Istituto Nazionale per le Malattie Infettive
"Lazzaro Spallanzani"

Istituto di Ricovero e Cura a Carattere Scientifico

T3650T

STMicroelectronics, Clonit, and Institute Spallanzani Develop Accurate Point-of-Care Analyzer for Early Ebola Detection

Collaboration among scientific and biotech research centers produces new rapid test to detect Ebola and other viruses in early stages of the disease

Rome, Italy, December 10, 2014 – Driven by the ambitious objective to quickly detect the Ebola virus in the blood at a very early stage to minimize further transmission, STMicroelectronics and Clonit, in collaboration with Italy's National Institute for Infectious Diseases Lazzaro Spallanzani, have developed, in a few weeks' time, a prototype portable analyzer able to identify the presence of the Ebola virus in less than 75 minutes.

The portable analyzer is based on the Real-Time Polymerase Chain Reaction (RT-PCR) molecular biology technique. The next step in development of the analyzer is to optimize the point-of-care Ebola-detection solution for large-scale deployment, including minimizing the threat of infection during the handling of the biological sample and lowering costs. This effort paves the way for enabling rapid diagnostic tests for Ebola as well as many other viruses that are much more widespread.

The prototype analyzer kit has been successfully tested for compliance with applicable international standards by the National Institute for Infectious Diseases Spallanzani, one of the two Italian institutions designated by the Italian Ministry of Health as a reference center for care and treatment of Ebola. The kit detects the presence of the Ebola virus with extreme accuracy in just a few microliters of human-blood samples and the accuracy of the result has been confirmed with a blood sample diluted up to a million times. The high sensitivity of the test allows the detection of the virus at a very early stage, which can significantly help limit the spread of the deadly disease.

The kit consists of four main components:

- An extractor, on which the blood sample is loaded to extract the virus RNA ;
- A stamp-sized silicon microchip, developed by STMicroelectronics' labs in Agrate Brianza and Catania, which acts as a miniaturized reactor and reproduces, in a micrometer scale, the entire process of amplification and screening of the extracted genetic material on which the extracted RNA is loaded, to be then reverse-transcribed into DNA and amplified according to the RT-PCR methodology.

- Specific reagents, developed by Clonit, that are pre-loaded on the microchip to perform a Quantitative Real-Time PCR (viral load) in compliance with all standards and controls required by the international quality-control regulations;
- A portable optical reader, also developed by STMicroelectronics, which detects the presence of viral DNA in the sample and sends the data to a PC that processes and presents them in graphical form.

In addition to accuracy, the speed and small size of the solution makes it very useful in urgent situations and for “field” diagnostics.

“This test will have important consequences for both medicine and public health,” underlined Giuseppe Ippolito, Scientific Director at the Spallanzani Institute. “In fact, a quick diagnosis leading to the identification of patients with Ebola would result in the immediate implementation of isolation measures, thus reducing the risk of spread of infection in the community and enabling the immediate start of an appropriate treatment for the patient.”

“With the development of this technique, the Institute once again meets the need of the scientific community and of the country to develop key technologies to cope with infectious diseases," added Valerio Fabio Alberti, Special Commissioner, at the Spallanzani Institute.

"We are proud to put our innovative capabilities and deep technology portfolio at the service of humanity and to bring our contribution to the fight against a serious epidemic that could threaten the entire world population,” said Andrea Cuomo, Corporate Vice President, Advanced Projects, STMicroelectronics. “Once again, STMicroelectronics’ Research demonstrates its capabilities for opening new opportunities for the microelectronics world."

"I consider this achievement of the Italian biomedical research an excellent example of collaboration between public and private organizations," noted Carlo Roccio, Clonit Chief Executive Officer.

Now the partners, in collaboration with other industry leaders in this field, are evaluating an integrated, completely self-contained, and fully automated disease-detection system capable of performing multiple analyses in parallel on a large number of samples. Time optimization, along with portability, automation, and integration will allow further cost reductions and produce a more efficient process with human intervention limited to sample taking, paving the way to affordable screening of Ebola and other viruses.

“The brilliant results of this cooperation stimulate our Institute to more vigorously pursue its mission to promote the development and validation of new technologies, in addition to testing the transfer of these new technologies into the national health system," concluded Valerio Fabio Alberti of the Spallanzani Institute.

Technical Notes:
Polymerase Chain Reaction (PCR) amplifies a target biological material, such as the Ebola virus, contained in a tiny sample of blood so it can be detected. The key procedure in PCR is the accurately controlled cycle of repetitive heating and cooling of the biological material that is subsequently evaluated against biological markers loaded on the microchip.

Silicon's low thermal capacity and the minute volumes of tested samples significantly reduce reaction times and allow the fast temperature cycling that enables quick amplification of complex biological materials without compromising accuracy and reliability.

About Clonit
Founded in 1987, Clonit srl was one of the first Italian companies operating in the field of biotechnology. Since the beginning the company has worked to develop innovative and reliable analytical methods in the field of In Vitro diagnostics using molecular biology techniques.

The systems are useful for human diagnostics with particular attention to the detection of viral, bacteria and protozoa infections, genetic mutations and oncological diseases.
The scientific innovations were transferred into ready to use diagnostic kits that, for the operating user-friendliness and the quality, are optimal for routine diagnostic laboratories.
Proprietary technology is covered by a number of International patents, some of which have been highly innovative for the field, such as the invention related to a solid state PCR amplification mix using thermoregulated polymers. The standardization of internal quality control system and cross-checks in outer reference labs have made Clonit able to assure the highest standards of care and quality (ISO 9001:2008 and ISO13485:2004 Certified).
The company is registered and authorized from the Italian Ministry of the Health for the production of Medical Diagnostic devices Clonit offers to its customers an unrivalled experience in molecular biology.

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