

Faster and more reliable screening for cystic fibrosis mutations

Alkor Bio has developed a rapid and accurate microarray-based diagnostic assay for cystic fibrosis using Tecan's HS 400™ Pro Hybridization Station and PowerScanner™, allowing one technician to screen 10 patients for 25 cystic fibrosis mutations in under seven hours.



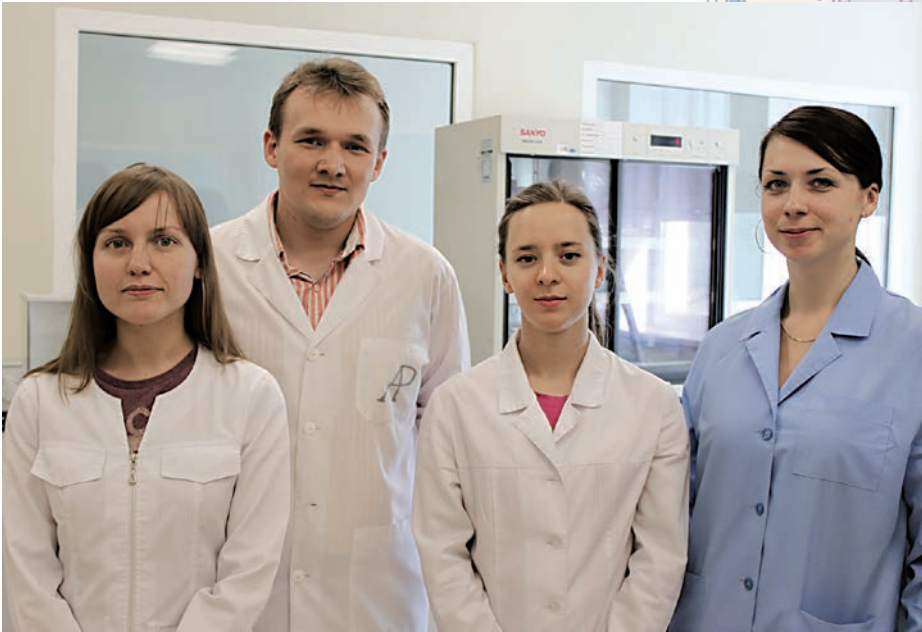
Alkor Bio, founded in 1992, is a large biotechnology group consisting of 12 companies in and around St Petersburg in Russia. Working in collaboration with hospitals and academic institutions both within Russia and across Europe, the group

develops, manufactures, distributes and markets medical diagnostics kits for detection of inherited, hormonal and infectious diseases, as well as allergies. The group has historically concentrated on ELISA-based testing – offering around 60 different diagnostic kits – but has recently developed its first DNA microarray-based assay, the CF-25 genomic test for cystic fibrosis (CF).

Caused by mutations of the CF transmembrane conductance regulator (*CFTR*) gene, cystic fibrosis is one of the most common autosomal recessive disorders in Europe, and is carried by one in 20 individuals of European descent. The CF-25 test is designed to identify 25 mutations which are frequently-occurring or associated with severe disease phenotypes. Alexander Pavlov, head of Alkor Bio's Laboratory of Molecular Diagnostics, explained why the test was developed: "CF has traditionally been detected using biochemical markers and sweat testing, which are not always reliable and are characterized by a high incidence of false-positive results, creating a need for accurate DNA-based testing. The CF-25 genomic test is based on reverse hybridization of fluorescently-labeled DNA probes to a microchip bearing mutant and corresponding wild type targets of the human *CFTR* gene. We have our own robotic printing facility to produce the microchips, and use an HS 400 Pro Hybridization Station and a PowerScanner, both from Tecan, to perform microarray processing and analysis. This set-up only requires minimal amounts of DNA for analysis – we can even extract enough material from dried blood spots – and hands-on time is significantly reduced; one technician can screen 10 samples for 25 distinct *CFTR* gene mutations in six or seven hours."



Application specialist Anna Buyanova loading slides into the cassette



Members of the Alkor Bio team. Left to right; Evgeniya Penzenceva, Alexander Pavlov, Nadezhda Seilieva, Ksenia Potarikina

“We have been very satisfied with both instruments and the service and support we receive from Tecan, as and when we require it.”

Alexander continued: “We purchased the HS 400 Pro in 2011 to establish the right quality control steps and protocols for fluorescence-based protein and DNA arrays, and to standardize hybridization as much as possible. It automates all the processing steps – pre-hybridization, blocking, hybridization, washing and drying – with minimal need for manual handling of the microarray slides, and is fully programmable, offering a wide range of settings for precise time and temperature control. The software is also easy to operate; it was really easy to adapt the station to our hybridization settings and parameters, and to integrate it into our protocol.”

“Following hybridization, slides are transferred to the PowerScanner for analysis. The main benefit of this instrument is its wide range of settings, allowing us to precisely tune the system to match the needs of our proprietary microarrays. It works with multiple microarray substrates and formats, and enables us to implement a wide range of applications; with 24 slides in the magazine, even high throughput protocols can be performed easily in automatic mode. Although we initially purchased this instrument because of its potential for research and development, we also wanted a high quality, reliable system that could withstand constant use. It was

very important for us to have the scanner ready for use at any time, because we use it to perform quality control on new batches of microarray slides, and the Tecan system is proving to be very robust.”

“The CF-25 genomic test was licensed in Russia last year, and received the EU’s CE mark in early 2013. We are now planning to use this microarray platform to extend our repertoire of microarray-based tests to include other genes of interest, as well as an extended CF panel with an increased number of *CFTR* mutations. We have been

very satisfied with both instruments and the service and support we receive from Tecan, as and when we require it. As a result, we are happy to recommend the Tecan equipment to our customers as a good solution for improving reproducibility and accuracy, particularly for high throughput laboratories,” concluded Alexander.

To learn more about Tecan’s microarray solutions, visit www.tecan.com/microarray

To find out more about Alkor Bio, go to www.english.alkorbio.ru



Olga Astasheva, Manager of Microarray, inserts the cassette into the PowerScanner