Abionic SA

Launching the next-generation intelligent point-of-care (POC) allergy diagnostic testing system

www.abionic.com

Abionic SA
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Founded in:	2010
No. of employees:	18
Type of Ownership:	Private
Primary stock exchange:	N/A

November 2015: Pioneering research on biomolecular diffusion in nanofluidics, Abionic has developed the abioSCOPE, an in-vitro platform performing quantitative diagnostic testing. Its first application products: abioKIT Total IgE (1 test in 5min) and abioKIT Aeroallergens (6 tests in 12 min) are now available in the POC diagnostic market in Europe, and in 2016 in the U.S. Venture Valuation (VV) interviewed the CEO, Dr. Nicolas Durand.

VV: **POC diagnostic testing technology is changing the practice of medicine. Your system is a good example. Please explain how it operates.**

Durand: Our platform system, abioSCOPE, (right photo) provides patients and medical professionals with test results on the spot. It detects and quantifies up to 6 different allergens simultaneously in 12 minutes and gives a first result after 5 minutes.

The system displays progress of analysis on the monitor and delivers graphic reports, by mobile app, to any electronic device (e.g. iPad, smartphone, etc.)

Due to its size (16cm x 29cm x 24cm) and weight (5kg), the stylish device nicely fits in any corner of pharmacies and doctors' offices. More importantly, it is easily operated even by non-medical people.

The abioKIT (left photo), consists of a blood collector (on the right), a phial of reagent (on the left), and a capsule (in the middle). Around 50µl finger-pricked blood sample is collected, mixed with the reagent, and deposited into a capsule containing biosensors. The capsule is placed on the abioDISC mounting plate and inserted in the abioSCOPE. It is quite similar to playing a DVD.

VV: **Abionic is globally the first company to market a quantitative system for speedy and cost-effective allergy tests. How does your technology work?**

Durand: Our technology is based on the biomolecular interaction taking place in the nanofluidic biosensors inside each capsule. As Fig. 1 shows, when a blood sample, diluted with detecting reagent (containing fluorescently-labelled anti-human IgE antibody), is placed in a capsule, biomolecules diffuse, interact, and form fluorescent molecular complexes within the biosensors.

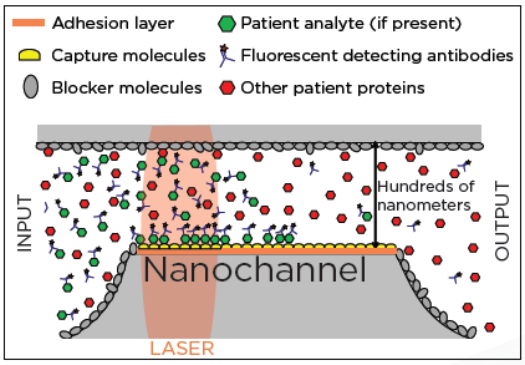

Fig. 1| Patient's sample mixed with fluorescent detecting antibodies goes through the nanometer-size channel and the analytes are specifically captured on the sensing area. Upon excitation, the emitted fluorescence is converted to kU/l.

Then, the immobilized fluorescent complexes are optically measured by a miniaturized fluorescent microscope integrated in the abioSCOPE. The amplitude of the detected fluorescent signal quantifies the IgE level.

The major advantages of our nanofluidic-based biosensors are to cut incubation time as well as to eliminate washing and cleaning steps. This is why the test result is quickly completed in a cost-effective way.

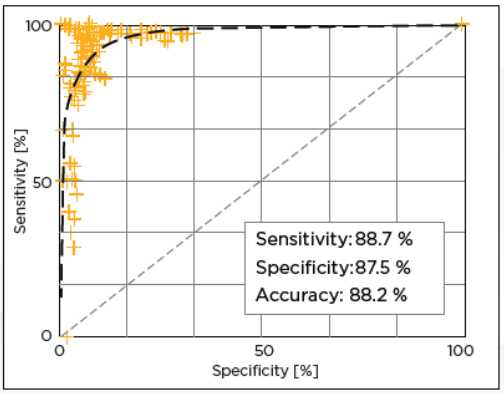

Fig. 4| Good agreement was found between total IgE values measured in Phadia 250 and in abioSCOPE, with values of sensitivity, specificity and accuracy computed from a ROC curve all above 85%.

In order to prove the performance of our technology, we have conducted a comparison study with the industry gold standard: Phadia 250 used at central laboratories. 70 serum samples from a panel of individuals representing the U.S. population diversity (age, gender, and ethnicity) were used. A good agreement was presented with values of sensitivity, specificity, accuracy above 85% (Fig.4).

VV: **Some laboratory experts mention that, as finger-pricked blood samples often mix with fluids from tissue and cells, they can't be pure as those drawn from a vein.**

Durand: For immunological tests, there is a consensus among key opinion leaders that, in terms of antibodies concentration, no difference is found between finger-pricked blood samples and venous blood.

VV: **What is your business development strategy in a global context?**

Durand: We are focusing on two distribution channels: one is pharmacies performing screening tests for the benefit of people who are concerned about their allergic reactions. The other is doctors' offices requiring more detailed tests prior to specific treatment or preventive care.

Each distribution channel has a different pricing scheme: the screening tests for pharmacies and the detailed test for doctors.

Regarding geographical regions, our priority is Europe, first in Switzerland, then Germany and the U.K. The market in the United States, the largest in the world, is challengingly competitive but attractive. With our Boston office, we plan to get FDA 510(k) clearances in 2016, and to be CLIA-waived in 2017. Asia and the rest of world will follow Europe and the U.S. in our medium-term or long-term plan.

VV: **How would you compete with well established diagnostic companies?**

Durand: 70% of the allergy testing market is dominated by Thermo Fisher Scientific. Their customers are mainly central laboratories. They are not our threat whereas they might think we are theirs. It is more critical for us to upgrade and improve our technology along with expanding various application product lines beyond allergy tests (e.g. cancers, infectious diseases, etc.)

In connection with allergy tests, it is said that over one hundred allergies are identified these days and more will be sooner or later discovered. We are currently concentrating our effort on principal ones, a total of around 20, with the aim of developing our allergy test product line. The abioDISC mounting plate of abioSCOPE is designed to hold up to six capsules.

VV: **You raised 3.8million CHF in 2014. What is your next financing plan?**

Durand: We are open to any collaboration and partnership opportunities. International investors are welcome as long as they support Abionic's management team to bring the company towards a great success.

VV Comments after the interview:

The U.S. blood testing market, the most leading and progressive in the world, is worth $75 billion a year.[1] The market is driven more and more by consumers. In this current market climate, Abionic is well positioned to leverage its accurate, speedy, and cost effective solutions. The company is going to play the role of change agent in the POC diagnostic testing market.

By courtesy of Abionic, the interviewer, who is aware of being allergic to wasps and possibly to pets, tried an abioKIT Aeroallergens kit in the company office. The results came back no later than 15 minutes with a comprehensive report along with the summery shown below. The quantitative result helps to understand what preventive care should be taken.

Summary of allergen-specific IgE results

Patient Information ID: 1
Name: MARIKO HIRANO
Sample Information ID: WB
Date: 11.11.2015

Allergy	Allergen	Class	%
Control 1	C pos	-	
Birch	rBet v 1	Low	
Timothy grass	rPhl p 5	Low	
Mite	nDer p 1	Moderate	
Cat	nFel d 1	Moderate	
Dog	rCan f 1	High	
Total IgE	Total IgE	Moderate	

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[1] The Economist, October 31st 2015 "Theranos: The fable of the unicorn"