care (PoC) device for fast diagnosis of tropical pathogens: Zika, Dengue e Chikungunya (ZIKV, DENV, CHIKV) which will have a significant impact on the world health system. To this end, Alifax will apply its innovative technology for rapid detection of nucleic acids partnering with ICGEB, a research institute with expertise in tropical diseases, and Laboratori Riuniti fortests on clinical samples. The technology is based on real-time qualitative polymerase chain reaction (qPCR), a molecular biology technique already established in the clinical field for the analysis of genetic material. The commercial kits for detection of tropical pathogens available on the market are all based on current qPCR instrumentation. These instruments are still very expensive, cumbersome, and complex, requiring qualified staff. Alifax's portable qPCR, instead, can easily perform rapid qualitative analysis of nucleic acids through an integrated approach of high-end nanotechnologies. The integrated user-friendly software platform will translate experimental raw data into a significant clinical report that will be immediately available to clinicians allowing for prompt personalized treatment. The competitiveness of the **ZIDECHIP** PoC device will rely on its key features, such as rapid time-to-result, higher automation, highly reliable data, lower cost, user-friendly interface, and secure data sharing. The outstanding cost-effectiveness of the **ZIDECHIP** device, together with its high reliability and accuracy, will extend the molecular diagnostic market of arboviruses from the current large centralized lab to near-patient sites, such as urgent care clinics. The **ZIDECHIP** device is the first example of a technology applicable to any viral infection included the SARS-CoV-2, responsible for the COVID-19 pandemia.

Molecular Mouse

The smallest Real-Time PCR device for qualitative and quick quantitative analysis of target molecules of DNA and RNA

MARKET SECTOR
& FUTURE COMMERCIAL PROSPECTIVES

The size of the ZIKV, DENV, and CHIKV test market was evaluated to be around USD 500 million in 2017, progressing at a Compounded Average Growth Rate (CAGR) of 6–8% during the forecast period (by 2023–2027). Recent outbreaks and the correlation between ZIKV infection and microcephaly in newborns, are fueling market growth, with an increased request for effective diagnostic point-of-care. In this regard, the compact, easy-to-use, rapid, and low-cost **ZIDECHIP** diagnostic tool has high potential to improve routine medical practice and impact all levels of healthcare.

Device features will let decentralization from highly specialized clinical laboratories to near-patient sites, such as urgent care clinics, especially in the developing world, having a substantial impact on preventive and welfare policies. Integration of this PoC device with screening and prevention programs will lead to an increase in patient longevity and improved quality of life; it will also reduce the economic burden on the public health system. The market potential for this diagnostic tool is broad, covering global small-to-large sized diagnostic laboratories.

Thanks to the important results achieved by the project, the innovative capacity of the partnership and the Poc versatility, a new product for the rapid diagnosis of the Coronavirus SARS-CoV-2 will soon be available together with the **ZIDECHIP** product and have a wide diffusion on the world market thanks to the vast and consolidated sales network of Alifax s.r.l.

TRAJECTORY

Biomedical Technologies,
in Vivo and in Vitro Diagnostics

SMART SPECIALISATION PLATFORM

PROJECT DURATION

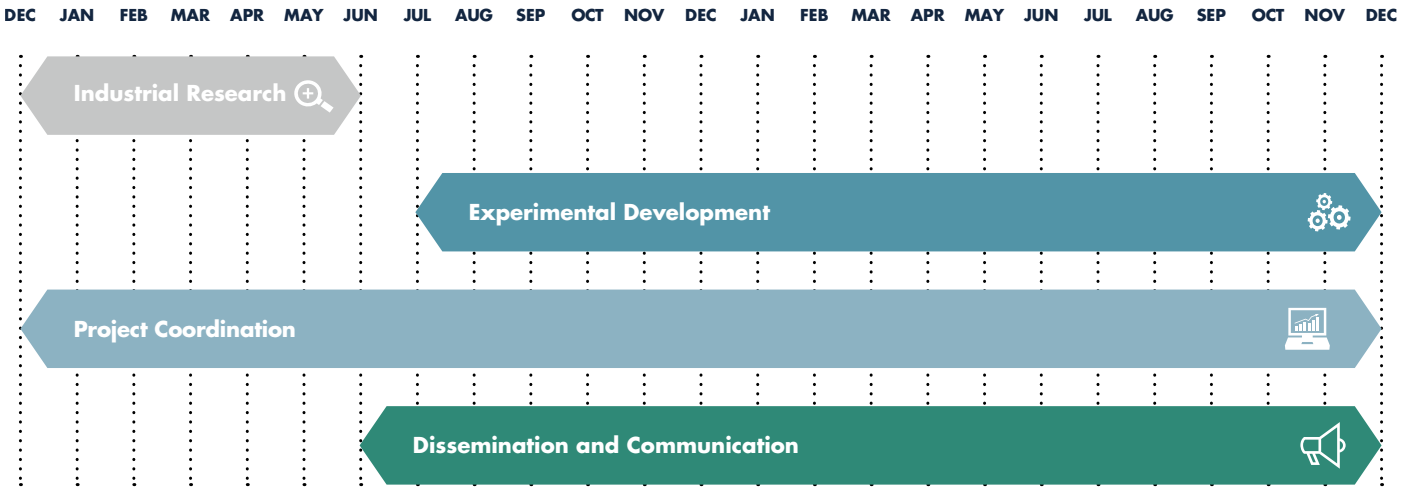
Start date:
December 2018

Finish date:
November 2020

PROJECT VALUE

Total Project:
€ 521,134.64

Total Grant:
€ 293,465.66



LP - Lead Partner

Founded in 1988 in Padua, Alifax operates in the laboratory diagnostics market, in particular in the hematology and microbiology fields. In only a few years, it established as a manufacturer of clinical diagnostic instruments for the analysis of ESR and rapid bacterial cultures, and begun a rapid spread in international markets. Currently, Alifax has branches in Russia, Spain, Germany, China, the United Arab Emirates, and Brazil; it also collaborates with relevant international commercial partners in over 90 other countries. Alifax has a strong orientation towards scientific research and technological innovation, supported by a well-funded investment program and, nowadays, it holds over 30 international patents. The company's growing interest in innovation was consolidated in 2017 with the opening of a new department, Alifax Research & Development (R&D) Srl in Trieste in one of the national main science and technology parks (Area Science Park). Alifax R&D is a molecular biology laboratory fully equipped to undertake the research and development of cutting-edge diagnostic systems in the field of biomolecular medicine.

www.alifax.com

PP - Project Partner

The International Center for Genetic Engineering and Biotechnology (ICGEB) is an intergovernmental organization that has been operating within the United Nations Common System since 1987. ICGEB is a center of excellence for research, training, and technology transfer. Due to the

group's goal is to identify diagnostic and vaccine candidates for the Zika virus, Dengue virus, and other flaviviruses, such as the tick-borne encephalitis virus and the recently introduced Usutu virus in Europe. To this end, in recent years, the laboratory has produced innovative molecular and serological diagnostic methods with the aim of developing portable, point-of-care devices to be used for viral diagnostics in developing countries.

www.icgeb.org

PP - Project Partner

Laboratori Riuniti is an authorized private laboratory that offers a wide range of tests, from normal blood tests to new genetic analyzes. An independent entity since 1999, the Laboratori Riuniti operates in the field of cytopathological and histological diagnosis. Since 2011, Laboratori Riuniti has constantly expanded its range of activities, based on three development directions:

- Seize new possibilities for diagnostic investigation offered by molecular analysis.
- Develop a new line of services in the fields of Medical Genetics and Predictive Genetics.
- In the field of biochemical analysis, offer diagnostic and prognostic tools that overcome the standards of chemical-diagnostic analysis laboratories.

www.labriuniti.it

POR FESR 2014 2020 Friuli Venezia Giulia
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