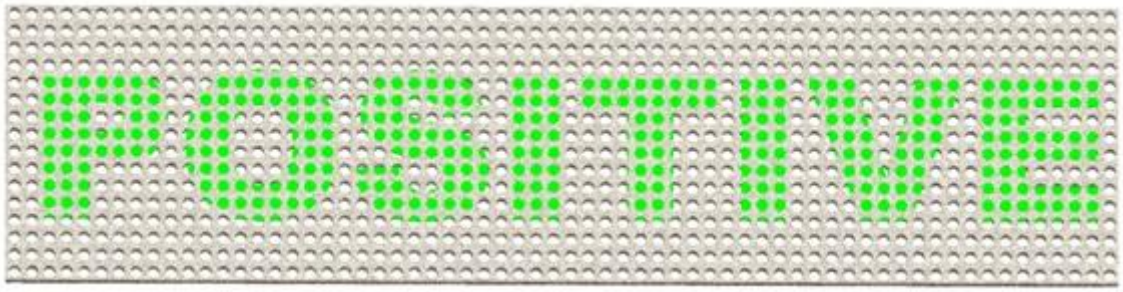

Project Number: 257401

A highly integrated and sensitive POrous SIlicon based lab on a chip for multiple quantitaTIVE monitoring of food allergies at point of care.

Specific Targeted Research Project

Information Society Technologies

Deliverable D10.9: Report on the final results, conclusions and future developments

Due date of deliverable: **December 31st 2013**

Actual submission date: 19 May 2014

Start date of project: 2010-09-01 Duration: 3 ½ Years

Organisation name of lead contractor for this deliverable: **C-UB, report prepared by UVEG**

Additional Contributions from: **C-UB, Farfield**

Revision **[2.0]**

Project co-funded by the European Commission within the Seventh Framework Programme		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

1 About this deliverable

1.1 Introduction

The POSITIVE POC diagnostic system for allergy has at its core a serum based IgE assay that takes place within a functionalised porous membrane whose concentration is measured by polarimetry. After the 2nd Periodic review meeting the Project was amended to focus on the progressive steps required to deliver the proof of principle for the POSITIVE diagnostic instrument, divided into 5 stages. The aim of this deliverable is to report on the final results, conclusions and future developments of the project, principally following the successful completion of all five stages. The stage V deliverable (D10.8) would have entailed a full validation trial of at least 20 patient samples be performed for three analytes, tested against a reference method but for reasons detailed in the same report could not be completed.

1.2 Scope of this deliverable

The deliverable D10.9 which replaced D10.5 was intended to be a fully comprehensive report summarising final results, conclusions and future developments of the project both in general and from the view point of a potential end-user, the C-UB partner. However as neither the objective of Stage II, Stage III, IV or V have been reached, it instead reports on that successfully demonstrated within those Stages as well as potentially exploitable foreground. This is followed by a report by C-UB the advances and benefits as a potential end-user of the technologies developed as well as a partner in the project.

1.3 Structure of this deliverable

The report is laid out according to the following topics:

2 Successes from the five stages and potentially exploitable foreground developed within the project.

3 The advances and benefits for C-UB as a potential end-user of the technologies developed and as a partner in the project.

2 Successes from the five stages and potentially exploitable foreground developed within the project.

From the Stages experiments we can successfully report that:

I. Stage I had previously been achieved satisfactorily after several months of extended work and the use of a new batch of membranes.

II. During the Stage II work, serum flow had been observed within the membrane chips in the fluidic setup and a large response seen in polarimetry measurements for physisorbed IgE to unfunctionalised membranes for the single spot UVEG system.

III. In work largely performed in parallel to Stage II, a multispot instrument and cartridge breadboard system was developed at CSEM in Stage III which demonstrated reproducible sensing results for volumetric sensing experiments.

In general from the foreground developed in the project we have identified several technologies or applications of technologies that are already being exploited or have great potential for doing so:

1. Combination of OSTE(+)[1] with copolymer. The method aims at improving and simplifying the batch back-end processing of microarrays and create microfluidic cells. The Biosticker is aimed to be a plug-in for existing microarray platforms to enable faster protein assays and DNA hybridizations through mass transport optimization. (KTH, CNR)
2. A micro-well platform enabling simultaneous flow through and optical inspection. This unique technology has applications in single cell studies, where the response of individual cells trapped in the micro-wells to stimulants supplied in the flow stream can be followed by microscopy in real-time. (KTH, CSEM, UVEG)
3. A high performance sensor chip thermal control system that has already been implemented in optical instrumentation in over a dozen international University and industrial research laboratories. (Farfield)
4. A module developed for blood filtering that enables several 100 µl of whole blood to be filtered and plasma to be generated for subsequent analysis. This will find uses in lab on chip applications which require alternatives for plasma extraction from whole blood samples which is currently done in dedicated laboratories by centrifugation. (CSEM)
5. A module for sequential actuation of a set of fluids through a microfluidic cartridge, which also enables priming of the cartridge with CO_2 and avoids the introduction of air plugs between the different fluids[2] (CSEM).
6. A fluorescence based milk and egg allergen microarray for detection of specific IgE and IgG with sensitivity and reproducibility comparable to the commercially available ImmunoCAP ISAC from Thermo Fisher. (C-UB, CNR)

Furthermore, serum samples of a large number of well-characterized food-allergic and tolerant children have been obtained that will be useful in future projects to develop better diagnostic instruments in food allergy.

[1] Mercene Labs AB is a spin-off Company from KTH commericializing OSTE, which was developed during FP7 InTopSens and FP7 Positive, for device fabrication by customers.

[2] CSEM is working on a demonstrator of a compact, stand-alone pressure driven fluid handling module anditt is intended to have this ready for SLAS 2015 in Washington DC to present to the lab automation and instrumentation community. CSEM is also implementing such a module in two currently running projects, one for food quality monitoring and one for 3D cell tissue generation for pharma research.

3 The advances and benefits for C-UB as a potential end-user of the technologies developed and as a partner in the project.

1. Worked with CNR on the immobilisation of allergens (for WP6) and testing the assay (with fluorescence)
2. Sorted out all the patient samples of well characterized food-allergic and tolerant children and calibrated them against the conventional techniques These samples will be very valuable for future development of better diagnostic instruments in food allergy
3. Developed the idea of internal and external chip calibration for T9.6 (for D10.6 reported on in D9.5)
4. Worked on developing the protocols for the instrument (using the available fluorescence technique) D10.1- D10.4 before amended.
5. Developed a fluorescence based milk and egg allergen microarray for detection of specific IgE and IgG with sensitivity and reproducibility comparable to the commercially available ImmunoCAP ISAC from Thermo Fisher. This multi-assay system can be further optimized to be useful for simultaneous detection of food-specific IgE and IgG antibodies to large amounts of allergens and allergic components in parallel.