

Picture of UCNP-stained HER2 marker in breast tissue. The colour is easily digitally edited after the image capture, which makes it possible to highlight interesting areas in each sample. The colours of the markers are digitally edited after the image capture.

With potential to revolutionize tissue immunostaining

Lumito's advisors in the field of pathology have now had the opportunity to review the company's UCNP immunostaining of invasive breast cancer with an antibody against HER2 (the target molecule) at a high image resolution. "The signals are uniquelly sharp and clear, which gives the impression of staining almost on the level of individual target molecules; in this sense, it is superior to any method currently in regular use in pathology laboratories," says one of Lumito's advisors, Björn L. Isfoss.

Today's industry-leading immunohistochemical systems are designed to help the pathologist differentiate between "positive" and "negative" during a subjective, quantitative assessment of tissue samples through a microscope. Such a system does not offer the possibility to conduct an actual quantitative analysis to the extent that will be in demand. The UCNP technology (upconversion nanoparticles) has the potential to meet these needs.

Another method that is comparable to Lumito's technology and currently in use in research laboratories, is immunofluorescence¹. Today's immunohistochemistry has limitations, because it was primarily developed with traditional pathology in mind, where samples are examined microscopically in visible light. Lumito's method has the potential to provide everything that immunofluorescence provides, including multiple staining, but with easier operation and without some of the drawbacks associated with immunofluorescence. Lumito's method does not require a special microscope that can be operated manually, only a simple scanning. The durability of the preparations is much longer than a couple of weeks. They are also resistant to daylight and do not require cool storage.

At this time, Björn Isfoss believes that UCNP seems to perform better than both the current immunohistochemical methods and immunofluorescence, thus offering the potential to revolutionize the tissue immunostaining conducted in research laboratories, pharmacologic toxicology laboratories, veterinary laboratories and clinical pathology laboratories.

The company's validation process is proceeding according to plan, and the results will be analyzed thereafter.

– We have many committed shareholders, and we have been asked when the results will be presented. We will adhere to the common standards of medical science, which entails that the research group first compiles the findings in preparation of the planned publication in scientific journals before we disclose them ourselves, says Urban Widén, acting CEO of Lumito.

The industry is set to be reformed, and as the population grows older, the number of tissue samples will increase. Björn Isfoss:

- For pathologists to be able to meet the rising demand, the method of analysis needs to be streamlined. We have, by and large, relied on the same technology since the early 1940s, when it was developed by Albert Coons, who found a way to mark antigen using antibodies². This laid the foundation of the immunohistochemistry of today, which has made it possible to identify cell types and thus make diagnosis.

A variant of the current premium standard, immunofluorescence, is super-resolution fluorescence microscopy, which was awarded the 2014 Nobel Prize in chemistry. Lumito's UCNP method, with its highly precise staining of the antigen, is able to compete with this method. This is a field in which considerable investments are made, since it has opened up new opportunities to image things that previously were impossible to see.

– For the future, there are many other technology areas, even beyond medical applications, where Lumito may benefit from its patent portfolio and know-how. Products for new market segments and licensing of technology are among the possibilities, says Urban Widén.

¹ Generally speaking, fluorescence means that a compound, a so-called fluorophore, re-emits previously absorbed light at a lower energy level.

² https://www.ne.se/uppslagsverk/encyklopedi/lång/immunhistokemi

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Lumito specializes in imaging technology within medical research and development. The technology is based on so called UCNP:s (Up Converting Nano Particles) and is aiming to increase image quality in biomedical applications. Lumito's IPR covers high-quality imaging of tissue, for instance in tumours, with UCNP:s as markers. The technology has several possible application areas, but Lumito has initially decided to focus on digital pathology. <u>www.lumito.se</u>

Lumito's share is traded under the ticker LUMITO on the Nordic Growth Market, NGM SME, where the Company's mentor is G&W Fondkommission, telephone: +468-503 000 50.

Björn L. Isfoss has extensive background and solid experience in pathology. He has worked within the field of pathology in the United States, Norway, Sweden and the UK since 1989. Björn Isfosss is Chief Pathologist at Unilabs in Norway and is a member of the Unilabs Pathology Expert Group in Geneva. Björn Isfoss holds two doctoral degrees in branches of pathology where immunohistochemistry and immunofluorescence are of great importance (bladder cancer in Oslo, 2014, and breast cancer in Lund, 2017).