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Microfluidic systems

Dermagnostix develops molecular diagnostic tests for skin diseases

Dermagnostix GmbH has developed a rapid test to differentiate between psoriasis and eczema. This test is currently undergoing preclinical testing, with market launch planned for 2023. The start-up, which was spun off from the Hahn-Schickard Institute in Freiburg, Helmholtz Zentrum München and Technical University of Munich, is already working on two other dermatological tests. Centrifugal microfluidics is the name of the technology on which the tests are based.

"One-third of the world's population suffers from at least one skin disease," says Dr. Natalie Garzorz-Stark, CEO and co-founder of Dermagnostix. "Psoriasis or eczema such as atopic dermatitis are among the most frequently diagnosed skin diseases. Psoriasis and eczema belong to the group of inflammatory, non-contagious, usually chronic skin diseases. These two skin diseases have similar symptoms, which often makes an accurate diagnosis difficult. "About ten percent of all patients with psoriasis or eczema are wrongly diagnosed and consequently often given the wrong therapy," explains Garzorz-Stark.



Natalie Garzorz-Stark, MD (left) and Katharina Dormanns, PhD (right), CEO and CTO at Dermagnostix.
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That said, effective therapies have been developed over the last decades. However, the methods used to diagnose the diseases have stayed the same: dermatologists visually examine and palpate the affected area and, if necessary, look at a skin sample under the microscope. If incorrectly treated, the condition often worsens, patients suffer, and the healthcare system comes under unnecessary financial burden because therapy with modern drugs costs over 20,000 euros per patient per year. "We have recognised that modern therapies require a modern diagnosis and have developed a test to clearly differentiate psoriasis from eczema," says Garzorz-Stark.

Miniaturised laboratory process is controlled by rotation

The test involves examining a skin sample for certain biomarkers. The dermatologist and her team were able to identify two genes in the genome that are active in a characteristic ratio in each of the two skin diseases. This ratio is detected using reverse transcriptase polymerase chain reaction (RT-PCR). The test system consists of an analyser and a CD-shaped plastic disk. This so-called LabDisk contains all the reagents required for the analysis. The skin sample is placed into the disk, which is then rotated in the analyser at different speeds and temperatures. The resulting centrifugal forces control a miniaturised laboratory process: fluids are transported, mixed and separated in fine channels and small chambers. This technology is referred to as centrifugal microfluidics. The result is available within 60 to 90 minutes.

The test is based on the LabDisk platform developed by the Hahn-Schickard Institute in Freiburg, a non-profit research institute in the field of microsystems technology that takes basic research from the university to the application stage. "The LabDisk technology is the result of decades of development in the field of centrifugal microfluidics, first at the University of Freiburg and then at Hahn-Schickard," explains Dr. Katharina Dormanns, technical director at Dermagnostix. The platform can be adapted to different analytical and diagnostic problems.

Dormans, a bionics engineer with a PhD in mechanical engineering, is fascinated by centrifugal microfluidics. From 2016 to 2021, she was a group leader in LabDisk technology at Hahn-Schickard. In 2021, she founded Dermagnostix together with Garzorz-Stark and other colleagues from the Technical University of Munich (TUM) and Helmholtz Zentrum München. The



The skin sample is analysed fully automatically in a microfluidic plastic disk.
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company is based in Friedberg near Augsburg; research and development are carried out in Freiburg. "Our intention is to make scientific findings available to patients as certified diagnostics. With the LabDisk platform, we have identified the ideal platform for this," says Garzorz-Stark, who previously conducted research in translational dermato-immunology at TUM.

Rapid test to be launched in 2023

A functional model of the player and the disk has been developed, and clinical trials are scheduled to start in 2022. After successful certification, Dermagnostix plans to bring the rapid test to market in 2023. Customers include clinics, laboratories and doctors' surgeries, as well as pharmaceutical companies that use the test in drug development. "We also have an agreement with the German Social Accident Insurance. Each test is reimbursed to the tune of 120 euros as part of a research project," Garzorz-Stark points out. This is a major milestone with regard to potential future reimbursement by the statutory health insurers, she adds.

Dermagnostix holds exclusive patent licenses for the test's marker combination, as well as 13 additional patents for the microfluidics required for implementation as a rapid test. Dermagnostix focuses on test development, microfluidic implementation, quality management and clinical trial execution. Other companies supply the analytical equipment, disks and reagents. The equipment is sold with a small profit margin or can be leased, and revenue is primarily generated from the disks.



Test system consisting of analyser and plastic disk. Automation and miniaturisation save personnel and reagent costs, and even minimally trained staff can perform the tests, allowing it to be used at what is known as the point-of-need, i.e. close to the patient. In addition, the risk of sample contamination is reduced and reproducibility is improved.
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The start-up has already received several awards: for example, it took second place in the CyberOne Hightech Award, won all three phases in the Science for Life Competition and was voted among Germany's top fifty start-ups. It has raised 2.7 million euros in competitive third-party funding to date. For the start-up to remain liquid until the planned break-even in 2026, it needs tens of millions more euros in investment. Two main investors have already been found.

Rapid tests for black skin cancer and skin lymphoma

Dermagnostix is already working on further products: a second rapid test will be used to examine all therapy-relevant tumour mutations of black skin cancer and prognosis markers. Another test concerns skin lymphomas - malignant tumours that arise from degenerated immune cells under the skin. The disease is curable in its early stages, but often cannot initially be distinguished from benign inflammatory skin diseases. The test aims to make this possible. "We are driven by wanting to provide patients with innovative tests that can be used to make accurate diagnoses, as well as to predict treatment response," Garzorz-Stark explains. "Molecular diagnostics is the key to personalised medicine in dermatology, and as Dermagnostix we want to be pioneers in this field."

Article

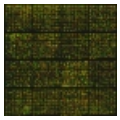
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