SINGULEX - EARLY STAGE BIOMARKER DETECTION

Singulex is a California-based company providing a unique technology that can detect single molecules in bodily fluids, such as blood or urine. This capability holds real promise for medical diagnostics, particularly when being used to detect biomarkers, measurable substances whose presence is often indicative of disease. Biomarkers are a very early indicator of disease, often the first, and many diseases have specific biomarkers associated with them.

While biomarkers are good indicators of disease, the concentration of cells present in a sample is very often too low to be detected with current technologies. As a result, they often remain unnoticed and the disease is not diagnosed.

The Singulex Clarity system overcomes this challenge with Single Molecule counting technology which can detect exremely low concentrations of biomarkers– present in the very earliest stages of a disease. This means patients can benefit from earlier diagnosis and treatment.

How biomarker detection works and why thermal sensors are essential

Singulex uses immunoassay testing to detect biomarkers. The process is a biochemical test that measures the presence or abscence of a small molecule in a solution by using an antibody or an antigen. Immunoassays rely on the ability of the antibody or antigen to recognize and bind to a specific macromolecule.

Immunoassay testing requires a measurable signal to indicate that binding has occurred. If a biomarker is present, the antibody, which is labeled with a fluorescent dye, will bind to the marker, and cause a detectable light flash when scanned by a laser. If no biomarkers are present, binding will not take place, and no flashes will occur. By measuring the number and intensity of these flashes, the system is quantitative -- in other words it can determine the concentration of biomarkers in a solution, down to single molecule.

This is when thermal measurement becomes important

The intensity of the light flashes, and thus the parameter for quantitative measurements, is sensitive to temperature fluctuations. So, for quantitative measurements to be consistent and reproducible, the temperature of each fluid sample must be gauged during scanning. If temperatures are not at a pre-defined set point during scanning, measurement data must be adjusted accordingly to ensure consistent results.

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How Exergen Non-Contact Sensors Helped Singulex Detect Biomarkers

The Singulex' engineers realized they needed a temperature sensor to assure uniformity of temperature, in order to determine the concentration of biomarkers (if any) in each scanned sample. *Without* a thermal sensor, it would still be possible to know *if* a biomarker was present (by seeing if there is a light flash), but the concentration of the biomarker (corresponding to stage of disease) would be temperature sensitive and hence unreliable. They needed a non-contact sensor because, as is the case with much medical testing, if the temperature sensor were to come in contact with the samples, it would contaminate the samples. Furthermore, contact sensors are too slow for this application and it's not practical to have to insert contact probes into an automated system using sealed containers of fluid.

Singulex began its search for a sensor and, asked Tecan, the manufacturer that supplies Singulex with sample handling equipment for its Singulex Clarify system, recommended Exergen. (Tecan uses Exergen's Micro IRt/c sensor in its plate reader systems which also perform immunoassays testing.) Engineers from Singulex, Tecan and Exergen collaborated to integrate the sensor into the Singulex Clarity system.

Exergen's IRt/c sensors provide Singulex with the perfect capabilities: they measure the sample temperature allowing the instrument to adjust results accordingly. This is an essential role in the process because all biomarker measurements must be normalized to a consistent temperature.

Benefits to patients

The Singulex Clarity systems, in conjunction with Exergen sensors, is providing significant benefits to patients through early detection of biomarkers and, thereby, early detection of disease. For almost all curable diseases, the likelihood of successful treatment increases considerably when the disease is detected at its earliest stage.

Benefits to Singulex

Singulex selected Exergen's sensors for a variety of reasons, including:

1. Non contact: fast, easy and safe
2. Accuracy and repeatability
3. Unpowered – no maintenance of recalibration
4. Size: Singulex uses the Micro IRt/c – the smallest sensor available
5. Price: cost effective