

HILYSENS II – Highly Sensitive low-cost lab-on-chip (Lyme card) system for Lyme disease diagnosis

Press Release

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Caparica, Portugal

Lyme card system validation at clinical laboratories

The HILYSENS II consortium has initiated the validation of Lyme Card system at clinical laboratories of HILYSENS II's clinical partners - Borreliose Center Augsburg (BCA) and Department of Clinical Microbiology of University of Gothenburg (UGOT).

The Lyme Card system will be validated using up to 400 sera samples from patients that have been tested positive for Lyme Disease using other commercially available kits, as well as from patients that have been tested negative for Lyme Disease. Furthermore, CSF samples from patients with suspected neuroborreliosis will also be tested and used for validation of Lyme Card system.

All appropriate ethical approvals and informed consent have been obtained by both BCA and UGOT to collect all samples and conduct this validation within their premises.

Validation results will be further confirmed at STAB VIDA using an ELISA specifically developed within HILYSENSII project for this purpose.

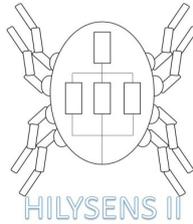
The validation is expected to end at the end of March 2016, with the closure of the HILYSENS II project.

The HILYSENS II project

HILYSENS II project is based on the 2-year Hilysens (www.hilysens.eu) research and development project funded by the 'Research for the Benefit of SMEs' program of the European Commission's Seventh Framework Programme (FP7). HILYSENS II proposes Demonstration Activities for the prototype Lab-on-a-Chip developed during the successful Hilysens research and development project. This Lab-on-a-Chip prototype (now called the 'Lyme card') was designed as a specific and sensitive diagnostic system for acute, chronic and autoimmunity-associated Lyme disease. In parallel, a dedicated reader for the Lyme Card (the 'Reader') was developed, together with customized software to enable diagnosis of Borrelia infections.

The HILYSENS II consortium

STAB VIDA (Coordinator) – STAB VIDA is a Portuguese biotech SME with 25 employees, specialized in DNA-based assays and focused in making easier applications in diagnostics/personalized medicine (mainly Alzheimer and Cancer diseases) and NextGenSequencing. The company started its activities in 2001 and nowadays are selling in Portugal, Spain, Brazil and Africa (Angola and Cabo Verde). STAB VIDA has extensive experience of participating and coordinating European projects (FP6, FP7 and H2020). STAB VIDA had previously worked in developing point-of-care diagnostic tests based on nanotechnology systems for DNA detection.



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microLIQUID – microLIQUID is Spanish SME that develops and produces disposable microfluidic cartridges from plastics for the diagnostic, pharmaceutical, analytical, and medical industries. The company started its activities in 2007 and nowadays is selling worldwide. They integrate components in a lab-on-a-chip technology enabling low consumption of reagents, portability and faster analysis. microLIQUID has extensive experience developing projects from the idea to the production level, integrating different technologies that is required in the field of point of care diagnostics.

Micro Bio Devices - Micro Bio Devices designs, manufactures, develops and markets biological devices for *in vitro* analysis, optical and robotic systems and software. They deal with third-party instrumentation and kits for biomedical research and laboratory analyses. They also provide consultancy to firms operating in their own sector, and are on their way to design an innovative optical/ fluorescence reader and relevant software.

BCA - Borreliose Center Augsburg is a medical institution for the treatment of tick-borne diseases, especially Lyme Disease (Borreliose) and co-infections. The centre combines diagnosis, laboratory, therapy and rehabilitation under one roof in a unique way. BCA has nine experienced physicians and they treat patients from all over the world, including EU countries, Russia, USA and Canada.

UGOT - The Department of Clinical Microbiology at University of Gothenburg is an integrated part of the Clinical Microbiology Laboratory (with 200 employees) at Sahlgrenska University Hospital. The laboratory performs the Lyme Borreliosis serological tests for Western Sweden, which has one of the highest incidences of Lyme Borreliosis in Sweden. The hospital is also the center for all Lyme neuroborreliosis diagnostics and treatment in the West Sweden.

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